Name: Liaoning Medical Device Test Institute

Address: No.600-1/600-2/600-3, Maizitun, Hunnan District, Shenyang, Liaoning, China

Registration No. CNAS L0201

Accreditation Criteria: ISO/IEC 17025:2017 and relevant requirements of CNAS

Effective Date: 2023-02-14 Expiry Date: 2028-11-20

SCHEDULE 3 ACCREDITED TESTING SCOPE

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
Common parameter						
chemical properties						
1	chemical properties	1	pH	Chinese pharmacopoeia 2020 edition of the foun general rules 0631		2023-02-14
		2	Viscosity	Chinese pharmacopoeia 2020 edition of the foun general rules 0633	accredited only for 3rd method	2023-02-14
		3	gas chromatogar	Chinese pharmacopoeia 2020 edition of the foun general rules 0521		2023-02-14
		4	Ethylene oxide sterilization residuals	Biological evaluation of medical devices-part 7:Ethylene oxide sterilization residuals idt ISO 10993-7:1995		2023-02-14
		5	Ultraviolet visible Spectrophotometer	Chinese pharmacopoeia 2020 edition of the foun general rules 0401		2023-02-14
		6	Atomic Absorption Spectrophotometer	Chinese pharmacopoeia 2020 edition of the foun general rules 0406		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	High-performance liquid chromatography	Chinese pharmacopoeia 2020 edition of the foun general rules 0512		2023-02-14
		8	Chloride method	Chinese pharmacopoeia 2020 edition of the foun general rules 0801		2023-02-14
		9	Sulphate method	Chinese pharmacopoeia 2020 edition of the foun general rules 0802		2023-02-14
		10	Heavy metal inspection	Chinese pharmacopoeia 2020 edition of the foun general rules 0821		2023-02-14
		11	Sulphide test	Chinese pharmacopoeia 2020 edition of the foun general rules 0803		2023-02-14
		12	loss on drying	Chinese pharmacopoeia 2020 edition of the foun general rules 0831		2023-02-14
		13	water determination	Chinese pharmacopoeia 2020 edition of the foun general rules 0832		2023-02-14
		14	residue on ignition method	Chinese pharmacopoeia 2020 edition of the foun general rules 0841		2023-02-14
		15	residual solvent method	Chinese pharmacopoeia 2020 edition of the foun general rules 0861		2023-02-14
		16	Solution Colour test	Chinese pharmacopoeia 2020 edition of the foun general rules 0901		2023-02-14
		17	Clarity test	Chinese pharmacopoeia 2020 edition of the foun general rules 0902		2023-02-14
		18	particulate determination	Chinese pharmacopoeia 2020 edition of the foun general rules 0902		2023-02-14
		19	visible particle	Chinese pharmacopoeia 2020 edition of the foun general rules 0904		2023-02-14
		20	Minimum loading capacity examination	Chinese pharmacopoeia 2020 edition of the foun general rules 0942		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
Biological assessment						
1	Biological evaluation	1	test for in vitro cytotoxicity	Biological evaluation of medical devices-Part 5:Test for in vitro cytotoxicity GB/T 16886.5-2017 /ISO 10993-5：2009 8		2023-02-14
				Test methods for infusion,transfusion,injiection equipment for medical use-part 2:biological test methods GB/T 14233.2-2005 8		2023-02-14
				Biologocal evaluation of dental materials-Part2:Biologocal evaluation test metnod of dental materials-cytotoxicity tests:Agar diffusion test and filter dissusion test YY/T 0127.9-2009 4		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14
				Medical gloves for single use-Requirements and testing for biological evaluation YY/T0616.1-2016 4.1		2023-02-14
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 5		2023-02-14
		2	Bacterial endotoxins test	Test methods for infusion,transfusion,injiection equipment for medical use-part 2:biological test methods GB/T 14233.2-2005 4		2023-02-14
				Chinese pharmacopoeia 2020 Part4 General Rule 1143		2023-02-14
				Bacterialendotoxins-Test methodologies,routine monitoring,and alternatives to batch testing YY/T 0618-2017 7		2023-02-14
				Medical gloves for single use-Requirements and testing for biological evaluation YY/T 0616.1-2016 4.3		2023-02-14
		3	Sterility test	Chinese pharmacopoeia 2020 Part4 General Rule 1101		2023-02-14
				Test methods for infusion,transfusion,injiection equipment for medical use-part 2:biological test methods GB/T 14233.2-2005 3		2023-02-14
		4	Microbiological Examination of Non-Sterile	Chinese pharmacopoeia 2020 Part4 General Rule 1105		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Products: Microbial Enumeration Tests			
		5	Microbiological Examination of Non-Sterile Products: controlling bacteria test	Chinese pharmacopoeia 2020 Part4 General Rule 1106		2023-02-14
		6	Microbiological indicator（Total bacterial count，Coliform，Pseudomonas aeruginosa，Staphylococcus aureus，Streptococcus haemolyticus，Total fungal colonies）	Hygienic standard for disposable sanitary products GB15979-2002 7.1.3		2023-02-14
		7	Bactericidal performance,antibacterial properties,and stability test	Hygienic standard for disposable sanitary products GB15979-2002 7.1.4		2023-02-14
		8	Test method to determine the resistance to wet bacterial penetration	Surgical drapes,gowns and clean air suits,used as medical devices,for patients,clinical staff and equipment-Part 6:Test method to determine the resistance to wet bacterial penetration YY/T 0506.2-2016		2023-02-14
		9	BFE	Surgical mask YY 0469-2011 5.6.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				the medical mask YY/T0969-2013 5.5		2023-02-14
		10	Pyrogen test	Biological evaluation of medical devices-Part 11:Tests for systemic toxicity ISO 10993-11:2017 Annex G		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14
				Test methods for infusion,transfusion,injiection equipment for medical use-part 2:biological test methods GB/T 14233.2-2005 5		2023-02-14
				Biological evaluation of medical devices-Part 11:Tests for systemic toxicity ISO 10993-11:2017 F		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 10		2023-02-14
				Pyrogen test YBB00022003-2015		2023-02-14
				Chinese pharmacopoeia 2020 edition of the four general rules 1142		2023-02-14
		11	Acute systemic tosicity	Biological evaluation of medical devices-Part 11:Tests for systemic toxicity ISO 10993-11:2017 5		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 5		2023-02-14
				Test methods for infusion,transfusion,injiection equipment for medical use-part 2:biological test methods GB/T 14233.2-2005 6		2023-02-14
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 8		2023-02-14
				iological evaluation of medical devices used in dentistry—Part 3:Endodontic usage test YY/T 0127.14-2009 4		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14

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		№	Item/ Parameter			
				Acute systemic toxicity test YBB00042003-2015		2023-02-14
		12	intradermal Irritancy test	Biological evaluation of medical devices — Part 23: Tests for irritation ISO 10993-23：2021 7.3		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 5		2023-02-14
				Test methods for infusion,transfusion,injiection equipment for medical use-part 2:biological test methods GB/T 14233.2-2005 10		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14
				Biological evaluationg of medecal devices-Part 10:Test for irrition and delayed-type hypersensitivity ISO 10993-10：2010 6.4		2023-02-14
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 7		2023-02-14
				Medical gloves for single use-Requirements and testing for biological evaluation YYT0616.1-2016 4		2023-02-14
				Biological evaluation of medical devices—Part 11:Tests for systemic toxicity GB/T 16886.11-2011 5		2023-02-14
				intradermal Irritancy test YBB00062003-2015		2023-02-14
		13	delayed-type hypersensitivity	Biological evaluation of medical devices — Part10: Tests for skin sensitization ISO 10993-10：2021 6		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 5		2023-02-14
				Test methods for infusion,transfusion,injiection equipment for medical use-part 2:biological test methods GB/T 14233.2-2005 9		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14

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		№	Item/ Parameter			
				Biological evaluationg of medecal devices-Part 10:Test for irrition and delayed-type hypersensitivity ISO 10993-10：2010 7		2023-02-14
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 6		2023-02-14
				Hygienic standard for disposable sanitary products GB 15979-2002 4		2023-02-14
				Medical gloves for single use-Requirements and testing for biological evaluation YYT0616.1-2016 4		2023-02-14
				Skin sensitization test YBB00052003-2015		2023-02-14
		14	ophthalmic Irritancy test	Biological evaluation of medical devices — Part 23: Tests for irritation ISO 10993-23：2021 D.2		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 5		2023-02-14
				Biological evaluationg of medecal devices-Part 10:Test for irrition and delayed-type hypersensitivity ISO 10993-10：2010 B2		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 7		2023-02-14
		15	Derma Irritancy Tests	Biological evaluation of medical devices — Part 23: Tests for irritation ISO 10993-23：2021 7.2		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 5		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14
				Biological evaluationg of medecal devices-Part 10:Test for irrition and delayed-type hypersensitivity ISO 10993-10：2010		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				6.3		
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 7		2023-02-14
				Hygienic standard for disposable sanitary products GB 15979-2002 4		2023-02-14
				Primary skin irritation test YBB00072003-2015		2023-02-14
		16	local effects after implantation	Test methods for infusion,transfusion,injiection equipment for medical use-part 2:biological test methods GB/T 14233.2-2005 11		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14
				Biologocal evaluation of medical devices-Part 6:Test for local effects after implantation GB/T 16886.6-2022 5	not incloud bone implantation	2023-02-14
				Biologocal evaluation of dental materials-Part2:Biologocal evaluation test metnod of dental materials-subcutaneous implant test YY/T 0127.8-2001 4		2023-02-14
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 12	not incloud bone implantation	2023-02-14
		17	Penile Irritancy test	Biological evaluation of medical devices — Part 23: Tests for irritation ISO 10993-23：2021 D.4		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 5		2023-02-14
				Biological evaluationg of medecal devices-Part 10:Test for irrition and delayed-type hypersensitivity ISO 10993-10：2010		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				B4		
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 7		2023-02-14
		18	Rectal Irritancy test	Biological evaluation of medical devices — Part 23: Tests for irritation ISO 10993-23：2021 D.5		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 5		2023-02-14
				Biological evaluationg of medecal devices-Part 10:Test for irrition and delayed-type hypersensitivity ISO 10993-10：2010 B5		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 7		2023-02-14
		19	Oral Irritancy test	Biological evaluation of medical devices — Part 23: Tests for irritation ISO 10993-23：2021 D.3		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 5		2023-02-14
				Biological evaluationg of medecal devices-Part 10:Test for irrition and delayed-type hypersensitivity ISO 10993-10：2010 B3		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14
				Biologocal evaluation of dental materials-Part2:Biologocal evaluation test metnod of dental materials-Oral mucous membrane irritation test YY/T 0127.13-2018 4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Dentistry-Biological evaluationg of medical devices uesd in dentistry-Part 1:Evaluation and test YY/T 0268-2008 4		2023-02-14
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 7		2023-02-14
		20	Vaginal Irritancy test	Biological evaluation of medical devices — Part 23: Tests for irritation ISO 10993-23：2021 D.6		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 5		2023-02-14
				Biological evaluationg of medical devices-Part 10:Test for irrition and delayed-type hypersensitivity ISO 10993-10：2010 B6		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 7		2023-02-14
				Hygienic standard for disposable sanitary products GB 15979-2002 4		2023-02-14
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 7		2023-02-14
		21	hemolysis test	Biological evaluationg of medecal devices-Part 4:selection of tests for interactions with blood ISO 10993-4：2017 5		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 5		2023-02-14
				Test methods for infusion,transfusion,injiection equipment for medical use-part 2:biological test methods GB/T 14233.2-2005 7		2023-02-14
				Biological evaluationg of medecal devices-Part 4:selection of tests for interactions with blood GB/T 16886.4-2022 B3.1		2023-02-14
				Biological evaluation of oral medical devices second unit: Test Method for acute oral toxicity test YY/T 0127.1-1993 4		2023-02-14
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008 13		2023-02-14

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		№	Item/ Parameter			
				Hemolysis test YBB00032003-2015		2023-02-14
		22	test for in vitro cytotoxicity	Biological evaluation of medical devices-Part 5:Test for in vitro cytotoxicity ISO 10993-5：2009 8		2023-02-14
				Biological evaluation of medical devices-Part 12:Sample preparation and reference materials ISO 10993-12：2012 5		2023-02-14
		23	Mammalian bone marrow erythocyte micronucleus test	Biological evaluation of medical devices. Part 3:Tests for genotoxicity,carcinogenicity and reproductive toxicity GB/T 16886.3-2019 4.4.2		2023-02-14
				Test for genotoxicity of medical devices. Part 4:Mammalian bone marrow erythocyte micronucleus test YY/T 0870.4-2014		2023-02-14
		24	Bactericidal index	Test method for bactericidal effect of disinfectant in laboratory GB/T 38502-2020	Accredited only for quantitative killing test of filtrate suspension by membrane filtration，except for mycobacterium quantitative killing test	2023-02-14
		25	resistance to dry microbial penetration	Surgical drapes, growns and clean air suits for patients, clincial staff and equipment-Part 5：Test method for resistance to dry microbial penetration YY/T 0506.5-2009		2023-02-14
		26	Abnormal toxicity	Chinese pharmacopoeia 2020 Part4 1141		2023-02-14

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2	medical devices	1	Acute systemic toxicity	Biological evaluation of medical devices. Part 11:Tests for systemic toxicity GB/T 16886.11-2021 5		2023-02-14
		2	Repeated exposure systemic toxicity (subacute, subchronic and chronic systemic toxicity)	Biological evaluation of medical devices —Part 11: Tests for systemic toxicity ISO 10993-11-2017 6		2023-02-14
				Biological evaluation of medical devices. Part 11:Tests for systemic toxicity GB/T 16886.11-2021 6		2023-02-14
				Biological evaluation of medical devices used in dentistry-Part 15:Subacute subchronic systemic toxicity test:oral route YY/T 0127.15-2018 5		2023-02-14
		3	Test methods for implantation in subcutaneous tissue	Biological evaluation of medical devices—Part 6:Tests for local effects after implantation GB/T 16886.6-2022 Annex A		2023-02-14
				Biological evaluation of medical devices —Part 6:Tests for local effects after implantation ISO 10993-6-2016 Annex A		2023-02-14
		4	Test method for implantation in muscle	Biological evaluation of medical devices—Part 6:Tests for local effects after implantation GB/T 16886.6-2022 Annex B		2023-02-14
				Biological evaluation of medical devices —Part 6:Tests for local effects after implantation ISO 10993-6-2016 Annex B		2023-02-14
		5	Micronucleus test	Test for genotoxicity of medical devices-Part 6: In vitro mammalian cell micronucleus test YY/T 0870.6-2019		2023-02-14
				Test for genotoxicity of medical devices-Part 4: Mammalian bone marrow erythocyte micronucleus test YY/T 0870.4-2014		2023-02-14
				Dentistry-Biological evaluation of medical devices used in dentistry Part 2:Test method-Micronucleus test YY/T 0127.12-2008		2023-02-14
				Biological evaluation of medical devices-Part 3:Tests for genotoxicity,carcinogenicity and reproductive toxicity GB/T 16886.3-2019 5		2023-02-14
				Biological evaluation of medical devices-Part 3:Tests for genotoxicity,carcinogenicity and reproductive toxicity ISO10993-3-2014 5		2023-02-14

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		№	Item/ Parameter			
		6	Chromosome aberration test	Test for genotoxicity of medical devices-Part 2: In vitro mammalian chromosome aberration test YY/T 0870.2-2019		2023-02-14
				Biological evaluation of medical devices used in dentistry Part 2: Test method In Vitro mammalian chromosome aberration test YY/T 0127.16-2009		2023-02-14
				Test for genotoxicity of medical devices-Part5:mammalian bone marrow chromosome aberration test YY/T 0870.5-2014		2023-02-14
				Biological evaluation of medical devices-Part 3:Tests for genotoxicity,carcinogenicity and reproductive toxicity GB/T 16886.3-2019 5		2023-02-14
				Biological evaluation of medical devices-Part 3:Tests for genotoxicity,carcinogenicity and reproductive toxicity ISO10993-3-2014 5		2023-02-14
		7	TK gene mutation test	Biological evaluation of medical devices used in dentistry-Part 17:Mouse lymphoma cells(TK) gene mutation test YY/T 0127.17-2014		2023-02-14
				Test for genotoxicity of medical devices-Part 3: TK gene mutation test using mouse lymphoma cells YY/T 0870.3-2019		2023-02-14
				Biological evaluation of medical devices-Part 3:Tests for genotoxicity,carcinogenicity and reproductive toxicity GB/T 16886.3-2019 5		2023-02-14
				Biological evaluation of medical devices-Part 3:Tests for genotoxicity,carcinogenicity and reproductive toxicity ISO10993-3-2014 5		2023-02-14
		8	Bacterial reverse mutation tes	Biological evaluation of medical devices used in dentistry Part 2: Test method -Salmonella typhimurium reverse mutation assay (Ames mutagenicity test) YY/T 0127.10-2009		2023-02-14
				Biological evaluation of medical devices-Part 3:Tests for genotoxicity,carcinogenicity and reproductive toxicity GB/T 16886.3-2019 5		2023-02-14

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		№	Item/ Parameter			
				Biological evaluation of medical devices-Part 3:Tests for genotoxicity,carcinogenicity and reproductive toxicity ISO10993-3-2014 5		2023-02-14
				YY/T 0870.1-2013		2023-02-14
		9	Coagulation	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood ISO 10993-4-2017 B3.2		2023-02-14
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2022 B3.2		2023-02-14
				Test methods for infusion,transfusion,injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005 B4		2023-02-14
		10	Platelets	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood ISO 10993-4-2017 B3.3		2023-02-14
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2022 B3.3		2023-02-14
				Test methods for infusion,transfusion,injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005 B5		2023-02-14
				Test methods for infusion,transfusion,injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005 B6		2023-02-14
		11	Haematology	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood ISO 10993-4-2017 B3.4		2023-02-14
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2022 B3.4		2023-02-14
		12	Complement system	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood ISO 10993-4-2017 B3.5		2023-02-14
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2022 B3.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Test methods for infusion,transfusion,injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005 B7		2023-02-14
3	medical packing material	1	Acute systemic toxicity of medical packing material	Chinese pharmacopoeia 2020 edition of the four general rules 4011		2023-02-14
		2	Hemolysis test of medical packing material	Chinese pharmacopoeia 2020 edition of the four general rules 4013		2023-02-14
		3	Cytotoxicitytest of medical packing material	Chinese pharmacopoeia 2020 edition of the four general rules 4014		2023-02-14
Active Medical Devices						
Active Medical Devices						
1	Dynamoelectric traction-table	1	All Parameters	Dynamoelectric traction-table YY 0697-2016		2023-02-14
		2	Traction mode	Dynamoelectric traction-table YY 0697-2016 4.2		2023-02-14
		3	Tolerance range and maximum traction	Dynamoelectric traction-table YY 0697-2016 4.3		2023-02-14
		4	Traction bed and traction treatment time and intermittent time tolerance	Dynamoelectric traction-table YY 0697-2016 4.4		2023-02-14
		5	protection	Dynamoelectric traction-table YY 0697-2016 4.5		2023-02-14
		6	Angle range and tolerance	Dynamoelectric traction-table YY 0697-2016 4.6		2023-02-14

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		№	Item/ Parameter			
		7	Having a quick pull function traction bed traction	Dynamoelectric traction-table YY 0697-2016 4.7.1		2023-02-14
		8	Having a quick pull function traction bed traction stroke	Dynamoelectric traction-table YY 0697-2016 4.7.2		2023-02-14
		9	Exterior	Dynamoelectric traction-table YY 0697-2016 4.8.1		2023-02-14
		10	Text logo	Dynamoelectric traction-table YY 0697-2016 4.8.2		2023-02-14
		11	structure	Dynamoelectric traction-table YY 0697-2016 4.8.3		2023-02-14
		12	noise	Dynamoelectric traction-table YY 0697-2016 4.9		2023-02-14
		13	Safety requirements	Dynamoelectric traction-table YY 0697-2016 4.1	See GB 9706.1-2007	2023-02-14
		14	Environmental Testing	Dynamoelectric traction-table YY 0697-2016 4.11	SeeGB/T 14710	2023-02-14
2	medical endoscopes-rigid endoscope	1	All Parameters	Medical Endoscopes-Rigid Endoscope-Part 3:Marking and instruction manual YY/T 0068.3-2008ISO 8600-1:2005		2023-02-14
		2	mark	Medical Endoscopes-Rigid Endoscope-Part 3:Marking and instruction manual YY/T 0068.3-2008ISO 8600-1:2005 3.1		2023-02-14
		3	attachment	Medical Endoscopes-Rigid Endoscope-Part 3:Marking and instruction manual YY/T 0068.3-2008ISO 8600-1:2005 3.2		2023-02-14
3	Automated coagulation analyzer	1	All Parameters	Automated coagulation analyzer YY/T0659-2017		2023-02-14
		2	Time temperature	Automated coagulation analyzer YY/T0659-2017 5.1		2023-02-14
		3	temperature control	Automated coagulation analyzer YY/T0659-2017 5.2		2023-02-14

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		№	Item/ Parameter			
		4	The test items and the reporting unit	Automated coagulation analyzer YY/T0659-2017 5.3		2023-02-14
		5	Channel difference	Automated coagulation analyzer YY/T0659-2017 5.4		2023-02-14
		6	carryover	Automated coagulation analyzer YY/T0659-2017 5.5		2023-02-14
		7	Test speed	Automated coagulation analyzer YY/T0659-2017 5.6		2023-02-14
		8	Repeatability of measurement	Automated coagulation analyzer YY/T0659-2017 5.7		2023-02-14
		9	Measurement accuracy	Automated coagulation analyzer YY/T0659-2017 5.8		2023-02-14
		10	Linear	Automated coagulation analyzer YY/T0659-2017 5.9		2023-02-14
		11	Continuous operating time	Automated coagulation analyzer YY/T0659-2017 5.10		2023-02-14
		12	Appearance	Automated coagulation analyzer YY/T0659-2017 5.11		2023-02-14
		13	Signs and instructions	Automated coagulation analyzer YY/T0659-2017 7		2023-02-14
		14	Packaging, transportation and storage	Automated coagulation analyzer YY/T0659-2017 8		2023-02-14
4	Electrical surgical equipment for osseous tissue	1	All Parameters	Electrical surgical equipment for osseous tissue YY/T 0752-2016		2023-02-14
		2	working status instructions	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.1.1		2023-02-14
		3	rotation speed/ frequency with no-load rotation speed/ frequency of	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.1.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			permissible error			
		4	tolerance of the rotation speed of point of a particular work load and measured rotation speed of that point	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.1.3		2023-02-14
		5	Corrosion Resistance	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.1.4		2023-02-14
		6	noise	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.1.5		2023-02-14
		7	cutter clamping with handpiece a)	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.1 a）		2023-02-14
		8	cutter clamping with handpiece b)	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.1 b）		2023-02-14
		9	Handing cutter	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.2		2023-02-14
		10	Radial circle run-out	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.3		2023-02-14
		11	Axial movement	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.4		2023-02-14
		12	Housing surface temperature	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.5		2023-02-14
		13	Surface roughness	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.6		2023-02-14
		14	Shaft and connector performance requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.3.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Shaft and connector performance requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.3.2		2023-02-14
		16	Shaft and connector performance requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.3.3		2023-02-14
		17	Cable and connector performance requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.4.1		2023-02-14
		18	Cable and connector performance requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.4.2		2023-02-14
		19	Cable and connector performance requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.4.3		2023-02-14
		20	Foot Controller Requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.5	SeeYY 1057	2023-02-14
		21	Environmental testing requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.6	SeeGB/T 14710	2023-02-14
		22	Safety requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.7	SeeGB 9706.1-2007, YY 0505	2023-02-14
5	Carbon dioxide laser treating instrument	1	All Parameters	Carbon dioxide laser treating instrument GB 11748-2005		2023-02-14
		2	Wavelength	Carbon dioxide laser treating instrument GB 11748-2005 5.2.1		2023-02-14
		3	Mode	Carbon dioxide laser treating instrument GB 11748-2005 5.2.2		2023-02-14
		4	Beam spot size	Carbon dioxide laser treating instrument GB 11748-2005 5.2.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Output laser power	Carbon dioxide laser treating instrument GB 11748-2005 5.3		2023-02-14
		6	Instability of Laser power	Carbon dioxide laser treating instrument GB 11748-2005 5.4		2023-02-14
		7	Reproductivity of laser power	Carbon dioxide laser treating instrument GB 11748-2005 5.5		2023-02-14
		8	transmission efficiency of optic fiber	Carbon dioxide laser treating instrument GB 11748-2005 5.6.3		2023-02-14
		9	output power of aiming beam	Carbon dioxide laser treating instrument GB 11748-2005 5.6.4		2023-02-14
		10	control and overload protection	Carbon dioxide laser treating instrument GB 11748-2005 5.7		2023-02-14
		11	cooling system	Carbon dioxide laser treating instrument GB 11748-2005 5.8		2023-02-14
		12	apparence	Carbon dioxide laser treating instrument GB 11748-2005 5.9		2023-02-14
		13	safety requirement	Carbon dioxide laser treating instrument GB 11748-2005 5.1	See GB 9706.1-2007、GB 9706.20-2000、GB 7247.1-2012	2023-02-14
		14	Environmental test	Carbon dioxide laser treating instrument GB 11748-2005 5.11	See GB/T 14710-2009	2023-02-14
6	Medical electrical equipment	1	All Parameters	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988		2023-02-14
		2	General	Medical electrical equipment –Part 1:General requirements for		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			requirements	safety GB9706.1-2007 IEC60601-1:1988 3		
		3	Classification	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 5		2023-02-14
		4	Identification, marking and documents	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 6		2023-02-14
		5	Power input	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 7		2023-02-14
		6	Environmental conditions	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 10		2023-02-14
		7	Requirements related to classification	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 14		2023-02-14
		8	Limitation of voltage and/or energy	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 15		2023-02-14
		9	ENCLOSURES and PROTECTIVE COVERS	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 16		2023-02-14
		10	Separation	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 17		2023-02-14
		11	Protective earthing, functional earthing and potential equalisation	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 18		2023-02-14
		12	Continuous LEAKAGE CURRENTS and PATIENT	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 19		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			AUXILIARY CURRENTS			
		13	Dielectric strength	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 20		2023-02-14
		14	Mechanical strength	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 21		2023-02-14
		15	Moving parts	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 22		2023-02-14
		16	Surfaces, corners and edges	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 23		2023-02-14
		17	Stability in NORMAL USE	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 24		2023-02-14
		18	Expelled parts	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 25		2023-02-14
		19	Suspension system with SAFETY DEVICES	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 28.3		2023-02-14
		20	Suspension systems of metal without SAFETY DEVICES	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 28.4		2023-02-14
		21	X-Radiation	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 29		2023-02-14
		22	PROTECTION AGAINST HAZARDS OF IGNITION OFFLAMMABLE ANAESTHETIC MIXTURES	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Electromagnetic compatibility	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 36		2023-02-14
		24	Excessive temperatures	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 42		2023-02-14
		25	Fire prevention	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 43		2023-02-14
		26	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilisation,disinfection and compatibility	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 44		2023-02-14
		27	Pressure vessels and parts subject to PRESSURE	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 45		2023-02-14
		28	Biocompatibility	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 48		2023-02-14
		29	Interruption of the power supply	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 49		2023-02-14
		30	ACCURACY OF OPERATING DATA AND PROTECTIONAGAINST HAZARDOUS OUTPUT	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 8		2023-02-14
		31	ABNORMAL OPERATION AND FAULT	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			CONDITIONS;ENVIRONMENTAL TESTS			
		32	CONSTRUCTIONAL REQUIREMENTS	Medical electrical equipment –Part 1:General requirements for safety GB9706.1-2007 IEC60601-1:1988 10	Accredited only for specific clients	2023-02-14
7	Medical electrical systems	1	All Parameters	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000		2023-02-14
		2	General requirements	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 3		2023-02-14
		3	Identification, marking and documents	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 6		2023-02-14
		4	Environmental conditions	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 10		2023-02-14
		5	ENCLOSURES and PROTECTIVE COVERS	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 16		2023-02-14
		6	Separation	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 17		2023-02-14
		7	Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 19		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			CURRENTS			
		8	Moving parts	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 22		2023-02-14
		9	PROTECTION AGAINST HAZARDS FROM UNWANTEDOR EXCESSIVE RADIATION	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 5		2023-02-14
		10	PROTECTION AGAINST HAZARDS OF IGNITIONOF FLAMMABLE ANAESTHETIC MIXTURES	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 6		2023-02-14
		11	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning,sterilizatio n, disinfection and compatibility	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 44		2023-02-14
		12	Interruption of the power supply	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 49		2023-02-14
		13	ACCURACY OF OPERATING DATA AND PROTECTIONAG	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 8		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			AINST HAZARDOUS OUTPUT			
		14	ABNORMAL OPERATION AND FAULT CONDITIONS;ENVIRONMENTAL TESTS	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 9		2023-02-14
		15	Components and general assembly	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 56		2023-02-14
		16	MAINS PARTS, components and layout	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 57		2023-02-14
		17	Protective earthing – Terminals and connection	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 58		2023-02-14
		18	Construction and layout	Medical electrical equipment Part 1:General requirements for safety 1.Collateral standard :Safety requirements for medical electrical systems GB9706.15-2008 IEC60601-1-1:2000 59		2023-02-14
8	Radiotherapy record and verify systems	1	All Parameters	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009		2023-02-14
		2	accompanying documents	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 5		2023-02-14
		3	Radiation quantities	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 6.1		2023-02-14
		4	Date and Time	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 6.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Coordinate systems and scale	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 6.3		2023-02-14
		6	Protecion against unauthorized use	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 6.4		2023-02-14
		7	Correctness of data transfer	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 6.5		2023-02-14
		8	Data acceptance	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 6.6		2023-02-14
		9	Deleting and editing data	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 6.7		2023-02-14
		10	Backing up data	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 6.8		2023-02-14
		11	Archiving data	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 6.9		2023-02-14
		12	Prevention of treatment	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 7.1		2023-02-14
		13	Override	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 7.2		2023-02-14
		14	Transfer of prescribed treatment data	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 7.3		2023-02-14
		15	accompanying information	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 7.4		2023-02-14
		16	TREATMENT recording and reporting	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 8		2023-02-14
		17	Accuracy	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 9		2023-02-14
		18	General hardware diagnostics	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 10.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	Data and code	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 10.2		2023-02-14
		20	Human errors in software design	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 11		2023-02-14
		21	Change in software versions	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 12		2023-02-14
		22	Human errors in use	Medical electrical equipment—Safety of radiotherapy record and verify systems YY0721-2009 13		2023-02-14
9	Medical digital imaging and communication (DICOM)Radiation therapy object	1	All Parameters	Medical electrical equipment Medical digital imaging and communication(DICOM)Radiation therapy object YY/T 0723-2009		2023-02-14
		2	Addendum Radiotherapy INFORMATION OBJECT DEFINITION	Medical electrical equipment Medical digital imaging and communication(DICOM)Radiation therapy object YY/T 0723-2009 3		2023-02-14
		3	Addendum Radiotherapy Storage SOP Classes	Medical electrical equipment Medical digital imaging and communication(DICOM)Radiation therapy object YY/T 0723-2009 4		2023-02-14
		4	Addendum Radiotherapy Data Dictionary	Medical electrical equipment Medical digital imaging and communication(DICOM)Radiation therapy object YY/T 0723-2009 6		2023-02-14
10	Protective clothing and protective devices for gonads	1	All Parameters	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998		2023-02-14
		2	Accompanying documents	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Language of the accompanying documents	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 4.2		2023-02-14
		4	General requirement on marking	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 4.3		2023-02-14
		5	Design	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 4.4.		2023-02-14
		6	Materials	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 4.5		2023-02-14
		7	Protective Aprons	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 5		2023-02-14
		8	Design	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 5.1		2023-02-14
		9	Materials	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 5.2		2023-02-14
		10	Dimensions	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 5.3		2023-02-14
		11	Marking	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 5.4		2023-02-14
		12	Statement of compliance	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 5.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Protective gloves	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 6		2023-02-14
		14	Design	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 6.1		2023-02-14
		15	Materials	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 6.2		2023-02-14
		16	Dimensions	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 6.3		2023-02-14
		17	Marking	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 6.4		2023-02-14
		18	Statement of compliance	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 6.5		2023-02-14
		19	Protective mittens	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 7		2023-02-14
		20	Design	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 7.1		2023-02-14
		21	Materials	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 7.2		2023-02-14
		22	Dimensions	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 7.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Marking	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 7.4		2023-02-14
		24	Statement of compliance	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 7.5		2023-02-14
		25	Protective gonad aprons	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 8		2023-02-14
		26	Design	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 8.1		2023-02-14
		27	Materials	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 8.2		2023-02-14
		28	Dimensions	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 8.3		2023-02-14
		29	Marking	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 8.4		2023-02-14
		30	Statement of compliance	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 8.5		2023-02-14
		31	Scrotum shields	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 9		2023-02-14
		32	Design	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 9.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		33	Materials	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 9.2		2023-02-14
		34	Dimensions	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 9.3		2023-02-14
		35	Marking	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 9.4		2023-02-14
		36	Statement of compliance	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 9.5		2023-02-14
		37	Ovary shields	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 10		2023-02-14
		38	Design	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 10.1		2023-02-14
		39	Materials	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 10.2		2023-02-14
		40	Dimensions	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 10.3		2023-02-14
		41	Marking	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 10.4		2023-02-14
		42	Statement of compliance	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 10.5		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		43	Shadow shields	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 11		2023-02-14
		44	Design	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 11.1		2023-02-14
		45	Materials	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 11.2		2023-02-14
		46	Dimensions	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 11.3		2023-02-14
		47	Marking	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 11.4		2023-02-14
		48	Statement of compliance	Protective device against diagnostic medical X-radiation—Part 3:Protective clothing and protective devices for gonads YY 0318-2000 IEC 61331-3:1998 11.5		2023-02-14
11	Magnetic resonance equipment for medical imaging	1	All Parameters	Magnetic resonance equipment for medical imaging-Part 1:Determination of essential image quality parameters YY/T 0482-2022 IEC 62464-1:2018,MOD		2023-02-14
		2	General requirements for all procedures	Magnetic resonance equipment for medical imaging-Part 1:Determination of essential image quality parameters YY/T 0482-2022 IEC 62464-1:2018,MOD 4.1		2023-02-14
		3	Rapport SIGNAL/BRUIT	Magnetic resonance equipment for medical imaging-Part 1:Determination of essential image quality parameters YY/T 0482-2022 IEC 62464-1:2018,MOD 4.2		2023-02-14
		4	Uniformite	Magnetic resonance equipment for medical imaging-Part 1:Determination of essential image quality parameters YY/T 0482-2022 IEC 62464-1:2018,MOD 4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Slice thickness in 2-D scannning	Magnetic resonance equipment for medical imaging-Part 1:Determination of essential image quality parameters YY/T 0482-2022 IEC 62464-1:2018,MOD 4.4		2023-02-14
		6	Two-dimensional geometric distortion	Magnetic resonance equipment for medical imaging-Part 1:Determination of essential image quality parameters YY/T 0482-2022 IEC 62464-1:2018,MOD 4.5		2023-02-14
		7	Spatial resolution	Magnetic resonance equipment for medical imaging-Part 1:Determination of essential image quality parameters YY/T 0482-2022 IEC 62464-1:2018,MOD 4.6		2023-02-14
		8	Ghosting artefacts	Magnetic resonance equipment for medical imaging-Part 1:Determination of essential image quality parameters YY/T 0482-2022 IEC 62464-1:2018,MOD 4.7		2023-02-14
		9	Constancy test	Magnetic resonance equipment for medical imaging-Part 1:Determination of essential image quality parameters YY/T 0482-2022 IEC 62464-1:2018,MOD 5		2023-02-14
12	Magnetic resonance equipment for medical diagnosis	1	All Parameters	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002		2023-02-14
		2	General	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 1		2023-02-14
		3	instruction for use	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 6.8.2		2023-02-14
		4	instruction for technology	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 6.8.3		2023-02-14
		5	Vibration and noise	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 26		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Electromagnetic compatibility	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 36		2023-02-14
		7	Pressure vessels and parts subject to Pressure	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 45		2023-02-14
		8	Interruption of the power supply	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 49		2023-02-14
		9	Emergency fields shut down unit	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 49.101		2023-02-14
		10	Scan interruption	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 49.102		2023-02-14
		11	Protection against hazardous output	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51		2023-02-14
		12	Operating mode	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51.101		2023-02-14
		13	All operating modes	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51.101.1		2023-02-14
		14	Normal operation mode	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51.101.2		2023-02-14
		15	First level controlled operating mode	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51.101.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Second level controlled operating mode	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51.101.4		2023-02-14
		17	Protection against excessive low frequency fields variations produced by thegradient system	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51.102		2023-02-14
		18	Objectives for limitation of gradient output	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51.102.1		2023-02-14
		19	Limits for gradient output	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51.102.2		2023-02-14
		20	Limits for temperature	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51.103.1		2023-02-14
		21	Limits for SAR	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51.103.2		2023-02-14
		22	Control of SAR	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51.103.3		2023-02-14
		23	Protection against exposure to static magnetic fieldss	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 51.104		2023-02-14
		24	Abnormal operation and fault conditions	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		25	Construction and layout	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 59		2023-02-14
		26	Liquid cryogen and cryogen gases	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis YY 0319-2008 IEC 60601-2-33:2002 59.101		2023-02-14
13	Medical polymer products	1	All Parameters	Medical polymer products-Test methods of radiopacity YY/T 0586-2016		2023-02-14
		2	Arrangement of test samples	Medical polymer products-Test methods of radiopacity YY/T 0586-2016 9.1		2023-02-14
		3	X-ray exposure	Medical polymer products-Test methods of radiopacity YY/T 0586-2016 9.2		2023-02-14
		4	The film developing	Medical polymer products-Test methods of radiopacity YY/T 0586-2016 9.3		2023-02-14
		5	Qualitative analysis	Medical polymer products-Test methods of radiopacity YY/T 0586-2016 9.4		2023-02-14
		6	Quantitative analysis	Medical polymer products-Test methods of radiopacity YY/T 0586-2016 9.5		2023-02-14
		7	Report	Medical polymer products-Test methods of radiopacity YY/T 0586-2016 10		2023-02-14
		8	Precision and bias	Medical polymer products-Test methods of radiopacity YY/T 0586-2016 11		2023-02-14
14	Medical electrical equipment	1	All Parameters	Environmental requirement and test methods for medical electrical equipment GB/T14710-2009		2023-02-14
		2	Rated work low temperature test	Environmental requirement and test methods for medical electrical equipment GB/T14710-2009 11.1		2023-02-14
		3	Low temperature storage test	Environmental requirement and test methods for medical electrical equipment GB/T14710-2009 11.2		2023-02-14
		4	Rated work high temperature test	Environmental requirement and test methods for medical electrical equipment GB/T14710-2009 11.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	High temperature storage test	Environmental requirement and test methods for medical electrical equipment GB/T14710-2009 11.4		2023-02-14
		6	Rated work humid heat test	Environmental requirement and test methods for medical electrical equipment GB/T14710-2009 11.5		2023-02-14
		7	Damp heat storage test	Environmental requirement and test methods for medical electrical equipment GB/T14710-2009 11.6		2023-02-14
		8	Vibration test	Environmental requirement and test methods for medical electrical equipment GB/T14710-2009 11.7		2023-02-14
		9	Crash test	Environmental requirement and test methods for medical electrical equipment GB/T14710-2009 11.8		2023-02-14
		10	The adaptability of the power supply test	Environmental requirement and test methods for medical electrical equipment GB/T14710-2009 11.9		2023-02-14
15	Vertical mode steam sterilizers	1	All Parameters	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018		2023-02-14
		2	Appearance and structure	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.2		2023-02-14
		3	Pressure vessels and components	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.3		2023-02-14
		4	Safety interlocking device	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.4		2023-02-14
		5	Pressure (temperature) test connector	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.5		2023-02-14
		6	Sterilizing chamber pressure indicator	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.6.1		2023-02-14
		7	Pressure indicator (if any)	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.6.2		2023-02-14
		8	Temperature indicator	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.6.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9		General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.6.4		2023-02-14
		10	Recording instruments and their records (if any)	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.6.4		2023-02-14
		11	Timer (if any)	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.6.5		2023-02-14
		12	Alarm display	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.6.6		2023-02-14
		13	Cycle counter (applicable to automatic control type sterilizer)	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.6.7		2023-02-14
		14	The air filter (for vacuum sterilizer)	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.7		2023-02-14
		15	The vacuum system (for vacuum sterilizer)	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.8		2023-02-14
		16	Steam generator (for vacuum sterilizer)	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.9		2023-02-14
		17	temperature control	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.10.1		2023-02-14
		18	Pressure controller (for manual control)	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.10.2		2023-02-14
		19	Sealing performance	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.11		2023-02-14
		20	BD test (for vacuum sterilizer)	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.12		2023-02-14
		21	Sterilization effect	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.13		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	Dryness (for vacuum sterilizer)	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.14		2023-02-14
		23	Noise	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.15		2023-02-14
		24	Loading device	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.16		2023-02-14
		25	safety requirements	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.17	see GB4793.1, GB4793.4, GB18268	2023-02-14
		26	environmental test	General specifications on medical diagnostic X-ray equipment YY/T 1007-2018 5.18		2023-02-14
16	electron accelerators	1	All Parameters	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998		2023-02-14
		2	classification	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 5		2023-02-14
		3	External marking of equipment or equipment components	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 6.1		2023-02-14
		4	Internal marking of equipment or equipment parts	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 6.2		2023-02-14
		5	Provisions for the scale and indication of moving parts	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 6.3.101		2023-02-14
		6	Indicator light and button	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				GB9706.5-2008IEC 60601-2-1：1998 6.7		
		7	instructions	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 6.8		2023-02-14
		8	environment condition	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 10		2023-02-14
		9	Casing and protective cover	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 16		2023-02-14
		10	Protection of grounding, function and point balance	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 18		2023-02-14
		11	Continuous drain current and patient auxiliary current	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 19		2023-02-14
		12	Drive motion	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 22.4		2023-02-14
		13	Pneumatic and hydraulic power	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 27		2023-02-14
		14	Suspended matter	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 28		2023-02-14
		15	Safety requirements for ionizing radiation	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 29		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	EMC	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 36		2023-02-14
		17	Abnormal operation and fault condition	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 52		2023-02-14
		18	Dot have parts, components and wiring	Medical electrical equipment-Part 2-1:particular requirements for the safety of electron accelerators in the range 1 MeV to 50MeV GB9706.5-2008IEC 60601-2-1：1998 57		2023-02-14
17	electron accelerators	1	All Parameters	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016		2023-02-14
		2	Repeatability	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.1.2		2023-02-14
		3	linear	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.1.3		2023-02-14
		4	With the change of equipment angle	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.1.4		2023-02-14
		5	With the change of equipment angle	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.1.5		2023-02-14
		6	The relation of the shape of the radiation field	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.1.6		2023-02-14
		7	Stability of measurement	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.1.7		2023-02-14
		8	Stability of mobile beam therapy	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.1.8		2023-02-14
		9	X- radiation	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.2.1		2023-02-14
		10	Electron radiation	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.2.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	X- radiation	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.3.1		2023-02-14
		12	Electron radiation	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.3.2		2023-02-14
		13	Radiation penumbra	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.3.3		2023-02-14
		14	X- radiation	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.4.1		2023-02-14
		15	Electron radiation	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.4.2		2023-02-14
		16	X- radiation and electron radiation can regulate the geometry and motion of the beam limiting system	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.4.3		2023-02-14
		17	Illumination and contrast of the light field	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.4.4		2023-02-14
		18	General requirements	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.5.1		2023-02-14
		19	Radiation beam axis in patients with an indication of the incident surface	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.5.2		2023-02-14
		20	Radiation beam axis in the patient out of the radiation surface of the instructions	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.5.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		21	Deflection of the beam axis with respect to the center of the beam	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.6.1		2023-02-14
		22	Center of instruction	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.6.2		2023-02-14
		23	Indicating device	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.7.1		2023-02-14
		24	Additional indication device for radiation source to equal center distance variable device and non center equipment	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.7.2		2023-02-14
		25	General requirements	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.8.1		2023-02-14
		26	Requirements for random files	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.8.2		2023-02-14
		27	Performance indication	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.8.3		2023-02-14
		28	Requirements for random files	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.9.1		2023-02-14
		29	Performance indication	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.9.2		2023-02-14
		30	General requirements	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.10.1		2023-02-14
		31	Vertical movement of the treatment bed	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.10.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		32	Rotation of the center of the treatment bed	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.10.3		2023-02-14
		33	Parallel degree of treatment bed rotary shaft	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.10.4		2023-02-14
		34	Stiffness of treatment bed	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.10.5		2023-02-14
		35	General requirements	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.11.1		2023-02-14
		36	Mechanical specifications for supporting structures	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.11.2		2023-02-14
		37	Imaging specifications	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.11.3		2023-02-14
		38	Files	Medical electrical equipment-Functional performance characteristics and test methods GB15213-2016 5.12		2023-02-14
18	electron accelerators	1	All Parameters	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ		2023-02-14
		2	Repeatability	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.1.1		2023-02-14
		3	linear	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.1.2		2023-02-14
		4	With the change of equipment angle	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.1.3		2023-02-14
		5	With the change of equipment angle	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.1.4		2023-02-14
		6	Daily stability	Medical electron accelerators-Acceptance and period tests		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				GB/T19046-2013IEC/TR 60977:2008，NEQ 4.1.5		
		7	The dose distribution of square X- radiation field varies with the change of the angular position	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.1.6		2023-02-14
		8	X- radiation	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.2.1		2023-02-14
		9	Electron radiation	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.2.2		2023-02-14
		10	X- radiation	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.3.1		2023-02-14
		11	Electron radiation	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.3.2		2023-02-14
		12	X- radiation	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.4.1		2023-02-14
		13	The geometry and motion speed of the X - ray and electron radiation can be regulated by the beam limiting system	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.4.2		2023-02-14
		14	Radiation beam axis in patients with an indication of the incident surface	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Position indication of the radiation beam axis on the exit surface of the patient	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.5.2		2023-02-14
		16	Position indication of the radiation beam axis on the patient's surface	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.6.1		2023-02-14
		17	Center of instruction	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.6.2		2023-02-14
		18	Indicating device	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.7.1		2023-02-14
		19	Additional indication device for radiation source to equal center distance variable device and non center equipment	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.7.2		2023-02-14
		20	Zero calibration position of rotary motion scale	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.8		2023-02-14
		21	The coincidence of the radiation field	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.9		2023-02-14
		22	Vertical movement of the treatment bed	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.10.1		2023-02-14
		23	Rotation of the center of the treatment bed	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.10.2		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		24	Stiffness of treatment bed	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.10.3		2023-02-14
		25	Spatial resolution of electronic imaging device	Medical electron accelerators-Acceptance and period tests GB/T19046-2013IEC/TR 60977:2008，NEQ 4.11		2023-02-14
19	electron accelerators	1	All Parameters	Radiotherapy equipment-Coordinates,movements and scales GB/T 18987-2015IEC 61217:2008		2023-02-14
		2	coordinate system	Radiotherapy equipment-Coordinates,movements and scales GB/T 18987-2015IEC 61217:2003 2		2023-02-14
		3	Definition of scale and digital display	Radiotherapy equipment-Coordinates,movements and scales GB/T 18987-2015IEC 61217:2008 3		2023-02-14
		4	Naming equipment movement	Radiotherapy equipment-Coordinates,movements and scales GB/T 18987-2015IEC 61217:2008 4		2023-02-14
		5	Zero position of equipment	Radiotherapy equipment-Coordinates,movements and scales GB/T 18987-2015IEC 61217:2008 5		2023-02-14
		6	Scale, division, direction and display directory	Radiotherapy equipment-Coordinates,movements and scales GB/T 18987-2015IEC 61217:2008 6		2023-02-14
20	electrocardiographs	1	All Parameters	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:1993		2023-02-14
		2	identification,marking and documents	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:1994 5.6		2023-02-14
		3	Marking on outside of equipment or equipment parts	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:1995 6.1		2023-02-14
		4	Instructions for use	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:1996 6.8.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	envirement condition	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:1997 10		2023-02-14
		6	insulation	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:1998 17.1		2023-02-14
		7	leakage current and patient auxiliary current	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:1999 19.3		2023-02-14
		8	deelectric strength	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2000 20		2023-02-14
		9	Ultraviolet radiation	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2001 34		2023-02-14
		10	protetive parts	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2002 42.5		2023-02-14
		11	spillage	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2003 44.4		2023-02-14
		12	protection against the effects of defibrillation	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2004 51.101.1		2023-02-14
		13	protection against hazardous output	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2005 51		2023-02-14
		14	protection against the effects of	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			defibrillation	25:2006 51.101.1		
		15	class 1electrocardiograph	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2007 51.101.2		2023-02-14
		16	Recovery time of the electrocardiograph from electrode polarization after defibrillation	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2008 51.102		2023-02-14
		17	indication of inoperable electrocardiograph	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2009 51.103		2023-02-14
		18	connection	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2010 56.3		2023-02-14
		19	internal power	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2011 56.7		2023-02-14
		20	mains parts,components and layout	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2012 57.5		2023-02-14
		21	creepage distants and air clearances	Medical electrical equipment –Part 2：Particular requirements for safety of electrocardiographs GB10793-2000IEC 60601-2-25:2013 57.10		2023-02-14
21	Diagnostic electrocardiographic devices	1	All Parameters	Diagnostic electrocardiographic device YY 1139-2013		2023-02-14
		2	requirmens	Diagnostic electrocardiographic device YY 1139-2013 4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Marking on outside of equipment or equipment parts	Diagnostic electrocardiographic device YY 1139-2013 4.1.1		2023-02-14
		4	Instructions for use	Diagnostic electrocardiographic device YY 1139-2013 4.1.2		2023-02-14
		5	service manual	Diagnostic electrocardiographic device YY 1139-2013 4.1.3		2023-02-14
		6	work condition	Diagnostic electrocardiographic device YY 1139-2013 4.2.1		2023-02-14
		7	LEADS	Diagnostic electrocardiographic device YY 1139-2013 4.2.2		2023-02-14
		8	input dynamic range	Diagnostic electrocardiographic device YY 1139-2013 4.2.3		2023-02-14
		9	gains control,accuracy and stability	Diagnostic electrocardiographic device YY 1139-2013 4.2.4		2023-02-14
		10	time base selecter ,accuracy	Diagnostic electrocardiographic device YY 1139-2013 4.2.5		2023-02-14
		11	display of output	Diagnostic electrocardiographic device YY 1139-2013 4.2.6		2023-02-14
		12	accuracy of input signal reconstruction	Diagnostic electrocardiographic device YY 1139-2013 4.2.7		2023-02-14
		13	calibration voltage	Diagnostic electrocardiographic device YY 1139-2013 4.2.8		2023-02-14
		14	input impedance	Diagnostic electrocardiographic device YY 1139-2013 4.2.9		2023-02-14
		15	DC currents of patient electrodes conection	Diagnostic electrocardiographic device YY 1139-2013 4.2.10		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	common rejection	Diagnostic electrocardiographic device YY 1139-2013 4.2.11		2023-02-14
		17	nosie of system	Diagnostic electrocardiographic device YY 1139-2013 4.2.12		2023-02-14
		18	base line control STABILITY	Diagnostic electrocardiographic device YY 1139-2013 4.2.13		2023-02-14
		19	protective over load	Diagnostic electrocardiographic device YY 1139-2013 4.2.14		2023-02-14
		20	dangerous current	Diagnostic electrocardiographic device YY 1139-2013 4.2.15		2023-02-14
		21	auxiliary output	Diagnostic electrocardiographic device YY 1139-2013 4.2.16		2023-02-14
22	electrocardiographs	1	All Parameters	Methods of the reliable test of electrocardiographs YY/T0195-1994		2023-02-14
		2	select of test plan	Methods of the reliable test of electrocardiographs YY/T0195-1994 4		2023-02-14
		3	statistics of typical parameter	Methods of the reliable test of electrocardiographs YY/T0195-1994 5		2023-02-14
		4	test sample and accumulated test time	Methods of the reliable test of electrocardiographs YY/T0195-1994 6		2023-02-14
		5	test condition	Methods of the reliable test of electrocardiographs YY/T0195-1994 7		2023-02-14
		6	test stress	Methods of the reliable test of electrocardiographs YY/T0195-1994 7.1		2023-02-14
		7	working condition and continouse monitor	Methods of the reliable test of electrocardiographs YY/T0195-1994 7.2		2023-02-14
		8	periodic control	Methods of the reliable test of electrocardiographs YY/T0195-1994 7.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	test method	Methods of the reliable test of electrocardiographs YY/T0195-1994 8		2023-02-14
		10	preview of sample	Methods of the reliable test of electrocardiographs YY/T0195-1994 8.1		2023-02-14
		11	test items period and test methods	Methods of the reliable test of electrocardiographs YY/T0195-1994 8.2		2023-02-14
		12	failure criterion and calculated failure data	Methods of the reliable test of electrocardiographs YY/T0195-1994 9		2023-02-14
		13	records &reports	Methods of the reliable test of electrocardiographs YY/T0195-1994 10		2023-02-14
23	surgical luminaries and luminaries for diagnosis	1	All Parameters	Medical electrical equipment –Part 2：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2000		2023-02-14
		2	classification	Medical electrical equipment –Part 2：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2000 5		2023-02-14
		3	identification,marking and documents	Medical electrical equipment –Part 3：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2001 6.1		2023-02-14
		4	instructions for use	Medical electrical equipment –Part 4：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2002 6.8.2		2023-02-14
		5	enclosure and protective cover	Medical electrical equipment –Part 5：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2003 14.2		2023-02-14
		6	enclosure and protective cover	Medical electrical equipment –Part 5：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2003 16		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	moving parts	Medical electrical equipment –Part 6：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2004 22		2023-02-14
		8	stability of normal use	Medical electrical equipment –Part 7：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2005 24		2023-02-14
		9	expelled parts	Medical electrical equipment –Part 8：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2006 25		2023-02-14
		10	ultraviolet radiation	Medical electrical equipment –Part 9：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2007 34		2023-02-14
		11	protective parts	Medical electrical equipment –Part 12：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2010 42.5		2023-02-14
		12	ingress of water	Medical electrical equipment –Part 13：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2011 44.6		2023-02-14
		13	cleaning,disinfection,sterilization	Medical electrical equipment –Part 14：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2012 44.7		2023-02-14
		14	interupt of power	Medical electrical equipment –Part 15：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2013 49		2023-02-14
		15	accuracy work data and hazards output	Medical electrical equipment –Part 16：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2014 50.102		2023-02-14
		16	indication of inoperable	Medical electrical equipment –Part 17：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				0627-2008IEC 60601-2-41:2015 52		
		17	requirments of constucture	Medical electrical equipment –Part 18：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2016 55		2023-02-14
		18	requirments of constucture	Medical electrical equipment –Part 18：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2016 56		2023-02-14
		19	requirments of constucture	Medical electrical equipment –Part 18：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2016 57.1		2023-02-14
		20	requirments of constucture	Medical electrical equipment –Part 18：Particular requirements for safety of surgical luminaries and luminaries for diagnosis YY 0627-2008IEC 60601-2-41:2016 59		2023-02-14
24	Large steam sterilizers-Manual control type	1	All Parameters	Large steam sterilizers-Manual control type YY0731-2009		2023-02-14
		2	Appearance and structure	Large steam sterilizers-Manual control type YY0731-2009 5.2		2023-02-14
		3	Sterilization room size	Large steam sterilizers-Manual control type YY0731-2009 5.3		2023-02-14
		4	Overview of pressure vessel	Large steam sterilizers-Manual control type YY0731-2009 5.4.1		2023-02-14
		5	Double door sterilizers	Large steam sterilizers-Manual control type YY0731-2009 5.4.2		2023-02-14
		6	Test connector	Large steam sterilizers-Manual control type YY0731-2009 5.4.3		2023-02-14
		7	Insulation materials	Large steam sterilizers-Manual control type YY0731-2009 5.4.4		2023-02-14
		8	Safety valve	Large steam sterilizers-Manual control type YY0731-2009 5.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Drain valve	Large steam sterilizers-Manual control type YY0731-2009 5.6		2023-02-14
		10	Pressure relief valve	Large steam sterilizers-Manual control type YY0731-2009 5.7		2023-02-14
		11	General valve	Large steam sterilizers-Manual control type YY0731-2009 5.8		2023-02-14
		12	The steam generator inlet water	Large steam sterilizers-Manual control type YY0731-2009 5.9.1		2023-02-14
		13	The steam generator water level mirror	Large steam sterilizers-Manual control type YY0731-2009 5.9.2		2023-02-14
		14	The low water level of steam generator breaker	Large steam sterilizers-Manual control type YY0731-2009 5.9.3		2023-02-14
		15	Steam generator indicator	Large steam sterilizers-Manual control type YY0731-2009 5.9.4		2023-02-14
		16	Pressure gauge	Large steam sterilizers-Manual control type YY0731-2009 5.10.1		2023-02-14
		17	thermometer	Large steam sterilizers-Manual control type YY0731-2009 5.10.2		2023-02-14
		18	Time display device	Large steam sterilizers-Manual control type YY0731-2009 5.10.3		2023-02-14
		19	Sterilization effect	Large steam sterilizers-Manual control type YY0731-2009 5.11		2023-02-14
		20	Temperature parameter	Large steam sterilizers-Manual control type YY0731-2009 5.12		2023-02-14
		21	Pressure controller	Large steam sterilizers-Manual control type YY0731-2009 5.13		2023-02-14
		22	Noise	Large steam sterilizers-Manual control type YY0731-2009 5.14		2023-02-14
		23	Loading device	Large steam sterilizers-Manual control type YY0731-2009 5.15		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		24	Safety	Large steam sterilizers-Manual control type YY0731-2009 5.16	seeGB4793.1,GB4793.4	2023-02-14
		25	environmental test	Large steam sterilizers-Manual control type YY0731-2009 5.17		2023-02-14
25	Technical requirements for large steam sterilizers-Automatic type	1	All Parameters	Technical requirements for large steam sterilizers-Automatic type GB8599-2008		2023-02-14
		2	Appearance, structure and sterilization size	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.2		2023-02-14
		3	Material Science	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.3		2023-02-14
		4	Overview of pressure vessels	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.4.1		2023-02-14
		5	Interlocking device	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.4.1.2		2023-02-14
		6	Double door sterilizers	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.4.2		2023-02-14
		7	Test connector	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.4.3		2023-02-14
		8	Heat insulating material	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.4.4		2023-02-14
		9	The Conduit	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.5.1		2023-02-14
		10	Steam source	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.5.2		2023-02-14
		11	Air filter	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.5.3		2023-02-14
		12	vacuum system	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.5.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	instrument	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.6		2023-02-14
		14	display device	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.6.1.3		2023-02-14
		15	Double door sterilizers	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.6.1.4		2023-02-14
		16	Sensors, indicating instruments and timing equipment	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.6.2		2023-02-14
		17	Temperature	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.6.2.1		2023-02-14
		18	pressure	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.6.2.2		2023-02-14
		19	Time indicator	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.6.2.3		2023-02-14
		20	Control system	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.7		2023-02-14
		21	Vapor permeation	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.8.1		2023-02-14
		22	Sterilization effect of rubber load	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.8.2		2023-02-14
		23	Temperature parameter	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.8.3		2023-02-14
		24	Vacuum leakage	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.8.3.4		2023-02-14
		25	Load drying degree	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.8.4		2023-02-14
		26	Noise	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		27	Pressure change rate	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.10		2023-02-14
		28	safety requirements	Technical requirements for large steam sterilizers-Automatic type GB8599-2008 5.11	seeGB4793.1,GB4793.3,GB/T18268	2023-02-14
26	Dentistry-Operating lights	1	All Parameters	Dentistry-Operating lights YY/T 1120-2009		2023-02-14
		2	General Requirements	Dentistry-Operating lights YY/T 1120-2009 5.1		2023-02-14
		3	Optical requirements for illumination	Dentistry-Operating lights YY/T 1120-2009 5.2.1		2023-02-14
		4	Lighting area	Dentistry-Operating lights YY/T 1120-2009 5.2.2.1		2023-02-14
		5	illumination	Dentistry-Operating lights YY/T 1120-2009 5.2.2.2		2023-02-14
		6	illumination uniformity	Dentistry-Operating lights YY/T 1120-2009 5.2.2.3		2023-02-14
		7	Lighting for the eyes of the patient	Dentistry-Operating lights YY/T 1120-2009 5.2.3		2023-02-14
		8	chromatic aberration	Dentistry-Operating lights YY/T 1120-2009 5.2.4		2023-02-14
		9	Color temperature	Dentistry-Operating lights YY/T 1120-2009 5.2.5		2023-02-14
		10	Radiant heat	Dentistry-Operating lights YY/T 1120-2009 5.2.6		2023-02-14
		11	shadow	Dentistry-Operating lights YY/T 1120-2009 5.2.7		2023-02-14
		12	Color rendering index	Dentistry-Operating lights YY/T 1120-2009 5.2.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Ultraviolet radiation	Dentistry-Operating lights YY/T 1120-2009 5.2.9		2023-02-14
		14	Moving Parts	Dentistry-Operating lights YY/T 1120-2009 5.3.1		2023-02-14
		15	Operation console	Dentistry-Operating lights YY/T 1120-2009 5.3.2		2023-02-14
		16	turn round	Dentistry-Operating lights YY/T 1120-2009 5.3.3		2023-02-14
		17	Operation and mechanical adjustment	Dentistry-Operating lights YY/T 1120-2009 5.3.4		2023-02-14
		18	Splash	Dentistry-Operating lights YY/T 1120-2009 5.3.5		2023-02-14
		19	Cleaning and disinfection	Dentistry-Operating lights YY/T 1120-2009 5.4		2023-02-14
		20	Electrical safety	Dentistry-Operating lights YY/T 1120-2009 5.5	seeGB9706.1	2023-02-14
27	Hydrogen Peroxide Low Temperature Plasma Sterilizer	1	All Parameters	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015		2023-02-14
		2	Appearance and structure	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.2		2023-02-14
		3	Material Science	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.3		2023-02-14
		4	Sterilizing chamber door and interlocking device	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.4		2023-02-14
		5	test connector	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.5		2023-02-14
		6	display device	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Recording device	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.7		2023-02-14
		8	Air filter	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.8		2023-02-14
		9	Control of sterilization cycle	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.9.1		2023-02-14
		10	Requirements for the operation of the sterilization cycle	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.9.2		2023-02-14
		11	Phase of the sterilization cycle, overview	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.9.3.1		2023-02-14
		12	Vacuum phase	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.9.3.2		2023-02-14
		13	Injection stage	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.9.3.3		2023-02-14
		14	Diffusion stage	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.9.3.4		2023-02-14
		15	Plasma phase	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.9.3.5		2023-02-14
		16	Ventilation stage	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.9.3.6		2023-02-14
		17	Alarm requirements	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.10.1		2023-02-14
		18	temperature alarm	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.10.2		2023-02-14
		19	Pressure alarm	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.10.3		2023-02-14
		20	Hydrogen peroxide measurement alarm	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.10.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		21	Hydrogen peroxide injection out of limit alarm	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.10.5		2023-02-14
		22	Plasma generator fault alarm	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.10.6		2023-02-14
		23	Fault handling	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.10.7		2023-02-14
		24	Sterilization effect	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.11		2023-02-14
		25	Vacuum sealing property	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.12		2023-02-14
		26	Volumetric error	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.13		2023-02-14
		27	Working noise	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.14		2023-02-14
		28	Concentration of hydrogen peroxide in air	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.15.1		2023-02-14
		29	Hydrogen peroxide residue	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.15.2		2023-02-14
		30	Electrical Safety Requirements for Employee Workplaces	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.15.3	seeGB4793.1	2023-02-14
		31	electromagnetic compatibility	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.15.4		2023-02-14
		32	environmental test	Hydrogen Peroxide Low Temperature Plasma Sterilizer GB/T32309-2015 5.16		2023-02-14
28	Nerve and muscle	1	All Parameters	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	stimulators			60601-2-10：1987		
		2	classification	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 5		2023-02-14
		3	External marking of equipment or equipment components	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 6.1		2023-02-14
		4	file	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 6.8		2023-02-14
		5	Power input	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 7		2023-02-14
		6	Leakage current and patient auxiliary current	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 19		2023-02-14
		7	Dielectric strength	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 20		2023-02-14
		8	Electromagnetic compatibility	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 36		2023-02-14
		9	Excessive temperatures	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 42		2023-02-14
		10	Human error	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				60601-2-10：1987 46		
		11	The accuracy of the data work	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 50		2023-02-14
		12	Supply voltage fluctuations	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 51.101		2023-02-14
		13	Output latch	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 51.102		2023-02-14
		14	Output indication	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 51.103		2023-02-14
		15	Limitation of output paramenters	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 51.104		2023-02-14
		16	Mains supply cables or cords	Medical electrical equipment-Part 2:-Particular requirements for the safety of nerve and muscle stimulators YY0607-2007/IEC 60601-2-10：1987 57.3		2023-02-14
29	Nerve and muscle stimulators	1	All Parameters	Test method for measuring output characteristics of the nerve and muscle stimulators YY/T 0696-2021		2023-02-14
		2	RMS measurement	Test method for measuring output characteristics of the nerve and muscle stimulators YY/T 0696-2021 5.1		2023-02-14
		3	Current density	Test method for measuring output characteristics of the nerve and muscle stimulators YY/T 0696-2021 5.2		2023-02-14
		4	Output amplitude	Test method for measuring output characteristics of the nerve and muscle stimulators YY/T 0696-2008 5.3		2023-02-14
		5	Pulse energy	Test method for measuring output characteristics of the nerve and muscle stimulators YY/T 0696-2021 5.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Pulse Width	Test method for measuring output characteristics of the nerve and muscle stimulators YY/T 0696-2021 5.4		2023-02-14
		7	Pulse repetition frequency	Test method for measuring output characteristics of the nerve and muscle stimulators YY/T 0696-2021 5.5		2023-02-14
		8	DC component	Test method for measuring output characteristics of the nerve and muscle stimulators YY/T 0696-2021 5.6		2023-02-14
30	Disposable ECG electrodes	1	All Parameters	Disposable ECG electrodes YY/T 0196-2005		2023-02-14
		2	Label	Disposable ECG electrodes YY/T 0196-2005 4.1		2023-02-14
		3	AC impedance	Disposable ECG electrodes YY/T 0196-2005 4.2.1		2023-02-14
		4	DC offset power supply	Disposable ECG electrodes YY/T 0196-2005 4.2.2		2023-02-14
		5	Composite offset instability and internal noise	Disposable ECG electrodes YY/T 0196-2005 4.2.3		2023-02-14
		6	Defibrillation overload recovery	Disposable ECG electrodes YY/T 0196-2005 4.2.4		2023-02-14
		7	Bias current tolerance	Disposable ECG electrodes YY/T 0196-2005 4.2.5		2023-02-14
		8	Bioreactor	Disposable ECG electrodes YY/T 0196-2005 4.3.1		2023-02-14
		9	Pre-wire connection security	Disposable ECG electrodes YY/T 0196-2005 4.3.2		2023-02-14
31	Blood refrigerator	1	All Parameters	Blood refrigerator YY/T 0168-2007		2023-02-14
		2	Effective volume	Blood refrigerator YY/T 0168-2007 5.2		2023-02-14
		3	Temperature Performance	Blood refrigerator YY/T 0168-2007 5.3.1		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Cooling rate	Blood refrigerator YY/T 0168-2007 5.3.2		2023-02-14
		5	Fluctuations in value	Blood refrigerator YY/T 0168-2007 5.3.3		2023-02-14
		6	Uniformity	Blood refrigerator YY/T 0168-2007 5.3.4		2023-02-14
		7	power consumption	Blood refrigerator YY/T 0168-2007 5.3.5		2023-02-14
		8	Start Performance	Blood refrigerator YY/T 0168-2007 5.3.6		2023-02-14
		9	Thermal insulation properties	Blood refrigerator YY/T 0168-2007 5.3.7		2023-02-14
		10	Over-temperature alarm	Blood refrigerator YY/T 0168-2007 5.3.8		2023-02-14
		11	Power failure alarm	Blood refrigerator YY/T 0168-2007 5.3.9		2023-02-14
		12	Defrosting performance	Blood refrigerator YY/T 0168-2007 5.3.10		2023-02-14
		13	Noise	Blood refrigerator YY/T 0168-2007 5.3.11		2023-02-14
		14	Vibration	Blood refrigerator YY/T 0168-2007 5.3.12		2023-02-14
		15	Lock	Blood refrigerator YY/T 0168-2007 5.4.1		2023-02-14
		16	Flashlight	Blood refrigerator YY/T 0168-2007 5.4.2		2023-02-14
		17	Door and cabinet	Blood refrigerator YY/T 0168-2007 5.4.3		2023-02-14
		18	Blood bottle bearer	Blood refrigerator YY/T 0168-2007 5.4.4		2023-02-14
		19	Blood bottle Shelving	Blood refrigerator YY/T 0168-2007 5.4.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		20	Temperature indicator	Blood refrigerator YY/T 0168-2007 5.4.6		2023-02-14
		21	Metal parts	Blood refrigerator YY/T 0168-2007 5.4.7		2023-02-14
		22	Exterior	Blood refrigerator YY/T 0168-2007 5.4.8		2023-02-14
		23	Housing and interior materials	Blood refrigerator YY/T 0168-2007 5.4.9		2023-02-14
		24	Environmental Testing	Blood refrigerator YY/T 0168-2007 5.5		2023-02-14
		25	Safety requirements	Blood refrigerator YY/T 0168-2007 6	seeGB4793.1	2023-02-14
32	Pharmaceutical refrigerator	1	All Parameters	Pharmaceutical refrigerator YY/T 0086-2020		2023-02-14
		2	Volume	Pharmaceutical refrigerator YY/T 0086-2020 5.2		2023-02-14
		3	Overall dimensions	Pharmaceutical refrigerator YY/T 0086-2020 5.3		2023-02-14
		4	Storage temperature	Pharmaceutical refrigerator YY/T 0086-2020 5.4.1		2023-02-14
		5	Cooling time	Pharmaceutical refrigerator YY/T 0086-2020 5.4.2		2023-02-14
		6	Power consumption	Pharmaceutical refrigerator YY/T 0086-2020 5.4.3		2023-02-14
		7	Temperature uniformity	Pharmaceutical refrigerator YY/T 0086-2020 5.4.4		2023-02-14
		8	Temperature fluctuation	Pharmaceutical refrigerator YY/T 0086-2020 5.4.5		2023-02-14
		9	Temperature display deviation	Pharmaceutical refrigerator YY/T 0086-2020 5.4.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Door opening and closing display temperature	Pharmaceutical refrigerator YY/T 0086-2020 5.4.7		2023-02-14
		11	Low temperature protection device (applicable to blood refrigerator)	Pharmaceutical refrigerator YY/T 0086-2020 5.4.8		2023-02-14
		12	Thermal insulation properties	Pharmaceutical refrigerator YY/T 0086-2020 5.5		2023-02-14
		13	Air tightness	Pharmaceutical refrigerator YY/T 0086-2020 5.6		2023-02-14
		14	Temperature monitoring	Pharmaceutical refrigerator YY/T 0086-2020 5.7		2023-02-14
		15	Power off alarm (applicable to blood refrigerator)	Pharmaceutical refrigerator YY/T 0086-2020 5.8		2023-02-14
		16	Shelves and containers	Pharmaceutical refrigerator YY/T 0086-2020 5.9		2023-02-14
		17	Automatic frosting, collection and treatment of defrosting water	Pharmaceutical refrigerator YY/T 0086-2020 5.10		2023-02-14
		18	Noise	Pharmaceutical refrigerator YY/T 0086-2020 5.11		2023-02-14
		19	Other requirements	Pharmaceutical refrigerator YY/T 0086-2020 5.13		2023-02-14
		20	Environmental Testing	Pharmaceutical refrigerator YY/T 0086-2020 5.13		2023-02-14
		21	Electromagnetic compatibility	Pharmaceutical refrigerator YY/T 0086-2020 5.14		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	Safety requirements	Pharmaceutical refrigerator YY/T 0086-2020 5.15	seeGB4793.1	2023-02-14
33	Recording and analysing single channel and multichannel of electrocardiographs	1	All Parameters	Medical eletrical equipment-Part 2-51:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003		2023-02-14
		2	External marking of equipment or equipment components	Medical eletrical equipment-Part 2-51:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 6.1		2023-02-14
		3	manual	Medical eletrical equipment-Part 2-51:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 6.8.2		2023-02-14
		4	Standard database used to assess the accuracy of ECG automated measurement	Medical eletrical equipment-Part 2-51:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 50.101.1		2023-02-14
		5	Requirements for amplitude measurements	Medical eletrical equipment-Part 2-51:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 50.101.2		2023-02-14
		6	Requirements for interval measurements	Medical eletrical equipment-Part 2-52:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 50.101.3.1		2023-02-14
		7	Requirements for interval measurements on	Medical eletrical equipment-Part 2-53:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			biological ECGs	YY0782-2010/IEC 60601-2-51:2003 50.101.3.2		
		8	Disclosure requirements for stability of measurements against noise	Medical eletrical equipment-Part 2-54:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 50.101.4		2023-02-14
		9	Open intended use	Medical eletrical equipment-Part 2-55:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 50.102.2		2023-02-14
		10	Public interpretation of diagnostic accuracy requirements	Medical eletrical equipment-Part 2-55:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 50.102.3.2		2023-02-14
		11	Requirements for accuracy of public rhythm diagnosis	Medical eletrical equipment-Part 2-55:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 50.102.4.2		2023-02-14
		12	Polarity of PATIENT LEADS	Medical eletrical equipment-Part 2-55:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.101.1		2023-02-14
		13	Goldberger and Wilson LEADS	Medical eletrical equipment-Part 2-56:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.101.2.2.1		2023-02-14
		14	Recovery time	Medical eletrical equipment-Part 2-57:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.101.2.3		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	CALIBRATION VOLTAGE	Medical eletrical equipment-Part 2-58:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.103.1		2023-02-14
		16	Reproduction of CALIBRATION VOLTAGE	Medical eletrical equipment-Part 2-59:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.103.2		2023-02-14
		17	Stability of SENSITIVITY	Medical eletrical equipment-Part 2-60:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.104.2		2023-02-14
		18	Accuracy of SENSITIVITY	Medical eletrical equipment-Part 2-61:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.104.3		2023-02-14
		19	COMMON MODE REJECTION	Medical eletrical equipment-Part 2-62:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.105.1		2023-02-14
		20	OVERLOAD TOLERANCE	Medical eletrical equipment-Part 2-63:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.105.2		2023-02-14
		21	Shift control	Medical eletrical equipment-Part 2-64:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.106.1		2023-02-14
		22	Temperature drift	Medical eletrical equipment-Part 2-65:Particularrequirements for safety ,including essential performance ,of recording and		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:200351.101.16 51.106.2		
		23	Stability	Medical eletrical equipment-Part 2-66:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.106.3		2023-02-14
		24	NOISE level	Medical eletrical equipment-Part 2-67:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:200351.101.18 51.106.4		2023-02-14
		25	Writing speed and trace width	Medical eletrical equipment-Part 2-68:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:200351.101.19 51.106.5		2023-02-14
		26	Interaction between CHANNELS of MULTICHANNEL ELECTROCARDIOGRAPHS	Medical eletrical equipment-Part 2-69:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.106.6		2023-02-14
		27	SENSITIVITY/baase-line interaction	Medical eletrical equipment-Part 2-70:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.106.7		2023-02-14
		28	High frequency response	Medical eletrical equipment-Part 2-71:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:200351.101.22 51.107.1.1.1		2023-02-14
		29	Low frequency response	Medical eletrical equipment-Part 2-72:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				YY0782-2010/IEC 60601-2-51:2003 51.107.1.1.2		
		30	Linearity and dynamic range	Medical eletrical equipment-Part 2-73:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.107.2		2023-02-14
		31	Response to minimum signal	Medical eletrical equipment-Part 2-74:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.107.3		2023-02-14
		32	Record identification	Medical eletrical equipment-Part 2-75:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.108.1		2023-02-14
		33	PATIENT identification	Medical eletrical equipment-Part 2-76:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.108.2		2023-02-14
		34	Recording duration	Medical eletrical equipment-Part 2-77:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.108.3		2023-02-14
		35	Rectangular co-ordinates,alignment of writing points	Medical eletrical equipment-Part 2-78:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.108.4.1		2023-02-14
		36	Time and event markers	Medical eletrical equipment-Part 2-79:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.108.4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		37	EFFECTIVE RECORDING WIDTH	Medical eletrical equipment-Part 2-80:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:200351.101.31 51.108.4.3		2023-02-14
		38	Recording speed	Medical eletrical equipment-Part 2-81:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.108.4.4		2023-02-14
		39	Time and amplitude ruling	Medical eletrical equipment-Part 2-82:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.108.4.5		2023-02-14
		40	Distortion of ECG	Medical eletrical equipment-Part 2-83:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.109.1		2023-02-14
		41	Visibility of pacemaker pulses	Medical eletrical equipment-Part 2-84:Particularrequirements for safety ,including essential performance ,of recording and analysing single channel and multichannel of electrocardiographs YY0782-2010/IEC 60601-2-51:2003 51.109.2		2023-02-14
34	Dental units	1	All Parameters	Dental units YY/T1043.1-2016 ISO7494: 1996		2023-02-14
		2	Design	Dental units YY/T1043.1-2016 ISO7494: 1996 5.1.1		2023-02-14
		3	Moving Parts	Dental units YY/T1043.1-2016 ISO7494: 1996 5.1.2		2023-02-14
		4	Operational control unit	Dental units YY/T1043.1-2016 ISO7494: 1996 5.1.3		2023-02-14
		5	Cleaning and disinfection	Dental units YY/T1043.1-2016 ISO7494: 1996 5.1.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Over temperature	Dental units YY/T1043.1-2016 ISO7494: 1996 5.1.5		2023-02-14
		7	Spittoon	Dental units YY/T1043.1-2016 ISO7494: 1996 5.2.1		2023-02-14
		8	Solid collector	Dental units YY/T1043.1-2016 ISO7494: 1996 5.2.2		2023-02-14
		9	malgam separating device	Dental units YY/T1043.1-2016 ISO7494: 1996 5.2.3		2023-02-14
		10	Bursting pressure	Dental units YY/T1043.1-2016 ISO7494: 1996 5.2.4		2023-02-14
		11	Pressure release	Dental units YY/T1043.1-2016 ISO7494: 1996 5.2.5		2023-02-14
		12	Stability in normal use	Dental units YY/T1043.1-2016 ISO7494: 1996 5.2.6		2023-02-14
		13	Electrical requirements	Dental units YY/T1043.1-2016 ISO7494: 1996 5.3	seeGB9706 .1	2023-02-14
35	Dental units	1	All Parameters	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003		2023-02-14
		2	General requirements	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003 4.1		2023-02-14
		3	Materials for processing water system in dental units	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003 4.2		2023-02-14
		4	Backflow prevention device for tap water supply system	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003 4.3		2023-02-14
		5	Spittoon	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Flow type pipe	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003 4.5		2023-02-14
		7	Particulate filter	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003 4.6		2023-02-14
		8	Provide water storage and supply system for water or solution input	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003 4.7		2023-02-14
		9	Suck back	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003 4.8		2023-02-14
		10	The water disinfection system	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003 4.9		2023-02-14
		11	General requirements	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003 5.1		2023-02-14
		12	Particulate filter	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003 5.2		2023-02-14
		13	Antimicrobial filter	Dentistry. Dental units. Part 2:Water and air supply YY/T1043.2-2018 ISO 7494-2:2003 5.3		2023-02-14
36	Dental handpieces	1	All Parameters	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997		2023-02-14
		2	Summary	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.1.1		2023-02-14
		3	Material Science	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.1.2		2023-02-14
		4	Structure and layout	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.1.3		2023-02-14
		5	Head dimensions and terminology	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.1.4		2023-02-14
		6	Summary	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.2.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Spring type chuck and friction type chuck	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.2.3		2023-02-14
		8	Mechanical chuck	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.2.4		2023-02-14
		9	Gland type chuck and the other chuck	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.2.5		2023-02-14
		10	Radial runout	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.2.6		2023-02-14
		11	Speed of revolution	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.3.1		2023-02-14
		12	Braking torque	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.3.2		2023-02-14
		13	Water cooling	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.4.2		2023-02-14
		14	Air cooling	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.4.3		2023-02-14
		15	Connector of handpieces	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.5		2023-02-14
		16	Pressure	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.6		2023-02-14
		17	Noise	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.7		2023-02-14
		18	Corrosion resistance	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.8		2023-02-14
		19	Resistance of sterilization	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.9		2023-02-14
		20	Light power supply	Dental handpieces. Part 1:High-speed air turbine handpieces YY 1045.1-2009 ISO 7785-1:1997 5.10		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
37	Electric dental engine	1	All Parameters	General technology condition for electric dental engine YY/T 1147-2004		2023-02-14
		2	Output power	General technology condition for electric dental engine YY/T 1147-2004 5.1.1		2023-02-14
		3	Positive and negative rotation	General technology condition for electric dental engine YY/T 1147-2004 5.1.2		2023-02-14
		4	Grade of spark	General technology condition for electric dental engine YY/T 1147-2004 5.1.3		2023-02-14
		5	Over speed test	General technology condition for electric dental engine YY/T 1147-2004 5.1.4		2023-02-14
		6	Current overload	General technology condition for electric dental engine YY/T 1147-2004 5.1.5		2023-02-14
		7	Noise	General technology condition for electric dental engine YY/T 1147-2004 5.2		2023-02-14
		8	Drive requirements of drive arm	General technology condition for electric dental engine YY/T 1147-2004 5.3		2023-02-14
		9	The coordination of the rotating arm and the connecting arm of the handpieces	General technology condition for electric dental engine YY/T 1147-2004 5.4		2023-02-14
		10	Dental handpieces	General technology condition for electric dental engine YY/T 1147-2004 5.5		2023-02-14
		11	safety requirements	General technology condition for electric dental engine YY/T 1147-2004 5.6	seeGB9706 .1	2023-02-14
		12	Environmental requirement	General technology condition for electric dental engine YY/T 1147-2004 5.7		2023-02-14
38	Electric dentistry chair	1	All Parameters	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011		2023-02-14
		2	Electrical requirements	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.1.1	seeGB9706 .1	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Moving Parts	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.1.2		2023-02-14
		4	Operation control device	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.1.3		2023-02-14
		5	Function stop system	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.1.4		2023-02-14
		6	Cover surface decoration material and filling material	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.1.5		2023-02-14
		7	Cleaning and disinfection	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.1.6		2023-02-14
		8	Over temperature	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.1.7		2023-02-14
		9	Summary	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.2.1		2023-02-14
		10	Headrest	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.2.2		2023-02-14
		11	Armrest	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.2.3		2023-02-14
		12	Load capacity	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.2.4		2023-02-14
		13	Bursting pressure	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.2.5		2023-02-14
		14	Extra load on first aid measures	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.2.6		2023-02-14
		15	Summary	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.3.1	seeGB9706.1	2023-02-14
		16	Safety failure of equipment	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.3.2		2023-02-14
		17	Test point	Dentistry. Patient chair YY/T 0058-2015 ISO 6875:2011 5.3.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
39	baby incubator	1	All Parameters	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008		2023-02-14
		2	External marking	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 6.1		2023-02-14
		3	Marking of controls and instruments	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 6.3		2023-02-14
		4	Indicator light and button	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 6.7		2023-02-14
		5	accompanying documents	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 6.8		2023-02-14
		6	environmental conditions	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 10		2023-02-14
		7	dielectric strength	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 20		2023-02-14
		8	mechanical strength	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 21		2023-02-14
		9	moving Parts	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 22		2023-02-14
		10	stability in normal use	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 24		2023-02-14
		11	excessive temperatures	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 42		2023-02-14
		12	fire prevention	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 43		2023-02-14
		13	spillage	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 44.3		2023-02-14
		14	leakage	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 44.4		2023-02-14
		15	cleaning、sterilization and	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 44.7		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			disinfection			
		16	erreurs humaines	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 46		2023-02-14
		17	interruption of the power supply	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 49		2023-02-14
		18	accuracy of operating data	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 50		2023-02-14
		19	general	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 54		2023-02-14
		20	enclosures and covers	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 55		2023-02-14
		21	temperature and overload control devices	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 56.6		2023-02-14
		22	supplement	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 56.10b）		2023-02-14
		23	alarm	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 101		2023-02-14
		24	sound pressure level	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 102		2023-02-14
		25	humidification device	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 103		2023-02-14
		26	Maximum air speed in box cover	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 104		2023-02-14
		27	carbon dioxide （CO2） concentration	Medical electrical equipment. Part 2:Particular requirements for safety of baby incubators GB 11243-2008 105		2023-02-14
40	implantable neural	1	All Parameters	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	stimulator	2	marking	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008 3.1		2023-02-14
		3	Nondestructive marking	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008 3.2		2023-02-14
		4	unit pack	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008 4.1		2023-02-14
		5	multiple pack	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008 4.2		2023-02-14
		6	General	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008 5.1		2023-02-14
		7	unit pack	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008 5.2		2023-02-14
		8	multiple pack	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008 5.3		2023-02-14
		9	General	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008 6.1		2023-02-14
		10	implant parts	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008 6.2		2023-02-14
		11	non-implant parts	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008 6.3		2023-02-14
		12	information for patient	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008 6.4		2023-02-14
		13	information for clinician	neurosurgical implants-marking and packaging of implantable neural stimulators YY/T 0684-2008 6.5		2023-02-14
41	high-speed dental airturbine unit	1	All Parameters	high-speed dental airturbine unit YY/T1044-2018		2023-02-14
		2	requirement	high-speed dental airturbine unit YY/T1044-2018 4.1		2023-02-14
		3	power	high-speed dental airturbine unit YY/T1044-2018 4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	handpiece	high-speed dental airturbine unit YY/T1044-2018 4.3		2023-02-14
		5	gas flow	high-speed dental airturbine unit YY/T1044-2018 4.4.1		2023-02-14
		6	temperature rise	high-speed dental airturbine unit YY/T1044-2018 4.4.2		2023-02-14
		7	regulating valve	high-speed dental airturbine unit YY/T1044-2018 4.5		2023-02-14
		8	drops of oil	high-speed dental airturbine unit YY/T1044-2018 4.6		2023-02-14
		9	water spraying device	high-speed dental airturbine unit YY/T1044-2018 4.7		2023-02-14
		10	connecting position	high-speed dental airturbine unit YY/T1044-2018 4.8		2023-02-14
		11	foot switch	high-speed dental airturbine unit YY/T1044-2018 4.9		2023-02-14
		12	noise	high-speed dental airturbine unit YY/T1044-2018 4.10		2023-02-14
		13	dielectric strength	high-speed dental airturbine unit YY/T1044-2018 4.11.1		2023-02-14
		14	the earth leakage current	high-speed dental airturbine unit YY/T1044-2018 4.11.2		2023-02-14
		15	plating parts	high-speed dental airturbine unit YY/T1044-2018 4.12		2023-02-14
		16	paint parts	high-speed dental airturbine unit YY/T1044-2018 4.13		2023-02-14
42	Buoy type oxygen inhalator	1	All Parameters	Buoy type oxygen inhalator YY 1107-2003		2023-02-14
		2	Appearance	Buoy type oxygen inhalator YY 1107-2003 4.1		2023-02-14
		3	working pressure	Buoy type oxygen inhalator YY 1107-2003 4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Flow range and basic error	Buoy type oxygen inhalator YY 1107-2003 4.3		2023-02-14
		5	Safety valve discharge pressure	Buoy type oxygen inhalator YY 1107-2003 4.4		2023-02-14
		6	Oxygen pressure gauge	Buoy type oxygen inhalator YY 1107-2003 4.5		2023-02-14
		7	The inhaler and oxygen bottle connection	Buoy type oxygen inhalator YY 1107-2003 4.6		2023-02-14
		8	Oxygen output connector	Buoy type oxygen inhalator YY 1107-2003 4.7		2023-02-14
		9	Flow tube	Buoy type oxygen inhalator YY 1107-2003 4.8		2023-02-14
		10	Flow regulation	Buoy type oxygen inhalator YY 1107-2003 4.9		2023-02-14
		11	Sealing property	Buoy type oxygen inhalator YY 1107-2003 4.10		2023-02-14
		12	humidification bottle	Buoy type oxygen inhalator YY 1107-2003 4.11		2023-02-14
		13	structural strength	Buoy type oxygen inhalator YY 1107-2003 4.12		2023-02-14
43	Direct impedance blood flow recorder	1	All Parameters	Direct impedance blood flow recorder YY/T 1078-2008		2023-02-14
		2	Input impedance	Direct impedance blood flow recorder YY/T 1078-2008 4.2		2023-02-14
		3	Base impedance	Direct impedance blood flow recorder YY/T 1078-2008 4.3		2023-02-14
		4	Impedance increment （ΔZ） and differential impedance (dZ/dt)	Direct impedance blood flow recorder YY/T 1078-2008 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			measurement range			
		5	Maximum sensitivity	Direct impedance blood flow recorder YY/T 1078-2008 4.5.1		2023-02-14
		6	Standard sensitivity	Direct impedance blood flow recorder YY/T 1078-2008 4.5.2		2023-02-14
		7	Standard sensitivity	Direct impedance blood flow recorder YY/T 1078-2008 4.5.3		2023-02-14
		8	Calibration resistor	Direct impedance blood flow recorder YY/T 1078-2008 4.6.1		2023-02-14
		9	Calibration cycle	Direct impedance blood flow recorder YY/T 1078-2008 4.6.2		2023-02-14
		10	Calibration signal	Direct impedance blood flow recorder YY/T 1078-2008 4.6.3		2023-02-14
		11	time constant	Direct impedance blood flow recorder YY/T 1078-2008 4.7		2023-02-14
		12	ΔZ external calibration square wave front	Direct impedance blood flow recorder YY/T 1078-2008 4.8		2023-02-14
		13	Noise	Direct impedance blood flow recorder YY/T 1078-2008 4.9		2023-02-14
		14	Constant current source frequency	Direct impedance blood flow recorder YY/T 1078-2008 4.10.1		2023-02-14
		15	The constant current source output current	Direct impedance blood flow recorder YY/T 1078-2008 4.10.2		2023-02-14
		16	The constant current source output impedance	Direct impedance blood flow recorder YY/T 1078-2008 4.10.3		2023-02-14
		17	Recording speed	Direct impedance blood flow recorder YY/T 1078-2008 4.11.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	Minimum detectable signal	Direct impedance blood flow recorder YY/T 1078-2008 4.11.2		2023-02-14
		19	Amplitude frequency characteristic	Direct impedance blood flow recorder YY/T 1078-2008 4.11.3.1		2023-02-14
		20	Overshoot	Direct impedance blood flow recorder YY/T 1078-2008 4.11.3.2		2023-02-14
		21	linear	Direct impedance blood flow recorder YY/T 1078-2008 4.11.4		2023-02-14
		22	The power supply voltage stability, baseline drift	Direct impedance blood flow recorder YY/T 1078-2008 4.11.5.1		2023-02-14
		23	Supply voltage transient fluctuations when the baseline drift	Direct impedance blood flow recorder YY/T 1078-2008 4.11.5.2		2023-02-14
		24	Time shift	Direct impedance blood flow recorder YY/T 1078-2008 4.11.5.3		2023-02-14
		25	temperature drift	Direct impedance blood flow recorder YY/T 1078-2008 4.11.5.4		2023-02-14
		26	Effect of sensitivity variation on baseline	Direct impedance blood flow recorder YY/T 1078-2008 4.11.5.5		2023-02-14
		27	When the record open about "closed" to "record", baseline drift	Direct impedance blood flow recorder YY/T 1078-2008 4.11.5.6		2023-02-14
		28	lagging	Direct impedance blood flow recorder YY/T 1078-2008 4.11.6		2023-02-14
		29	Safety requirements	Direct impedance blood flow recorder YY/T 1078-2008 4.12	seeGB9706.1，	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					YY0505	
		30	Environmental test requirements	Direct impedance blood flow recorder YY/T 1078-2008 4.13		2023-02-14
44	Bridge type impedance blood flow recorder	1	All Parameters	Bridge type impedance blood flow recorder YY/T 1143-2008		2023-02-14
		2	Battery indicator	Bridge type impedance blood flow recorder YY/T 1143-2008 5.2		2023-02-14
		3	Maximum sensitivity	Bridge type impedance blood flow recorder YY/T 1143-2008 5.3		2023-02-14
		4	Calibration	Bridge type impedance blood flow recorder YY/T 1143-2008 5.4		2023-02-14
		5	measuring range	Bridge type impedance blood flow recorder YY/T 1143-2008 5.5		2023-02-14
		6	Equivalent noise	Bridge type impedance blood flow recorder YY/T 1143-2008 5.6		2023-02-14
		7	Output impedance	Bridge type impedance blood flow recorder YY/T 1143-2008 5.7.1		2023-02-14
		8	Output DC voltage	Bridge type impedance blood flow recorder YY/T 1143-2008 5.7.2		2023-02-14
		9	Capacitor grading	Bridge type impedance blood flow recorder YY/T 1143-2008 5.8.1		2023-02-14
		10	Balance indicator	Bridge type impedance blood flow recorder YY/T 1143-2008 5.8.2		2023-02-14
		11	Range of balance	Bridge type impedance blood flow recorder YY/T 1143-2008 5.8.3		2023-02-14
		12	Calibration wave comparison	Bridge type impedance blood flow recorder YY/T 1143-2008 5.8.4		2023-02-14
		13	dcbridge voltage	Bridge type impedance blood flow recorder YY/T 1143-2008 5.9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Paper speed	Bridge type impedance blood flow recorder YY/T 1143-2008 5.10		2023-02-14
		15	High frequency characteristic	Bridge type impedance blood flow recorder YY/T 1143-2008 5.11.1		2023-02-14
		16	Low frequency characteristic	Bridge type impedance blood flow recorder YY/T 1143-2008 5.11.2		2023-02-14
		17	oscillation frequency	Bridge type impedance blood flow recorder YY/T 1143-2008 5.12		2023-02-14
		18	Baseline drift of AC power supply equipment	Bridge type impedance blood flow recorder YY/T 1143-2008 5.13		2023-02-14
		19	Baseline drift of AC power supply equipment	Bridge type impedance blood flow recorder YY/T 1143-2008 5.14		2023-02-14
		20	safety requirements	Bridge type impedance blood flow recorder YY/T 1143-2008 5.15	seeGB9706.1, YY0505	2023-02-14
		21	Environmental test requirements	Bridge type impedance blood flow recorder YY/T 1143-2008 5.16		2023-02-14
45	heat radiation therapy equipment	1	All Parameters	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018		2023-02-14
		2	Marking on the outside of equipment or equipment components	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 6.1		2023-02-14
		3	Controller and instrument marking	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 6.3		2023-02-14
		4	instructions for use	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 6.8.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Description technique	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 6.8.3		2023-02-14
		6	Stability in NORMAL USE	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 24		2023-02-14
		7	Excessive temperatures	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 42		2023-02-14
		8	Guards	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 42.5		2023-02-14
		9	Excessive temperatures alarm	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 42.102		2023-02-14
		10	Cleaning, sterilization and disinfection	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 44.7		2023-02-14
		11	Protection agaist hazardous output	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 51		2023-02-14
		12	Indication of parameters relevant to safety	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 51.2		2023-02-14
		13	The contact type equipment should have the measures of overheat protection	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 51.101		2023-02-14
		14	Indicators	Particular requirements for the safety of heat radiation therapy equipment YY 0306-2018 56.8		2023-02-14
46	medical foot switch	1	All Parameters	General Specifications for medical foot switch YY/T 1057-2016		2023-02-14
		2	Starting power	General Specifications for medical foot switch YY/T 1057-2016 4.1.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Working Resistance	General Specifications for medical foot switch YY/T 1057-2016 4.1.2		2023-02-14
		4	Mechanical strength	General Specifications for medical foot switch YY/T 1057-2016 4.1.3		2023-02-14
		5	Mechanical durability	General Specifications for medical foot switch YY/T 1057-2016 4.1.4		2023-02-14
		6	Connecting wire bending test	General Specifications for medical foot switch YY/T 1057-2016 4.1.5		2023-02-14
		7	Ingress of liquids	General Specifications for medical foot switch YY/T 1057-2016 4.1.6		2023-02-14
		8	Safety requirements	General Specifications for medical foot switch YY/T 1057-2016 4.2		2023-02-14
47	Oxygen Supply System in Medical Center	1	All Parameters	Oxygen Supply System in Medical Center YY/T0187-1994		2023-02-14
		2	Gas cylinders	Oxygen Supply System in Medical Center YY/T0187-1994 4.1.1.1		2023-02-14
		3	Bus bar	Oxygen Supply System in Medical Center YY/T0187-1994 4.1.1.2		2023-02-14
		4	Switching performance requirements	Oxygen Supply System in Medical Center YY/T0187-1994 4.1.1.3		2023-02-14
		5	Liquid oxygen supply of oxygen Center	Oxygen Supply System in Medical Center YY/T0187-1994 4.1.2		2023-02-14
		6	Piping material	Oxygen Supply System in Medical Center YY/T0187-1994 4.2.1		2023-02-14
		7	Pipe diameter	Oxygen Supply System in Medical Center YY/T0187-1994 4.2.2		2023-02-14
		8	Pipeline laying	Oxygen Supply System in Medical Center YY/T0187-1994 4.2.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Pipeline grounding impedance	Oxygen Supply System in Medical Center YY/T0187-1994 4.2.4		2023-02-14
		10	Relief valve safety valve	Oxygen Supply System in Medical Center YY/T0187-1994 4.2.5		2023-02-14
		11	enclosure	Oxygen Supply System in Medical Center YY/T0187-1994 4.2.6		2023-02-14
		12	Pressure test of piping system	Oxygen Supply System in Medical Center YY/T0187-1994 4.2.7		2023-02-14
		13	Air tightness test for piping system	Oxygen Supply System in Medical Center YY/T0187-1994 4.2.8		2023-02-14
		14	terminal	Oxygen Supply System in Medical Center YY/T0187-1994 4.3		2023-02-14
		15	Alarm device requirements	Oxygen Supply System in Medical Center YY/T0187-1994 4.4		2023-02-14
48	Medical center suction system	1	All Parameters	Medical center suction system YY/T0186-1994		2023-02-14
		2	Determination of negative pressure range	Medical center suction system YY/T0186-1994 4.1.1		2023-02-14
		3	Suction system negative pressure air tightness test	Medical center suction system YY/T0186-1994 4.1.2		2023-02-14
		4	Vacuum gauge accuracy test	Medical center suction system YY/T0186-1994 4.1.3		2023-02-14
		5	The suction system pressure is not higher than the environmental pressure test	Medical center suction system YY/T0186-1994 4.2.1		2023-02-14
		6	Pressure vessel inspection	Medical center suction system YY/T0186-1994 4.2.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Automatic starting test of standby vacuum pump unit	Medical center suction system YY/T0186-1994 4.2.3		2023-02-14
		8	Alarm device test	Medical center suction system YY/T0186-1994 4.2.4		2023-02-14
		9	Drain tank inspection	Medical center suction system YY/T0186-1994 4.2.5		2023-02-14
		10	The exhaust mouth bacteria quantity determination	Medical center suction system YY/T0186-1994 4.2.6		2023-02-14
		11	Noise Test	Medical center suction system YY/T0186-1994 4.2.7		2023-02-14
		12	Grounding resistance test	Medical center suction system YY/T0186-1994 4.2.8		2023-02-14
		13	Insulation resistance test	Medical center suction system YY/T0186-1994 4.2.9		2023-02-14
		14	Material inspection	Medical center suction system YY/T0186-1994 4.3.1		2023-02-14
		15	Suction pipe laying test	Medical center suction system YY/T0186-1994 4.3.2.1		2023-02-14
		16	Measurement of bearing spacing	Medical center suction system YY/T0186-1994 4.3.2.2		2023-02-14
		17	Terminal test	Medical center suction system YY/T0186-1994 4.4.1		2023-02-14
		18	End joint pumping rate test	Medical center suction system YY/T0186-1994 4.4.2		2023-02-14
		19	Joint loading and unloading test	Medical center suction system YY/T0186-1994 4.4.3		2023-02-14
		20	Installation technical requirements	Medical center suction system YY/T0186-1994 4.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
49	motor driven operating table	1	All Parameters	motor driven operating table YY/T1106-2008		2023-02-14
		2	Basic parameter	motor driven operating table YY/T1106-2008 4.1		2023-02-14
		3	leakage	motor driven operating table YY/T1106-2008 4.2		2023-02-14
		4	Movement stability	motor driven operating table YY/T1106-2008 4.3		2023-02-14
		5	Table swing	motor driven operating table YY/T1106-2008 4.4		2023-02-14
		6	Loading and unloading lock	motor driven operating table YY/T1106-2008 4.5		2023-02-14
		7	Table mat material	motor driven operating table YY/T1106-2008 4.6		2023-02-14
		8	General safety requirements	motor driven operating table YY/T1106-2008 4.7	seeGB9706.1	2023-02-14
		9	Special safety requirements	motor driven operating table YY/T1106-2008 4.8	seeYY0505	2023-02-14
		10	environmental test	motor driven operating table YY/T1106-2008 4.9		2023-02-14
		11	appearance	motor driven operating table YY/T1106-2008 4.10		2023-02-14
50	special electromagnetic therapeutic apparatus	1	All Parameters	special electromagnetic therapeutic apparatus YY/T0061-2007		2023-02-14
		2	Wavelength range	special electromagnetic therapeutic apparatus YY/T0061-2007 5.2		2023-02-14
		3	temperature control	special electromagnetic therapeutic apparatus YY/T0061-2007 5.3		2023-02-14
		4	time control	special electromagnetic therapeutic apparatus YY/T0061-2007 5.4		2023-02-14
		5	Overheat protection	special electromagnetic therapeutic apparatus YY/T0061-2007		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				5.5		
		6	working life	special electromagnetic therapeutic apparatus YY/T0061-2007 5.6		2023-02-14
		7	harmful rays	special electromagnetic therapeutic apparatus YY/T0061-2007 5.7		2023-02-14
		8	Indicating device of non luminous heater	special electromagnetic therapeutic apparatus YY/T0061-2007 5.8		2023-02-14
		9	External mark	special electromagnetic therapeutic apparatus YY/T0061-2007 5.9		2023-02-14
		10	instructions	special electromagnetic therapeutic apparatus YY/T0061-2007 5.10		2023-02-14
		11	Appearance and structure	special electromagnetic therapeutic apparatus YY/T0061-2007 5.11		2023-02-14
		12	Safety	special electromagnetic therapeutic apparatus YY/T0061-2007 5.12	seeGB9706 .1	2023-02-14
		13	Environmental test requirements	special electromagnetic therapeutic apparatus YY/T0061-2007 5.13		2023-02-14
		14	electromagnetic compatibility	special electromagnetic therapeutic apparatus YY/T0061-2007 5.14		2023-02-14
51	General maternity beds	1	All Parameters	General maternity beds YY/T 0045-2013		2023-02-14
		2	appearance	General maternity beds YY/T 0045-2013 4.1		2023-02-14
		3	size	General maternity beds YY/T 0045-2013 4.2		2023-02-14
		4	No-load performance	General maternity beds YY/T 0045-2013 4.3.1		2023-02-14
		5	The bed surface of hip	General maternity beds YY/T 0045-2013 4.3.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Two side rail	General maternity beds YY/T 0045-2013 4.3.3		2023-02-14
		7	The swing of the hip plate on the back plate	General maternity beds YY/T 0045-2013 4.3.4		2023-02-14
		8	Bearing load	General maternity beds YY/T 0045-2013 4.3.5		2023-02-14
		9	The plating bed	General maternity beds YY/T 0045-2013 4.4		2023-02-14
		10	Paint the table	General maternity beds YY/T 0045-2013 4.5		2023-02-14
52	Multi effect distilled watermachine	1	All Parameters	Multi effect distilled watermachine JB/T20030-2012		2023-02-14
		2	Material Science	Multi effect distilled watermachine JB/T20030-2012 4.1		2023-02-14
		3	surface quality	Multi effect distilled watermachine JB/T20030-2012 4.2		2023-02-14
		4	There is no leakage at the junction.	Multi effect distilled watermachine JB/T20030-2012 4.3.1		2023-02-14
		5	Diaphragm valve	Multi effect distilled watermachine JB/T20030-2012 4.3.2		2023-02-14
		6	drainage	Multi effect distilled watermachine JB/T20030-2012 4.3.3		2023-02-14
		7	conductivity	Multi effect distilled watermachine JB/T20030-2012 4.3.4		2023-02-14
		8	Steam pressure	Multi effect distilled watermachine JB/T20030-2012 4.3.5		2023-02-14
		9	Outlet temperature of distilled water	Multi effect distilled watermachine JB/T20030-2012 4.3.6		2023-02-14
		10	Pipe and welding line treatment	Multi effect distilled watermachine JB/T20030-2012 4.3.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Outer surface temperature of thermal insulation layer	Multi effect distilled watermachine JB/T20030-2012 4.3.8		2023-02-14
		12	shunt	Multi effect distilled watermachine JB/T20030-2012 4.3.9		2023-02-14
		13	Auto-Control	Multi effect distilled watermachine JB/T20030-2012 4.3.10		2023-02-14
		14	Aquatic product quantity	Multi effect distilled watermachine JB/T20030-2012 4.3.11		2023-02-14
		15	0.3MPa steam consumption, cooling water consumption and raw water consumption under steam pressure	Multi effect distilled watermachine JB/T20030-2012 4.3.12		2023-02-14
		16	0.6MPa steam consumption, cooling water consumption and raw water consumption under steam pressure	Multi effect distilled watermachine JB/T20030-2012 4.3.13		2023-02-14
		17	The noise sound level meter	Multi effect distilled watermachine JB/T20030-2012 4.3.14		2023-02-14
		18	safety requirements	Multi effect distilled watermachine JB/T20030-2012 4.4		2023-02-14
		19	Distilled water quality	Multi effect distilled watermachine JB/T20030-2012 4.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		20	Design and manufacture of pressure bearing parts	Multi effect distilled watermachine JB/T20030-2012 4.6		2023-02-14
53	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements	1	All Parameters	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001		2023-02-14
		2	Standard test condition	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 4.3		2023-02-14
		3	Signs and documents	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 5		2023-02-14
		4	protection against electric shock	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 6		2023-02-14
		5	Determination of accessible parts	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 6.2		2023-02-14
		6	Allowable limits for parts to be touched	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 6.3		2023-02-14
		7	Protection under normal conditions	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 6.4		2023-02-14
		8	Protection under a single fault condition	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 6.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Connection with external circuit	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 6.6		2023-02-14
		10	Clearances and creepage distances	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 6.7		2023-02-14
		11	Dielectric strength test	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 6.8		2023-02-14
		12	Structural requirements for protection against electric shock	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 6.9		2023-02-14
		13	The connection between the power supply of the power grid and the equipment parts	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 6.10		2023-02-14
		14	Mechanical hazard prevention	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 7		2023-02-14
		15	Resistance to mechanical shock and impact	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 8		2023-02-14
		16	To prevent the fire from spreading	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 9		2023-02-14
		17	Temperature limits and heat resistance of equipment	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				requirements GB 4793.1-2007 IEC:61010-1：2001 10		
		18	Liquid risk prevention	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 11		2023-02-14
		19	Radiation protection, sound pressure and ultrasonic pressure	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 12		2023-02-14
		20	To prevent the fire from spreading	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 13		2023-02-14
		21	Temperature limits and heat resistance of equipment	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 14.2		2023-02-14
		22	Over temperature protection device	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 14.3		2023-02-14
		23	Liquid risk prevention	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 14.4		2023-02-14
		24	Power supply voltage selection device	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 14.5		2023-02-14
		25	High integrity components	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 14.6		2023-02-14
		26	Radiation protection, sound pressure and	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			ultrasonic pressure	requirements GB 4793.1-2007 IEC:61010-1：2001 14.7		
		27	Printed circuit board	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 14.8		2023-02-14
		28	Circuit and element for transient overvoltage limiting device	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 14.9		2023-02-14
		29	Protection of interlocking device	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 15		2023-02-14
		30	Test and measurement equipment	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.1-2007 IEC:61010-1：2001 16		2023-02-14
54	autoclaves and sterilizers	1	All Parameters	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.8-2008 IEC:61010-2-042：1997		2023-02-14
		2	test	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.8-2008 IEC:61010-2-042：1997 4		2023-02-14
		3	Marking and documentation	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.8-2008 IEC:61010-2-042：1997 5		2023-02-14
		4	Protection against electric shock	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.8-2008 IEC:61010-2-042：1997 6		2023-02-14
		5	Mechanical hazard prevention	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				requirements GB 4793.8-2008 IEC:61010-2-042：1997 7		
		6	Resistance to mechanical shock and impact	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.8-2008 IEC:61010-2-042：1997 8		2023-02-14
		7	Device temperature limits and prevents flame spread	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.8-2008 IEC:61010-2-042：1997 9		2023-02-14
		8	Temperature	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.8-2008 IEC:61010-2-042：1997 10		2023-02-14
		9	Liquid risk prevention	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.8-2008 IEC:61010-2-042：1997 11		2023-02-14
		10	Radiation, sound pressure and ultrasonic pressure, including the laser source.	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.8-2008 IEC:61010-2-042：1997 12		2023-02-14
		11	Gas release, anti explosion and explosion	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.8-2008 IEC:61010-2-042：1997 13		2023-02-14
		12	components and parts	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.8-2008 IEC:61010-2-042：1997 14		2023-02-14
		13	Entrance and exit	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General requirements GB 4793.8-2008 IEC:61010-2-042：1997 15		2023-02-14
		14	measuring circuit	Safety requirements for electrical equipment for measurement,control,and laboratory use. Part 1:General		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				requirements GB 4793.8-2008 IEC:61010-2-042：1997 16		
55	Ethylene oxide sterilizer	1	All Parameters	Ethylene oxide sterilizer YY0503-2016		2023-02-14
		2	Sterilizing box	Ethylene oxide sterilizer YY0503-2016 5.1		2023-02-14
		3	auxiliary equipment	Ethylene oxide sterilizer YY0503-2016 5.2		2023-02-14
		4	Monitoring and control device	Ethylene oxide sterilizer YY0503-2016 5.3		2023-02-14
		5	No load temperature uniformity in sterilization room	Ethylene oxide sterilizer YY0503-2016 5.4.1		2023-02-14
		6	Leakage rate of sterilization room	Ethylene oxide sterilizer YY0503-2016 5.4.2		2023-02-14
		7	The rate of vacuum sterilizer	Ethylene oxide sterilizer YY0503-2016 5.4.3		2023-02-14
		8	Humidification effect of sterilization room	Ethylene oxide sterilizer YY0503-2016 5.4.4		2023-02-14
		9	The appearance and structure of sterilizer	Ethylene oxide sterilizer YY0503-2016 5.4.5		2023-02-14
		10	preheat	Ethylene oxide sterilizer YY0503-2016 5.5.1		2023-02-14
		11	Vacuum pumping	Ethylene oxide sterilizer YY0503-2016 5.5.2		2023-02-14
		12	humidification	Ethylene oxide sterilizer YY0503-2016 5.5.3		2023-02-14
		13	Dosing	Ethylene oxide sterilizer YY0503-2016 5.5.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	sterilization	Ethylene oxide sterilizer YY0503-2016 5.5.5		2023-02-14
		15	clean	Ethylene oxide sterilizer YY0503-2016 5.5.6		2023-02-14
		16	The use of gas sterilization sterilizer	Ethylene oxide sterilizer YY0503-2016 5.6.1		2023-02-14
		17	Electrical safety sterilizer	Ethylene oxide sterilizer YY0503-2016 5.6.2		2023-02-14
56	autoclaves using steam for the treatment of maedical materials and for laboratory process	1	All Parameters	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005		2023-02-14
		2	Signs and documents	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 5		2023-02-14
		3	Protection against electric shock	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 6		2023-02-14
		4	Mechanical hazard protection	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 7		2023-02-14
		5	Reverse motion and blocking of the door	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 7.2.101.2		
		6	Sliding door	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 7.2.101.3		2023-02-14
		7	Power cut	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 7.2.101.4		2023-02-14
		8	The bell shaped pressure vessel	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 7.2.102		2023-02-14
		9	Protection of load in and out of autoclave	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 7.4.101		2023-02-14
		10	Door interlock General requirements	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 7.101.1		2023-02-14
		11	Interlocking of the door of the steam	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			pressure vessel with fluid in the container	for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 7.101.2		
		12	Interlocking of double ended autoclave door	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 7.101.3		2023-02-14
		13	Door with inflatable or pressure driven sealing washer	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 7.102		2023-02-14
		14	To prevent the door from closing.	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 7.103		2023-02-14
		15	Resistance to mechanical shock and impact	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 8		2023-02-14
		16	Temperature limits of equipment and to prevent the spread of fire	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 9		2023-02-14
		17	heat-resisting	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 10		
		18	Risk of fluid prevention	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 11		2023-02-14
		19	Display and indication device	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 11.7.101		2023-02-14
		20	Radiation protection (including Ji Guangyuan), sound pressure and ultrasonic pressure	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 12		2023-02-14
		21	Anti gas release, explosion and explosion	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 13		2023-02-14
		22	components and parts	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 14		2023-02-14
		23	Pressure vessel	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 14.101		
		24	Display and indication device visibility and readability	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 14.102		2023-02-14
		25	Close to port	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 14.103		2023-02-14
		26	Control system	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 14.104		2023-02-14
		27	microprocessor	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 14.105		2023-02-14
		28	Interlock protection	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 15		2023-02-14
		29	measuring circuit	afety requirements for electrical equipment for measurement,control and laboratory use. Particular requirements		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				for autoclaves using steam for the treatment of maedical materials and for laboratory process GB4793.4-2019 IEC 60601-2-040:2005 16		
57	Electrodes for nerve and muscle stimulators	1	All Parameters	Electrodes for nerve and muscle stimulators YY/T 0868-2021		2023-02-14
		2	Dimensions	Electrodes for nerve and muscle stimulators YY/T 0868-2021 4.1		2023-02-14
		3	Impedance	Electrodes for nerve and muscle stimulators YY/T 0868-2021 4.2.1		2023-02-14
		4	Temperature	Electrodes for nerve and muscle stimulators YY/T 0868-2021 4.2.2		2023-02-14
		5	Connection with nerve and muscle stimulator devices	Electrodes for nerve and muscle stimulators YY/T 0868-2021 4.2.3		2023-02-14
		6	Electrodes connected to electrode lead	Electrodes for nerve and muscle stimulators YY/T 0868-2021 4.2.4		2023-02-14
		7	Cross-sectional area of the electrode cable	Electrodes for nerve and muscle stimulators YY/T 0868-2021 4.2.5		2023-02-14
		8	Sterile	Electrodes for nerve and muscle stimulators YY/T 0868-2021 4.2.6		2023-02-14
		9	Residual ethylene oxide	Electrodes for nerve and muscle stimulators YY/T 0868-2021 4.2.7		2023-02-14
		10	Biocompatibility	Electrodes for nerve and muscle stimulators YY/T 0868-2021 4.3		2023-02-14
		11	User's Guide	Electrodes for nerve and muscle stimulators YY/T 0868-2021 4.4		2023-02-14
		12	Exterior	Electrodes for nerve and muscle stimulators YY/T 0868-2021 4.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
58	Diagnostic and Theraputic Laser Equipment	1	All Parameters	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995		2023-02-14
		2	Marking on the outside of laser equipment	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 6.1		2023-02-14
		3	Marking of control and instruments	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 6.3		2023-02-14
		4	Accompanying Document	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 6.8		2023-02-14
		5	Leak Current	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 19		2023-02-14
		6	Remote interlock connector	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 32a）		2023-02-14
		7	Key control	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 32b）		2023-02-14
		8	viewing optics	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 32c）		2023-02-14
		9	Laser ready indicator	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 32d）		2023-02-14
		10	Laser Emission occurring indicator	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 32e）		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Target Indicating device	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 32f）		2023-02-14
		12	interruption of the power supply	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 49		2023-02-14
		13	Accuracy of control and instrument	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 50.2		2023-02-14
		14	Indication of parameters relevant to safety	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 51.2		2023-02-14
		15	Incorrect output	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 51.5		2023-02-14
		16	Emergency Laser stop	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 51.101		2023-02-14
		17	Safety hazards	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 52.4.101		2023-02-14
		18	Failure of component	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 52.5.9		2023-02-14
		19	Enclosure and covers	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 55.3		2023-02-14
		20	cord-connected hand-held and foot-operated control	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 56.11		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			devices			
		21	stand-by/ready	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 56.101		2023-02-14
		22	Failure protection for timing terminator	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 56.102		2023-02-14
		23	Creepage distance and air clearance	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 57.10		2023-02-14
		24	Conductivity of the cooling water	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 57.101		2023-02-14
		25	Target Indicating device	Medical electrical equipment. Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000 IEC 60601-2-22:1995 59.101		2023-02-14
59	Medical Laser Equipment	1	All Parameters	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007		2023-02-14
		2	General remarks	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.1		2023-02-14
		3	Protective housing	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.2		2023-02-14
		4	Access panels and safety interlocks	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.3		2023-02-14
		5	Remote interlock connector	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.4		2023-02-14
		6	Manual reset	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Key control	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.6		2023-02-14
		8	Laser radiation emission warning	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.7		2023-02-14
		9	Beam stop or attenuator	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.8		2023-02-14
		10	Controls	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.9		2023-02-14
		11	Viewing optics	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.10		2023-02-14
		12	Scanning safeguard	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.11		2023-02-14
		13	"Walk-in" access	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.12		2023-02-14
		14	Environmental conditions	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.13		2023-02-14
		15	Protection against other hazards	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 4.14		2023-02-14
		16	Labelling	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 5.1-5.6		2023-02-14
		17	Aperture label	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 5.7		2023-02-14
		18	Radiation output and standards information	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 5.8		2023-02-14
		19	Labels for access panels	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 5.9		2023-02-14
		20	Warning for invisible laser	Safety of Laser Product—Part 1：Equipment Classification and		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			radiation	requirements GB 7247.1-2012 IEC 60825-1:2007 5.10		
		21	Warning for visible laser radiation	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 5.11		2023-02-14
		22	Information for the user	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 6.1		2023-02-14
		23	Purchasing and servicing information	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 6.2		2023-02-14
		24	Additional requirements for specific laser products	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 7		2023-02-14
		25	Classification	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 8		2023-02-14
		26	Determination of the accessible emission level	Safety of Laser Product—Part 1：Equipment Classification and requirements GB 7247.1-2012 IEC 60825-1:2007 9		2023-02-14
60	Medical Laser Equipment	1	All Parameters	Safety of Laser Product—Part 13：Measurement for Classification of Laser products GB/T 7247.13-2018 IEC TR 60825-13:2011		2023-02-14
		2	Classification flow	Safety of Laser Product—Part 13：Measurement for Classification of Laser products GB/T 7247.13-2018 IEC TR 60825-13:2011 6.1		2023-02-14
		3	Wavelength	Safety of Laser Product—Part 13：Measurement for Classification of Laser products GB/T 7247.13-2018 IEC TR 60825-13:2011 7.1		2023-02-14
		4	Multiple wavelength sources	Safety of Laser Product—Part 13：Measurement for Classification of Laser products GB/T 7247.13-2018 IEC TR 60825-13:2011 7.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Spectrally broad sources	Safety of Laser Product—Part 13：Measurement for Classification of Laser products GB/T 7247.13-2018 IEC TR 60825-13:2011 7.3		2023-02-14
		6	Source temporal characteristics	Safety of Laser Product—Part 13：Measurement for Classification of Laser products GB/T 7247.13-2018 IEC TR 60825-13:2011 7.4		2023-02-14
		7	Angular subtense	Safety of Laser Product—Part 13：Measurement for Classification of Laser products GB/T 7247.13-2018 IEC TR 60825-13:2011 7.5		2023-02-14
		8	Emission duration	Safety of Laser Product—Part 13：Measurement for Classification of Laser products GB/T 7247.13-2018 IEC TR 60825-13:2011 7.6		2023-02-14
		9	Measurement conditions	Safety of Laser Product—Part 13：Measurement for Classification of Laser products GB/T 7247.13-2018 IEC TR 60825-13:2011 7.7		2023-02-14
		10	Scanning beams	Safety of Laser Product—Part 13：Measurement for Classification of Laser products GB/T 7247.13-2018 IEC TR 60825-13:2011 7.8		2023-02-14
61	Medical Laser Equipment	1	All Parameters	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004		2023-02-14
		2	Laser product	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 4.1		2023-02-14
		3	exposure to laser radiation	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 4.2		2023-02-14
		4	determining the level of laser exposure	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 4.3		2023-02-14
		5	General remarks	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Repetitively pulsed or modulated lasers	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 5.2		2023-02-14
		7	multiple wavelenths	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 5.3		2023-02-14
		8	extended source MPEs	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 5.4		2023-02-14
		9	Hazard distance and hazard area	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 5.5		2023-02-14
		10	additional health hazards	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 6.1		2023-02-14
		11	hazards arising from the laser	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 6.2		2023-02-14
		12	hazards arising from the enviroment	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 6.3		2023-02-14
		13	control of associated hazards	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 6.4		2023-02-14
		14	Hazards and risks	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 7.1		2023-02-14
		15	identifying potentially injurious situations	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 7.2		2023-02-14
		16	assessing risks for potentially injurious situations	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 7.3		2023-02-14
		17	selecting control measures	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 7.4		2023-02-14
		18	General	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 8.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	hazard reduction	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 8.2		2023-02-14
		20	enclosing the hazard	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 8.3		2023-02-14
		21	hazard mitigation	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 8.4		2023-02-14
		22	equipment servicing	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 8.5		2023-02-14
		23	maintenance of safe operation	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 9		2023-02-14
		24	incident reporting and accident investigation	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 10		2023-02-14
		25	medical surveillance	Safety of Laser Product—Part 14：A user's guide GB/T 7247.14-2012 IEC TR 60825-14:2004 11		2023-02-14
62	Carbon dioxide laser treating instrument	1	All Parameters	Carbon dioxide laser treating instrument GB 11748-2005		2023-02-14
		2	Wavelength	Carbon dioxide laser treating instrument GB 11748-2005 5.2.1		2023-02-14
		3	Mode	Carbon dioxide laser treating instrument GB 11748-2005 5.2.2		2023-02-14
		4	Beam spot size	Carbon dioxide laser treating instrument GB 11748-2005 5.2.3		2023-02-14
		5	Output laser power	Carbon dioxide laser treating instrument GB 11748-2005 5.3		2023-02-14
		6	Instability of Laser power	Carbon dioxide laser treating instrument GB 11748-2005 5.4		2023-02-14
		7	Reproductivity of laser power	Carbon dioxide laser treating instrument GB 11748-2005 5.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	transmission efficiency of optic fiber	Carbon dioxide laser treating instrument GB 11748-2005 5.6.3		2023-02-14
		9	output power of aiming beam	Carbon dioxide laser treating instrument GB 11748-2005 5.6.4		2023-02-14
		10	control and overload protection	Carbon dioxide laser treating instrument GB 11748-2005 5.7		2023-02-14
		11	cooling system	Carbon dioxide laser treating instrument GB 11748-2005 5.8		2023-02-14
		12	apparence	Carbon dioxide laser treating instrument GB 11748-2005 5.9		2023-02-14
		13	safety requirement	Carbon dioxide laser treating instrument GB 11748-2005 5.1	See GB 9706.1-2007、GB 9706.20-2000、GB 7247.1-2012	2023-02-14
		14	Environmental test	Carbon dioxide laser treating instrument GB 11748-2005 5.11	See GB/T 14710-2009	2023-02-14
63	He-Ne laser medical equipment	1	All Parameters	General specification of He-Ne laser medical equipment GB 12257-2000		2023-02-14
		2	Mode	General specification of He-Ne laser medical equipment GB 12257-2000 5.2.2		2023-02-14
		3	Instability of Laser power	General specification of He-Ne laser medical equipment GB 12257-2000 5.3		2023-02-14
		4	Reproductivity of laser power	General specification of He-Ne laser medical equipment GB 12257-2000 5.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	timing error	General specification of He-Ne laser medical equipment GB 12257-2000 5.5		2023-02-14
		6	Mearuring error of laser power	General specification of He-Ne laser medical equipment GB 12257-2000 5.6		2023-02-14
		7	current or power indicator	General specification of He-Ne laser medical equipment GB 12257-2000 5.7		2023-02-14
		8	transmission efficiency of optic fiber	General specification of He-Ne laser medical equipment GB 12257-2000 5.8.2		2023-02-14
		9	Key control	General specification of He-Ne laser medical equipment GB 12257-2000 5.9.1		2023-02-14
		10	Emergency Laser stop	General specification of He-Ne laser medical equipment GB 12257-2000 5.9.2		2023-02-14
		11	Protective housing	General specification of He-Ne laser medical equipment GB 12257-2000 5.9.3		2023-02-14
		12	safety interlocks	General specification of He-Ne laser medical equipment GB 12257-2000 5.9.4		2023-02-14
		13	Laser ready warning	General specification of He-Ne laser medical equipment GB 12257-2000 5.9.5		2023-02-14
		14	Laser Emission occurring warning	General specification of He-Ne laser medical equipment GB 12257-2000 5.9.6		2023-02-14
		15	Dielectric strength	General specification of He-Ne laser medical equipment GB 12257-2000 5.10.1		2023-02-14
		16	leakage current	General specification of He-Ne laser medical equipment GB 12257-2000 5.10.2		2023-02-14
		17	impedance to the protective earth	General specification of He-Ne laser medical equipment GB 12257-2000 5.10.3		2023-02-14
		18	residual high voltage	General specification of He-Ne laser medical equipment GB 12257-2000 5.10.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	labels and documents	General specification of He-Ne laser medical equipment GB 12257-2000 5.11		2023-02-14
		20	painted element	General specification of He-Ne laser medical equipment GB 12257-2000 5.12		2023-02-14
		21	electroplated element	General specification of He-Ne laser medical equipment GB 12257-2000 5.13		2023-02-14
		22	aluminium element	General specification of He-Ne laser medical equipment GB 12257-2000 5.14		2023-02-14
		23	Environmental test	General specification of He-Ne laser medical equipment GB 12257-2000 5.15		2023-02-14
64	Infrared inspect equipment for mammary	1	All Parameters	Infrared inspect equipment for mammary YY/T 0324-2019		2023-02-14
		2	actual spectrum range	Infrared inspect equipment for mammary YY/T 0324-2019 4.2.1		2023-02-14
		3	beam power of probe	Infrared inspect equipment for mammary YY/T 0324-2019 4.2.2		2023-02-14
		4	image resolution	Infrared inspect equipment for mammary YY/T 0324-2019 4.2.3		2023-02-14
		5	function	Infrared inspect equipment for mammary YY/T 0324-2019 4.3		2023-02-14
		6	apparence	Infrared inspect equipment for mammary YY/T 0324-2019 4.4		2023-02-14
		7	safety requirement	Infrared inspect equipment for mammary YY/T 0324-2019 4.5	See GB 9706.1-2007	2023-02-14
		8	Environmental test	Infrared inspect equipment for mammary YY/T 0324-2019 4.6	See GB/T 14710-2009	2023-02-14
65	Therapeutic laser fiber	1	All Parameters	General requirements for medical laser fiber YY/T 0758-2021		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	product information	General requirements for medical laser fiber YY/T 0758-2021 5.1		2023-02-14
		3	whole length	General requirements for medical laser fiber YY/T 0758-2021 5.2.1		2023-02-14
		4	diameter	General requirements for medical laser fiber YY/T 0758-2021 5.2.2		2023-02-14
		5	transmission efficiency of optic fiber	General requirements for medical laser fiber YY/T 0758-2021 5.3.1		2023-02-14
		6	Instability of transmission efficiency	General requirements for medical laser fiber YY/T 0758-2021 5.3.2		2023-02-14
		7	Reproductivity of transmission efficiency	General requirements for medical laser fiber YY/T 0758-2021 5.3.3		2023-02-14
		8	transmission efficiency after stero	General requirements for medical laser fiber YY/T 0758-2021 5.3.4		2023-02-14
		9	tensile strength	General requirements for medical laser fiber YY/T 0758-2021 5.4.1		2023-02-14
		10	minmum bending radius	General requirements for medical laser fiber YY/T 0758-2021 5.4.2		2023-02-14
		11	fatigue resistance	General requirements for medical laser fiber YY/T 0758-2021 5.4.3		2023-02-14
		12	non flat fiber	General requirements for medical laser fiber YY/T 0758-2021 5.5		2023-02-14
		13	intergace	General requirements for medical laser fiber YY/T 0758-2021 5.6		2023-02-14
		14	apparence requiment	General requirements for medical laser fiber YY/T 0758-2021 5.7		2023-02-14
		15	sterility	GGeneral requirements for medical laser fiber YY/T 0758-2021 5.8		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Ethylene oxide residues	General requirements for medical laser fiber YY/T 0758-2021 5.9		2023-02-14
		17	biocompatibility	General requirements for medical laser fiber YY/T 0758-2021 5.10		2023-02-14
		18	safety	General requirements for medical laser fiber YY/T 0758-2021 5.11		2023-02-14
66	Medical endoscope fiber optical cables for lighting	1	All Parameters	Medical endoscope fiber optical cables for lighting YY/T 0763-2009		2023-02-14
		2	whole length	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.1.1		2023-02-14
		3	size of mechanical interface	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.1.2		2023-02-14
		4	light output angle	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.2.1		2023-02-14
		5	spectrum transmittance	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.2.2		2023-02-14
		6	light transmissivity	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.2.3		2023-02-14
		7	twist	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.3.1		2023-02-14
		8	flattening	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.3.2		2023-02-14
		9	stretch	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.3.3		2023-02-14
		10	minmum bending radius	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.3.4		2023-02-14
		11	Drop impact test	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.3.5		2023-02-14
		12	genral requirement	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	stero	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.5		2023-02-14
		14	Dielectric strength	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.6		2023-02-14
		15	labeling	Medical endoscope fiber optical cables for lighting YY/T 0763-2009 4.7		2023-02-14
67	Anoscope	1	All Parameters	Anoscope YY/T 0190-2008		2023-02-14
		2	usability	Anoscope YY/T 0190-2008 4.1		2023-02-14
		3	hardness	Anoscope YY/T 0190-2008 4.2		2023-02-14
		4	surface roughness	Anoscope YY/T 0190-2008 4.3		2023-02-14
		5	electroplate	Anoscope YY/T 0190-2008 4.4		2023-02-14
		6	decay resistance	Anoscope YY/T 0190-2008 4.5		2023-02-14
68	Nasal specula	1	All Parameters	Nasal specula YY/T 0189-2008		2023-02-14
		2	usability	Nasal specula YY/T 0189-2008 4.1		2023-02-14
		3	physical and chemical property	Nasal specula YY/T 0189-2008 4.2		2023-02-14
		4	surface roughness	Nasal specula YY/T 0189-2008 4.3		2023-02-14
		5	decay resistance	Nasal specula YY/T 0189-2008 4.4		2023-02-14
		6	appearance	Nasal specula YY/T 0189-2008 4.5		2023-02-14
69	Large intestine fiber	1	All Parameters	Large intestine fiber endoscope YY/T 0283-2007		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	endoscope	2	surface requirements	Large intestine fiber endoscope YY/T 0283-2007 4.2		2023-02-14
		3	luminance test	Large intestine fiber endoscope YY/T 0283-2007 4.3.1		2023-02-14
		4	resolution ratio test	Large intestine fiber endoscope YY/T 0283-2007 4.3.2		2023-02-14
		5	fiber facture test	Large intestine fiber endoscope YY/T 0283-2007 4.3.3		2023-02-14
		6	field angle test	Large intestine fiber endoscope YY/T 0283-2007 4.3.4		2023-02-14
		7	repeatability of lighting source and field of view	Large intestine fiber endoscope YY/T 0283-2007 4.3.5		2023-02-14
		8	range of clearly observation	Large intestine fiber endoscope YY/T 0283-2007 4.3.6		2023-02-14
		9	water piping test	Large intestine fiber endoscope YY/T 0283-2007 4.4.1		2023-02-14
		10	attraction and backward flow test	Large intestine fiber endoscope YY/T 0283-2007 4.4.2		2023-02-14
		11	vacuum cleanability	Large intestine fiber endoscope YY/T 0283-2007 4.4.3		2023-02-14
		12	bend locking test	Large intestine fiber endoscope YY/T 0283-2007 4.5.1		2023-02-14
		13	insert ability test	Large intestine fiber endoscope YY/T 0283-2007 4.5.2		2023-02-14
		14	curve angle test	Large intestine fiber endoscope YY/T 0283-2007 4.5.3		2023-02-14
		15	seal pressure test	Large intestine fiber endoscope YY/T 0283-2007 4.6.1		2023-02-14
		16	haze performance test	Large intestine fiber endoscope YY/T 0283-2007 4.6.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	mark	Large intestine fiber endoscope YY/T 0283-2007 4.7		2023-02-14
		18	size	Large intestine fiber endoscope YY/T 0283-2007 4.8		2023-02-14
		19	biocompatibility	Large intestine fiber endoscope YY/T 0283-2007 4.9	See GB 16886.1-2001	2023-02-14
		20	dissolving deposition	Large intestine fiber endoscope YY/T 0283-2007 4.10	See GB/T 14233.1-2008	2023-02-14
		21	environment test	Large intestine fiber endoscope YY/T 0283-2007 4.11	See GB/T 14710-2009	2023-02-14
		22	safety	Large intestine fiber endoscope YY/T 0283-2007 4.12	See GB 9706.1-2007、GB9706.4-2009、GB9706.19-2000	2023-02-14
70	Upper gastro intestinal fiberscope	1	All Parameters	Upper gastro intestinal fiberscope YY/T1028-2008		2023-02-14
		2	dissolving deposition test	Upper gastro intestinal fiberscope YY/T1028-2008 4.1.1	See GB/T 14233.1-2008	2023-02-14
		3	biocompatibility	Upper gastro intestinal fiberscope YY/T1028-2008 4.1.2	See GB 16886 standard series	2023-02-14
		4	surface safety	Upper gastro intestinal fiberscope YY/T1028-2008 4.1.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	basic requirements of optical system	Upper gastro intestinal fiberscope YY/T1028-2008 4.2.1		2023-02-14
		6	effectiveness of illumination	Upper gastro intestinal fiberscope YY/T1028-2008 4.2.2.1		2023-02-14
		7	luminous energy transfer efficiency——effective luminosity rate	Upper gastro intestinal fiberscope YY/T1028-2008 4.2.2.2		2023-02-14
		8	detectability	Upper gastro intestinal fiberscope YY/T1028-2008 4.2.3		2023-02-14
		9	diopter regulation	Upper gastro intestinal fiberscope YY/T1028-2008 4.2.4		2023-02-14
		10	fature of fiber image bundles	Upper gastro intestinal fiberscope YY/T1028-2008 4.2.5		2023-02-14
		11	field angle test	Upper gastro intestinal fiberscope YY/T1028-2008 4.2.6		2023-02-14
		12	observe depth of field	Upper gastro intestinal fiberscope YY/T1028-2008 4.2.7		2023-02-14
		13	water and gas supply system	Upper gastro intestinal fiberscope YY/T1028-2008 4.3		2023-02-14
		14	attraction and biopsy channel system	Upper gastro intestinal fiberscope YY/T1028-2008 4.4		2023-02-14
		15	bend control system	Upper gastro intestinal fiberscope YY/T1028-2008 4.5		2023-02-14
		16	seal performance	Upper gastro intestinal fiberscope YY/T1028-2008 4.6		2023-02-14
		17	coordinate with accessory	Upper gastro intestinal fiberscope YY/T1028-2008 4.7		2023-02-14
		18	mark	Upper gastro intestinal fiberscope YY/T1028-2008 4.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	size deviation	Upper gastro intestinal fiberscope YY/T1028-2008 4.9		2023-02-14
		20	environment test	Upper gastro intestinal fiberscope YY/T1028-2008 4.11	See GB 14710-2009	2023-02-14
71	Sheaths	1	All Parameters	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011		2023-02-14
		2	metal chemical component	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011 4.1.1		2023-02-14
		3	biocompatibility	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011 4.1.2	See GB 16886 standard series	2023-02-14
		4	work lenth	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011 4.2.1		2023-02-14
		5	maximum width of insert part	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011 4.2.2		2023-02-14
		6	minimum width of main tunnel	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011 4.2.3		2023-02-14
		7	lock and disassembly	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011 4.3.1		2023-02-14
		8	position and seal	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011 4.3.2		2023-02-14
		9	connection	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011 4.4		2023-02-14
		10	surface quality of insert part	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011 4.5		2023-02-14
		11	water and/or gas pipeline	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011 4.6.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	water and/or gas connection	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011 4.6.2		2023-02-14
		13	tolerance	Medical endoscopes-Endoscope accessories-Sheaths YY/T 0842-2011 4.7		2023-02-14
72	Cold light sources	1	All Parameters	Medical endoscopes-Endoscope supply units-Cold light sources YY/T 1081-2011		2023-02-14
		2	constitution	Medical endoscopes-Endoscope supply units-Cold light sources YY/T 1081-2011 4.1		2023-02-14
		3	color rendering index	Medical endoscopes-Endoscope supply units-Cold light sources YY/T 1081-2011 4.2.1		2023-02-14
		4	correlated color temperature	Medical endoscopes-Endoscope supply units-Cold light sources YY/T 1081-2011 4.2.2		2023-02-14
		5	radiant flux ratio	Medical endoscopes-Endoscope supply units-Cold light sources YY/T 1081-2011 4.2.3		2023-02-14
		6	spectral characteristic of cold light source for special purpose	Medical endoscopes-Endoscope supply units-Cold light sources YY/T 1081-2011 4.2.4		2023-02-14
		7	illumination uniformity	Medical endoscopes-Endoscope supply units-Cold light sources YY/T 1081-2011 4.3.1		2023-02-14
		8	illumination over-limit point	Medical endoscopes-Endoscope supply units-Cold light sources YY/T 1081-2011 4.3.2		2023-02-14
		9	total output luminous flux	Medical endoscopes-Endoscope supply units-Cold light sources YY/T 1081-2011 4.4.1		2023-02-14
		10	electric safety	Medical endoscopes-Endoscope supply units-Cold light sources YY/T 1081-2011 4.5		2023-02-14
		11	specification of mechanical connector	Medical endoscopes-Endoscope supply units-Cold light sources YY/T 1081-2011 4.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	safety precautions for antifailure	Medical endoscopes-Endoscope supply units-Cold light sources YY/T 1081-2011 4.7		2023-02-14
73	Rigid arthroscope	1	All Parameters	Rigid arthroscope YY 1082-2007		2023-02-14
		2	general requirements	Rigid arthroscope YY 1082-2007 4.1	See YY 0068 standard series	2023-02-14
		3	surface and edge	Rigid arthroscope YY 1082-2007 4.2		2023-02-14
		4	basical dimentions	Rigid arthroscope YY 1082-2007 4.3		2023-02-14
		5	basical parameters	Rigid arthroscope YY 1082-2007 4.4		2023-02-14
		6	field of view	Rigid arthroscope YY 1082-2007 4.5a)		2023-02-14
		7	eyepiece hood	Rigid arthroscope YY 1082-2007 4.5b)		2023-02-14
		8	fogging	Rigid arthroscope YY 1082-2007 4.5c)		2023-02-14
		9	sealing	Rigid arthroscope YY 1082-2007 4.5d)		2023-02-14
		10	lighting	Rigid arthroscope YY 1082-2007 4.5e)		2023-02-14
		11	illuminance uniformity	Rigid arthroscope YY 1082-2007 4.5f)		2023-02-14
		12	steam sterilizing test	Rigid arthroscope YY 1082-2007 4.5g)		2023-02-14
		13	water penetration test	Rigid arthroscope YY 1082-2007 4.6		2023-02-14
		14	water flow	Rigid arthroscope YY 1082-2007 4.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	shape of puncture needle	Rigid arthroscope YY 1082-2007 4.8		2023-02-14
		16	coordinate of instrument and trocar cannula	Rigid arthroscope YY 1082-2007 4.9		2023-02-14
		17	hardness of puncture instrument	Rigid arthroscope YY 1082-2007 4.10		2023-02-14
		18	appearance	Rigid arthroscope YY 1082-2007 4.11		2023-02-14
		19	biocompatibility	Rigid arthroscope YY 1082-2007 4.13	See GB 16886 standard series	2023-02-14
		20	safety requirements	Rigid arthroscope YY 1082-2007 4.14	See GB 9706.1、GB9706.19	2023-02-14
		21	environment test	Rigid arthroscope YY 1082-2007 4.15	See GB/T 14710-2009	2023-02-14
74	medical endoscopes-rigid endoscope	1	All Parameters	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-3:1997ISO 8600-5:2005ISO 8600-6:2005		2023-02-14
		2	field angle test	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-3:1997ISO 8600-5:2005ISO 8600-6:2005 4.2.1		2023-02-14
		3	#N/A	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-3:1997ISO 8600-5:2005ISO 8600-6:2005 4.2.2		2023-02-14
		4	angular resolution	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				3:1997ISO 8600-5:2005ISO 8600-6:2005 4.3.1		
		5	effective depth of field	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-3:1997ISO 8600-5:2005ISO 8600-6:2005 4.3.2		2023-02-14
		6	quality of field of view	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-3:1997ISO 8600-5:2005ISO 8600-6:2005 4.3.3		2023-02-14
		7	color distinguishability and color reducibility	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-3:1997ISO 8600-5:2005ISO 8600-6:2005 4.4		2023-02-14
		8	rate of illumination change	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-3:1997ISO 8600-5:2005ISO 8600-6:2005 4.5.1		2023-02-14
		9	edge uniformity	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-3:1997ISO 8600-5:2005ISO 8600-6:2005 4.5.2.1		2023-02-14
		10	relative self-effect of illumination light luminosity	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-3:1997ISO 8600-5:2005ISO 8600-6:2005 4.5.2.2		2023-02-14
		11	relative self-effect of imaging light energy	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-3:1997ISO 8600-5:2005ISO 8600-6:2005 4.6		2023-02-14
		12	synthetical relative self-effect of light energy	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-3:1997ISO 8600-5:2005ISO 8600-6:2005 4.6		2023-02-14
		13	luminous energy transmission efficiency	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				3:1997ISO 8600-5:2005ISO 8600-6:2005 4.7		
		14	unit relative distortion	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008ISO 8600-1：2005ISO 8600-3:1997ISO 8600-5:2005ISO 8600-6:2005 4.8		2023-02-14
75	medical endoscopes-rigid endoscope	1	All Parameters	Medical Endoscopes-Rigid Endoscope-Part 2:Mechanical properties and test methods YY/T 0068.2-2008ISO 8600-1：2005ISO 8600-4:1997		2023-02-14
		2	work lenth	Medical Endoscopes-Rigid Endoscope-Part 2:Mechanical properties and test methods YY/T 0068.2-2008ISO 8600-1：2005ISO 8600-4:1997 4.1.1		2023-02-14
		3	width of insert part	Medical Endoscopes-Rigid Endoscope-Part 2:Mechanical properties and test methods YY/T 0068.2-2008ISO 8600-1：2005ISO 8600-4:1997 4.1.2		2023-02-14
		4	minmum width of instrument tunnel	Medical Endoscopes-Rigid Endoscope-Part 2:Mechanical properties and test methods YY/T 0068.2-2008ISO 8600-1：2005ISO 8600-4:1997 4.1.3		2023-02-14
		5	size of eyepiece hood	Medical Endoscopes-Rigid Endoscope-Part 2:Mechanical properties and test methods YY/T 0068.2-2008ISO 8600-1：2005ISO 8600-4:1997 4.1.4		2023-02-14
		6	coordinate	Medical Endoscopes-Rigid Endoscope-Part 2:Mechanical properties and test methods YY/T 0068.2-2008ISO 8600-1：2005ISO 8600-4:1997 4.2		2023-02-14
		7	packaging	Medical Endoscopes-Rigid Endoscope-Part 2:Mechanical properties and test methods YY/T 0068.2-2008ISO 8600-1：2005ISO 8600-4:1997 4.3		2023-02-14
		8	strength and intensity	Medical Endoscopes-Rigid Endoscope-Part 2:Mechanical properties and test methods YY/T 0068.2-2008ISO 8600-1：2005ISO 8600-4:1997 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	connection	Medical Endoscopes-Rigid Endoscope-Part 2:Mechanical properties and test methods YY/T 0068.2-2008ISO 8600-1：2005ISO 8600-4:1997 4.5		2023-02-14
		10	quality of surface	Medical Endoscopes-Rigid Endoscope-Part 2:Mechanical properties and test methods YY/T 0068.2-2008ISO 8600-1：2005ISO 8600-4:1997 4.6		2023-02-14
76	medical endoscopes-rigid endoscope	1	All Parameters	Medical Endoscopes-Rigid Endoscope-Part 3:Marking and instruction manual YY/T 0068.3-2008 ISO 8600-1:2005		2023-02-14
		2	mark	Medical Endoscopes-Rigid Endoscope-Part 3:Marking and instruction manual YY/T 0068.3-2008ISO 8600-1:2005 3.1		2023-02-14
		3	attachment	Medical Endoscopes-Rigid Endoscope-Part 3:Marking and instruction manual YY/T 0068.3-2008ISO 8600-1:2005 3.2		2023-02-14
77	medical endoscopes-rigid endoscope	1	All Parameters	Medical Endoscopes-Rigid Endoscope-Part 4:Fundamental requirement YY 0068.4-2009 ISO 8600-1:2005		2023-02-14
		2	general rules	Medical Endoscopes-Rigid Endoscope-Part 4:Fundamental requirement YY 0068.4-2009ISO 8600-1:2005 4		2023-02-14
		3	optical and mechanical performance	Medical Endoscopes-Rigid Endoscope-Part 4:Fundamental requirement YY 0068.4-2009ISO 8600-1:2005 5		2023-02-14
		4	electric safety	Medical Endoscopes-Rigid Endoscope-Part 4:Fundamental requirement YY 0068.4-2009ISO 8600-1:2005 6		2023-02-14
		5	biocompatibility	Medical Endoscopes-Rigid Endoscope-Part 4:Fundamental requirement YY 0068.4-2009ISO 8600-1:2005 7	See GB 16886 standard series	2023-02-14
		6	safety of connector	Medical Endoscopes-Rigid Endoscope-Part 4:Fundamental requirement YY 0068.4-2009ISO 8600-1:2005 8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	manufacture	Medical Endoscopes-Rigid Endoscope-Part 4:Fundamental requirement YY 0068.4-2009ISO 8600-1:2005 9		2023-02-14
		8	tolerance of resterilizable product	Medical Endoscopes-Rigid Endoscope-Part 4:Fundamental requirement YY 0068.4-2009ISO 8600-1:2005 10.1		2023-02-14
		9	sterile provided product	Medical Endoscopes-Rigid Endoscope-Part 4:Fundamental requirement YY 0068.4-2009ISO 8600-1:2005 10.2	See GB 18279、GB 18280、GB 18278、GB/T 16886.7	2023-02-14
78	sigmoidoscopy and rectoscopy set	1	All Parameters	Sigmoidoscopy and rectoscopy set YY/T 0071-2018		2023-02-14
		2	basic dimensions	Sigmoidoscopy and rectoscopy set YY/T 0071-2018 4.1		2023-02-14
		3	surface and edge	Sigmoidoscopy and rectoscopy set YY/T 0071-2018 4.2		2023-02-14
		4	illumination	Sigmoidoscopy and rectoscopy set YY/T 0071-2018 4.3		2023-02-14
		5	mark	Sigmoidoscopy and rectoscopy set YY/T 0071-2018 4.4		2023-02-14
		6	coodinate performance	Sigmoidoscopy and rectoscopy set YY/T 0071-2018 4.5		2023-02-14
		7	surface roughness	Sigmoidoscopy and rectoscopy set YY/T 0071-2018 4.6		2023-02-14
		8	corrosion resistance test	Sigmoidoscopy and rectoscopy set YY/T 0071-2018 4.7		2023-02-14
		9	biocompatibility	Sigmoidoscopy and rectoscopy set YY/T 0071-2018 4.9	See GB 16886	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					standard series	
79	rigid hysteroscope	1	All Parameters	Rigid hysteroscope YY 1075-2007		2023-02-14
		2	surface and edge	Rigid hysteroscope YY 1075-2007 4.2		2023-02-14
		3	basical dimentions	Rigid hysteroscope YY 1075-2007 4.3		2023-02-14
		4	field angle test	Rigid hysteroscope YY 1075-2007 4.4		2023-02-14
		5	#N/A	Rigid hysteroscope YY 1075-2007 4.4		2023-02-14
		6	#N/A	Rigid hysteroscope YY 1075-2007 4.4		2023-02-14
		7	Resolution	Rigid hysteroscope YY 1075-2007 4.4		2023-02-14
		8	range of clearly observation	Rigid hysteroscope YY 1075-2007 4.4		2023-02-14
		9	illumination	Rigid hysteroscope YY 1075-2007 4.4		2023-02-14
		10	quality of field of view	Rigid hysteroscope YY 1075-2007 4.5a)		2023-02-14
		11	eyepiece hood	Rigid hysteroscope YY 1075-2007 4.5b)		2023-02-14
		12	fogging test	Rigid hysteroscope YY 1075-2007 4.5c）		2023-02-14
		13	sealing	Rigid hysteroscope YY 1075-2007 4.5d）		2023-02-14
		14	illuminance uniformity	Rigid hysteroscope YY 1075-2007 4.5f）		2023-02-14
		15	steam sterilizing test	Rigid hysteroscope YY 1075-2007 4.5h）		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	coodinate of sheathe and instruments	Rigid hysteroscope YY 1075-2007 4.6		2023-02-14
		17	waterflooding flow	Rigid hysteroscope YY 1075-2007 4.7		2023-02-14
		18	limiting stopper	Rigid hysteroscope YY 1075-2007 4.8		2023-02-14
		19	appearance	Rigid hysteroscope YY 1075-2007 4.9		2023-02-14
		20	biocompatibility	Rigid hysteroscope YY 1075-2007 4.11	See GB 16886 standard series	2023-02-14
		21	environment test	Rigid hysteroscope YY 1075-2007 4.13	See GB/T 14710-2009	2023-02-14
80	rigid resectosocope	1	All Parameters	Medical endoscopes-Rigid resectosocope YY/T 0619-2017		2023-02-14
		2		Medical endoscopes—Rigid resectosocope YY/T 0619-2017 4.1		2023-02-14
		3		Medical endoscopes—Rigid resectosocope YY/T 0619-2017 4.2		2023-02-14
		4		Medical endoscopes—Rigid resectosocope YY/T 0619-2017 4.3		2023-02-14
		5		Medical endoscopes—Rigid resectosocope YY/T 0619-2017 4.4		2023-02-14
		6		Medical endoscopes—Rigid resectosocope YY/T 0619-2017 4.5		2023-02-14
		7		Medical endoscopes—Rigid resectosocope YY/T 0619-2017 4.6		2023-02-14
		8		Medical endoscopes—Rigid resectosocope YY/T 0619-2017 4.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9		Medical endoscopes—Rigid resectosocope YY/T 0619-2017 4.8		2023-02-14
		10		Medical endoscopes—Rigid resectosocope YY/T 0619-2017 4.9		2023-02-14
81	Temperature control blanket for medical use	1	All Parameters	Temperature control blanket for medical use YY/T 0952-2015		2023-02-14
		2	normal working condition	Temperature control blanket for medical use YY/T 0952-2015 5.1		2023-02-14
		3	temperature of cycle liquid	Temperature control blanket for medical use YY/T 0952-2015 5.2.1		2023-02-14
		4	body temperature sensor	Temperature control blanket for medical use YY/T 0952-2015 5.2.2		2023-02-14
		5	average no-load rate	Temperature control blanket for medical use YY/T 0952-2015 5.2.3		2023-02-14
		6	maximum average load rate	Temperature control blanket for medical use YY/T 0952-2015 5.2.4		2023-02-14
		7	noise	Temperature control blanket for medical use YY/T 0952-2015 5.2.5		2023-02-14
		8	load-bearing requirement	Temperature control blanket for medical use YY/T 0952-2015 5.2.6		2023-02-14
		9	sealing	Temperature control blanket for medical use YY/T 0952-2015 5.2.7		2023-02-14
		10	size of blanket	Temperature control blanket for medical use YY/T 0952-2015 5.2.8		2023-02-14
		11	appearance	Temperature control blanket for medical use YY/T 0952-2015 5.3		2023-02-14
		12	function	Temperature control blanket for medical use YY/T 0952-2015 5.4		2023-02-14
		13	biocompatibility	Temperature control blanket for medical use YY/T 0952-2015 5.5	See GB/T 16886.1-2011	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	safety	Temperature control blanket for medical use YY/T 0952-2015 5.6	See GB 9706.1-2007、YY 0834-2011	2023-02-14
		15	EMC	Temperature control blanket for medical use YY/T 0952-2015 5.7		2023-02-14
		16	environment test	Temperature control blanket for medical use YY/T 0952-2015 5.8	See GB/T 14710-2009	2023-02-14
82	Ultraviolet therapy equipment	1	All Parameters	Ultraviolet therapy equipment YY/T 0901-2013		2023-02-14
		2	working condition	Ultraviolet therapy equipment YY/T 0901-2013 5.1		2023-02-14
		3	appearance	Ultraviolet therapy equipment YY/T 0901-2013 5.2		2023-02-14
		4	enabled ultraviolet radiation	Ultraviolet therapy equipment YY/T 0901-2013 5.3.1		2023-02-14
		5	not anticipate ultraviolet radiation	Ultraviolet therapy equipment YY/T 0901-2013 5.3.2		2023-02-14
		6	residual ultraviolet radiation	Ultraviolet therapy equipment YY/T 0901-2013 5.3.3		2023-02-14
		7	ultraviolet radiation spectrum	Ultraviolet therapy equipment YY/T 0901-2013 5.4		2023-02-14
		8	timing	Ultraviolet therapy equipment YY/T 0901-2013 5.5		2023-02-14
		9	blinking	Ultraviolet therapy equipment YY/T 0901-2013 5.6		2023-02-14
		10	classification according to electric shock prevention level	Ultraviolet therapy equipment YY/T 0901-2013 5.7.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	user manual	Ultraviolet therapy equipment YY/T 0901-2013 5.7.2		2023-02-14
		12	technical manual	Ultraviolet therapy equipment YY/T 0901-2013 5.7.3		2023-02-14
		13	prevention of dangerous output	Ultraviolet therapy equipment YY/T 0901-2013 5.7.4		2023-02-14
		14	biocompatibility	Ultraviolet therapy equipment YY/T 0901-2013 5.8	See GB/T 16886.1	2023-02-14
		15	environment test requirement	Ultraviolet therapy equipment YY/T 0901-2013 5.9	See GB/T 14710	2023-02-14
83	High frequency surgical equipment	1	All Parameters	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006		2023-02-14
		2	According to the degree of protection against electric shock	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 5.2		2023-02-14
		3	Marking on the outside of EQUIPMENT or EQUIPMENT parts	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 6.1		2023-02-14
		4	Marking of controls and instruments	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 6.3		2023-02-14
		5	Indicator lights and push-buttons	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 6.7		2023-02-14
		6	A CCOMPANYING	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			DOCUMENTS	2009 IEC60601-2-2:2006 6.8		
		7	Power input	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 7		2023-02-14
		8	Separation	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 17		2023-02-14
		9	Protective earthing, functional earthing and potential equalization	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 18		2023-02-14
		10	Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 19		2023-02-14
		11	Thermal effects of HF LEAKAGE CURRENTS	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 19.3.101		2023-02-14
		12	Dielectric strength	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 20		2023-02-14
		13	Electromagnetic compatibility	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 36		2023-02-14
		14	Prevention of electrostatic charges	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 39.3		2023-02-14

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		№	Item/ Parameter			
		15	Excessive temperatures	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 42		2023-02-14
		16	Spillage	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 44.3		2023-02-14
		17	Ingress of liquids	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 44.6		2023-02-14
		18	Cleaning, sterilization and disinfection	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 44.7		2023-02-14
		19	Human errors	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 46		2023-02-14
		20	Accuracy of operating data	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 50		2023-02-14
		21	Protection against hazardous output	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 51		2023-02-14
		22	Protection against the effects of short-circuiting of the electrodes	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 52.101		2023-02-14
		23	Connections	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 56.3		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		24	Cord-connected hand-held and foot-operated control devices	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 56.11		2023-02-14
		25	SWITCH SENSORS	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 56.101		2023-02-14
		26	Anchorages of cords of ACTIVE ACCESSORIES	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 56.102		2023-02-14
		27	Active accessories with detachable ACTIVE ELECTRODES	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 56.103		2023-02-14
		28	CREEPAGE DISTANCES and AIR CLEARANCES	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 57.10		2023-02-14
		29	N EUTRAL ELECTRODE monitoring circuit	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 59.101		2023-02-14
		30	Output indicator	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 59.102		2023-02-14
		31	ACTIVE ACCESSORIES insulation	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 59.103.5		2023-02-14
		32	HF dielectric strength	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 59.103.6		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		33	Mains frequency dielectric strength	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 59.103.7		2023-02-14
		34	Neutral electrode	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 59.104		2023-02-14
		35	Neuromuscular stimulation	Medical electrical equipment -Part 2-2 ： Particular requirements for the safety of high frequency surgical equipment GB9706.4-2009 IEC60601-2-2:2006 59.105		2023-02-14
84	Hysteroscopy	1	All Parameters	Medical electrical equipment Part 2:Particular requirements for the safety of endoscopic equipment GB9706.19-2000 IEC 60601-2 18:1996		2023-02-14
		2	Marking on the outside of EQUIPMENT or EQUIPMENT parts	Medical electrical equipment Part 2:Particular requirements for the safety of endoscopic equipment GB9706.19-2000 IEC 60601-2 18:1996 6.1		2023-02-14
		3	A CCOMPANYING DOCUMENTS	Medical electrical equipment Part 2:Particular requirements for the safety of endoscopic equipment GB9706.19-2000 IEC 60601-2 18:1996 6.8		2023-02-14
		4	With application of equipment requirements	Medical electrical equipment Part 2:Particular requirements for the safety of endoscopic equipment GB9706.19-2000 IEC 60601-2 18:1996 20.2	See GB 9706.1-2007	2023-02-14
		5	Mechanical strength	Medical electrical equipment Part 2:Particular requirements for the safety of endoscopic equipment GB9706.19-2000 IEC 60601-2 18:1996 21	See GB 9706.1-2007	2023-02-14
		6	Moving parts	Medical electrical equipment Part 2:Particular requirements for the safety of endoscopic equipment GB9706.19-2000 IEC 60601-2 18:1996 22	See GB 9706.1-2007	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Expelled parts	Medical electrical equipment Part 2:Particular requirements for the safety of endoscopic equipment GB9706.19-2000 IEC 60601-2 18:1996 25	See GB 9706.1-2007	2023-02-14
		8	Suspended masses	Medical electrical equipment Part 2:Particular requirements for the safety of endoscopic equipment GB9706.19-2000 IEC 60601-2 18:1996 28	See GB 9706.1-2007	2023-02-14
		9	Electromagnetic compatibility	Medical electrical equipment Part 2:Particular requirements for the safety of endoscopic equipment GB9706.19-2000 IEC 60601-2 18:1996 36		2023-02-14
		10	Excessive temperatures	Medical electrical equipment Part 2:Particular requirements for the safety of endoscopic equipment GB9706.19-2000 IEC 60601-2 18:1996 42	See GB 9706.1-2007	2023-02-14
		11	Cleaning, sterilisation and disinfection	Medical electrical equipment Part 2:Particular requirements for the safety of endoscopic equipment GB9706.19-2000 IEC 60601-2 18:1996 44.7	See GB 9706.1-2007	2023-02-14
		12	CREEPAGE DISTANCES and AIR CLEARANCES	Medical electrical equipment Part 2:Particular requirements for the safety of endoscopic equipment GB9706.19-2000 IEC 60601-2 18:1997 57.10	See GB 9706.1-2007	2023-02-14
85	Electric bright light therapy equipment	1	All Parameters	Particular requirements for the safety of infrared therapy equipment YY0323-2018		2023-02-14
		2	classification	Particular requirements for the safety of infrared therapy equipment YY0323-2018 5		2023-02-14
		3	Marking on the outside of EQUIPMENT or EQUIPMENT parts	Particular requirements for the safety of infrared therapy equipment YY0323-2018 6.1		2023-02-14
		4	Sign controller and instrumen	Particular requirements for the safety of infrared therapy equipment YY0323-2018 6.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	A CCOMPANYING DOCUMENTS	Particular requirements for the safety of infrared therapy equipment YY0323-2018 6.8		2023-02-14
		6	Power input	Particular requirements for the safety of infrared therapy equipment YY0323-2018 7		2023-02-14
		7	Marking of controls and instruments	Particular requirements for the safety of infrared therapy equipment YY0323-2018 50.1		2023-02-14
		8	controller and instrumen accuracy	Particular requirements for the safety of infrared therapy equipment YY0323-2018 50.2		2023-02-14
		9	prevent the risk of output	Particular requirements for the safety of infrared therapy equipment YY0323-2018 51		2023-02-14
86	in vitrod diagnostic(IVD) medical equipment	1	All Parameters	Particular requirements for in vitrod diagnostic(IVD) medical equipment YY0648-2008		2023-02-14
		2	Sign and file	Particular requirements for in vitrod diagnostic(IVD) medical equipment YY0648-2008 5		2023-02-14
		3	Sprinkling	Particular requirements for in vitrod diagnostic(IVD) medical equipment YY0648-2008 11.3		2023-02-14
		4	The protection of the release of gases and substances, explosion and implosion	Particular requirements for in vitrod diagnostic(IVD) medical equipment YY0648-2008 13	See GB4793.1	2023-02-14
		5	Over temperature protection device	Particular requirements for in vitrod diagnostic(IVD) medical equipment YY0648-2008 14.3		2023-02-14
87	automatic and semi-automatic laboratory equipment for analysis and	1	All Parameters	Particular requirements for equipment,control and laboratory use-Part 9:automatic and semi-automatic laboratory equipment for analysis and other purposes GB4793.9-2013 IEC61010-2-081:2009		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	other purposes	2	Sign and file	Particular requirements for equipment,control and laboratory use-Part 9:automatic and semi-automatic laboratory equipment for analysis and other purposes GB4793.9-2013 IEC61010-2-081:2009 5		2023-02-14
		3	Moving parts	Particular requirements for equipment,control and laboratory use-Part 9:automatic and semi-automatic laboratory equipment for analysis and other purposes GB4793.9-2013 IEC61010-2-081:2009 7.2		2023-02-14
		4	Other devices except for handheld devices and in-line equipment	Particular requirements for equipment,control and laboratory use-Part 9:automatic and semi-automatic laboratory equipment for analysis and other purposes GB4793.9-2013 IEC61010-2-081:2009 8.2.1		2023-02-14
		5	Sprinkling	Particular requirements for equipment,control and laboratory use-Part 9:automatic and semi-automatic laboratory equipment for analysis and other purposes GB4793.9-2013 IEC61010-2-081:2009 11.3		2023-02-14
		6	The protection of the release of gases and substances, explosion and implosion	Particular requirements for equipment,control and laboratory use-Part 9:automatic and semi-automatic laboratory equipment for analysis and other purposes GB4793.9-2013 IEC61010-2-081:2009 13		2023-02-14
88	Automatic chemistry analyzer	1	All Parameters	Automatic chemistry analyzer YY/T0654-2017		2023-02-14
		2	Stray light	Automatic chemistry analyzer YY/T0654-2017 5.2		2023-02-14
		3	The linear range of the absorbance	Automatic chemistry analyzer YY/T0654-2017 5.3		2023-02-14
		4	The accuracy of absorbance	Automatic chemistry analyzer YY/T0654-2017 5.4		2023-02-14
		5	The absorbance of stability	Automatic chemistry analyzer YY/T0654-2017 5.5		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Repeatability of absorbance	Automatic chemistry analyzer YY/T0654-2017 5.6		2023-02-14
		7	The temperature accuracy and volatility	Automatic chemistry analyzer YY/T0654-2017 5.7		2023-02-14
		8	Sample carryover	Automatic chemistry analyzer YY/T0654-2017 5.8		2023-02-14
		9	Accuracy and repeatability of sample addition	Automatic chemistry analyzer YY/T0654-2017 5.9		2023-02-14
		10	Intra group precision of clinical projects	Automatic chemistry analyzer YY/T0654-2017 5.10		2023-02-14
		11	Appearance requirements	Automatic chemistry analyzer YY/T0654-2017 5.11		2023-02-14
		12	Environmental test requirements	Automatic chemistry analyzer YY/T0654-2017 5.12	See GB/T14710	2023-02-14
		13	Safety requirements	Automatic chemistry analyzer YY/T0654-2017 5.13	See GB4793.1、4793.9、YY0648	2023-02-14
		14		YY/T0654-2017 5.14		2023-02-14
89	Semiautomatic chemistry analyzer	1	All Parameters	Semiautomatic chemistry analyzer YY/T0014-2005		2023-02-14
		2	Wavelength accuracy and repeatability	Semiautomatic chemistry analyzer YY/T0014-2005 4.2		2023-02-14
		3	Stray light	Semiautomatic chemistry analyzer YY/T0014-2005 4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	The linear absorbance	Semiautomatic chemistry analyzer YY/T0014-2005 4.4		2023-02-14
		5	Repetitive analyzer	Semiautomatic chemistry analyzer YY/T0014-2005 4.5		2023-02-14
		6	Repetitive analyzer	Semiautomatic chemistry analyzer YY/T0014-2005 4.6		2023-02-14
		7	The accuracy and fluctuation of temperature	Semiautomatic chemistry analyzer YY/T0014-2005 4.7		2023-02-14
		8	Cross contamination rate	Semiautomatic chemistry analyzer YY/T0014-2005 4.8		2023-02-14
		9	Clinical projects within batch precision	Semiautomatic chemistry analyzer YY/T0014-2005 4.9		2023-02-14
		10	Basic function analyzer	Semiautomatic chemistry analyzer YY/T0014-2005 4.10		2023-02-14
		11	Appearance	Semiautomatic chemistry analyzer YY/T0014-2005 4.11		2023-02-14
		12	Safety requirements	Semiautomatic chemistry analyzer YY/T0014-2005 4.12	See GB9706.1-2007	2023-02-14
		13	Environmental testing requirements	Semiautomatic chemistry analyzer YY/T0014-2005 4.13	See GB 9706.1-2007	2023-02-14
		14	Signs, labels and instructions	Semiautomatic chemistry analyzer YY/T0014-2005 6		2023-02-14
		15	Packaging, transportation and storage	Semiautomatic chemistry analyzer YY/T0014-2005 7		2023-02-14
90	Blood coagulation	1	All Parameters	Automated coagulation analyzer YY/T0659-2017		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	analyzer	2	Time temperature	Automated coagulation analyzer YY/T0659-2017 5.1		2023-02-14
		3	temperature control	Automated coagulation analyzer YY/T0659-2017 5.2		2023-02-14
		4	The test items and the reporting unit	Automated coagulation analyzer YY/T0659-2017 5.3		2023-02-14
		5	Channel difference	Automated coagulation analyzer YY/T0659-2017 5.4		2023-02-14
		6	carryover	Automated coagulation analyzer YY/T0659-2017 5.5		2023-02-14
		7	Test speed	Automated coagulation analyzer YY/T0659-2017 5.6		2023-02-14
		8	Repeatability of measurement	Automated coagulation analyzer YY/T0659-2017 5.7		2023-02-14
		9	Measurement accuracy	Automated coagulation analyzer YY/T0659-2017 5.8		2023-02-14
		10	Linear	Automated coagulation analyzer YY/T0659-2017 5.9		2023-02-14
		11	Continuous operating time	Automated coagulation analyzer YY/T0659-2017 5.10		2023-02-14
		12	Appearance	Automated coagulation analyzer YY/T0659-2017 5.11		2023-02-14
		13	Signs and instructions	Automated coagulation analyzer YY/T0659-2017 7		2023-02-14
		14	Packaging, transportation and storage	Automated coagulation analyzer YY/T0659-2017 8		2023-02-14
91	High frequency fulguration therapy	1	All Parameters	High frequency fulguration therapy equipment YY/T 0322-2018		2023-02-14
		2	Work frequency error	High frequency fulguration therapy equipment YY/T 0322-2018 4.2.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	equipment	3	Output power	High frequency fulguration therapy equipment YY/T 0322-2018 4.2.2		2023-02-14
		4	The applicability of the power supply	High frequency fulguration therapy equipment YY/T 0322-2018 4.2.3		2023-02-14
		5	Output indicator	High frequency fulguration therapy equipment YY/T 0322-2018 4.2.4		2023-02-14
		6	Output Controller	High frequency fulguration therapy equipment YY/T 0322-2018 4.2.5		2023-02-14
		7	Appearance	High frequency fulguration therapy equipment YY/T 0322-2018 4.6		2023-02-14
		8	Logo, packaging, transport and storage	High frequency fulguration therapy equipment YY/T 0322-2018 7		2023-02-14
92	In vitro diagnostic medical devices	1	All Parameters	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements GB/T 29791.1-2013 ISO18113-1:2009		2023-02-14
		2	General	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements GB/T 29791.1-2013 ISO18113-1:2009 4.1		2023-02-14
		3	language	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements GB/T 29791.1-2013 ISO18113-1:2009 4.2		2023-02-14
		4	Symbols and color recognition	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements GB/T 29791.1-2013 ISO18113-1:2009 4.3		2023-02-14
		5	Value and naming	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements GB/T 29791.1-2013 ISO18113-1:2009 4.4		2023-02-14
		6	Microbial state	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				requirements GB/T 29791.1-2013 ISO18113-1:2009 4.5		
		7	instructions	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements GB/T 29791.1-2013 ISO18113-1:2009 4.6		2023-02-14
		8	In vitro diagnostic medical device changes	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements GB/T 29791.1-2013 ISO18113-1:2009 4.7		2023-02-14
		9	Residual risk disclosure	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements GB/T 29791.1-2013 ISO18113-1:2009 4.8		2023-02-14
		10	Component identification	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements GB/T 29791.1-2013 ISO18113-1:2009 4.9		2023-02-14
		11	assistance	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements GB/T 29791.1-2013 ISO18113-1:2009 4.10		2023-02-14
93	In vitro diagnostic medical devices	1	All Parameters	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009		2023-02-14
		2	Basic Requirements	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 4		2023-02-14
		3	General	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 5.1		2023-02-14
		4	Performance of IVD instrument	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 5.2		2023-02-14
		5	Elements of use	In vitro diagnostic medical devices-Information supplied by the		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 6		
		6	manufacturer	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.1		2023-02-14
		7	Performance of IVD instrument	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.2		2023-02-14
		8	Intended use	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.3		2023-02-14
		9	Storage and handling	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.4		2023-02-14
		10	Warnings and precautions	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.5		2023-02-14
		11	Instrument installation	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.6		2023-02-14
		12	working principle	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.7		2023-02-14
		13	function	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.8		2023-02-14
		14	Performance of IVD instrument	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Limitations of use	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.10		2023-02-14
		16	Preparation before operation	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.11		2023-02-14
		17	Operating procedure	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.12		2023-02-14
		18	control program	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.13		2023-02-14
		19	Calculation of test results	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.14		2023-02-14
		20	Specific function	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.15		2023-02-14
		21	Emergency raw sample	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.16		2023-02-14
		22	Shutdown procedure	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.17		2023-02-14
		23	Disposal information	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.18		2023-02-14
		24	maintain	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.19		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		25	Trouble shooting	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3:In vitro diagnostic instruments for professional use GB/T 29791.3-2013 ISO18113-1:2009 7.20		2023-02-14
94	In vitro diagnostic medical devices	1	All Parameters	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009		2023-02-14
		2	Basic Requirements	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 4		2023-02-14
		3	General	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 5.1		2023-02-14
		4	Performance of IVD instrument	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 5.2		2023-02-14
		5	Elements of use	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 6		2023-02-14
		6	manufacturer	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.1		2023-02-14
		7	Performance of IVD instrument	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.2		2023-02-14
		8	Intended use	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.3		2023-02-14
		9	Storage and handling	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Warnings and precautions	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.5		2023-02-14
		11	Instrument installation	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.6		2023-02-14
		12	measuring principle	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.7		2023-02-14
		13	Performance of IVD instrument	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.8		2023-02-14
		14	Limitations of use	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.9		2023-02-14
		15	Preparation before operation	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.10		2023-02-14
		16	Operating procedure	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.11		2023-02-14
		17	control program	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.12		2023-02-14
		18	Reading of test results	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.13		2023-02-14
		19	Specific function	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.14		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		20	Shutdown procedure	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.15		2023-02-14
		21	Disposal information	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.16		2023-02-14
		22	maintain	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.17		2023-02-14
		23	Trouble shooting	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.18		2023-02-14
		24	Follow-up measures	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 5:In vitro diagnostic instruments for selftesting GB/T 29791.5-2013 ISO18113-5:2009 7.19		2023-02-14
95	Single Photon Emission and Tomograph Scanning Dvice	1	All Parameters	Radionuclide imaging device-Characteristics and test conditiongs- Part 2:single photon emission computed tomograph GB/T 18988.2-2013 IEC 61675-2:1998		2023-02-14
		2	Deviation of rotating center	Radionuclide imaging device-Characteristics and test conditiongs- Part 2:single photon emission computed tomograph GB/T 18988.2-2013 IEC 61675-2:1998 4.1		2023-02-14
		3	Probe leaning angle	Radionuclide imaging device-Characteristics and test conditiongs- Part 2:single photon emission computed tomograph GB/T 18988.2-2013 IEC 61675-2:1998 4.2		2023-02-14
		4		Radionuclide imaging device-Characteristics and test conditiongs- Part 2:single photon emission computed tomograph GB/T 18988.2-2013 IEC 61675-2:1998 4.3		2023-02-14
		5	Spect system ensitivity	Radionuclide imaging device-Characteristics and test conditiongs- Part 2:single photon emission computed tomograph GB/T 18988.2-2013 IEC 61675-2:1998 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	scatter measurement	Radionuclide imaging device-Characteristics and test conditiongs- Part 2:single photon emission computed tomograph GB/T 18988.2-2013 IEC 61675-2:1998 4.5		2023-02-14
		7	Spect system spatial resolution	Radionuclide imaging device-Characteristics and test conditiongs- Part 2:single photon emission computed tomograph GB/T 18988.2-2013 IEC 61675-2:1998 4.6		2023-02-14
		8	Attachment paper	Radionuclide imaging device-Characteristics and test conditiongs- Part 2:single photon emission computed tomograph GB/T 18988.2-2013 IEC 61675-2:1999 5		2023-02-14
96	Multi-function flush and suction equipment	1	All Parameters	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999		2023-02-14
		2	classification	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 5		2023-02-14
		3	Identification,marking and documents	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 6		2023-02-14
		4	Power input	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 7		2023-02-14
		5	Environmental conditions	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 8		2023-02-14
		6	Requirements related to classification	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 9.2		2023-02-14
		7	Limitation of voltage an/or energy	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 9.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Enclosures and protective covers	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 9.4		2023-02-14
		9	Separation	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 9.5		2023-02-14
		10	Protectve earthing,functional earthing and peotential equalization	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 9.6		2023-02-14
		11	Continuous leakage currents and patient auxiliary currents	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 9.7		2023-02-14
		12	Dielectric strength	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 9.8		2023-02-14
		13	Protection against mechanical hazards	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 10		2023-02-14
		14	Protection againse hazards from unwanted or excessive radiation	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 11		2023-02-14
		15	Protection against hazards of ignition of flammable anaesthetic mixtures	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 12		2023-02-14
		16	Protection against excessive	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			temperatures and other safety hazards	1:1999 13		
		17	Accuracy of operating data and peotection againse hazardous output	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 14		2023-02-14
		18	Abnormal operation and fault conditions:environmental tests	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 15		2023-02-14
		19	Constructional requirements	Medical suction equipment- Part 1:Electrically powered suction equipment-safety requirements YY 0636.1-2008 ISO10079-1:1999 16		2023-02-14
97	Refrigerators for conserved blood	1	All Parameters	Refrigerators for conserved blood GB/T 21278-2007		2023-02-14
		2	Total Volume	Refrigerators for conserved blood GB/T 21278-2007 4.1.1		2023-02-14
		3	effective volume	Refrigerators for conserved blood GB/T 21278-2007 4.1.2		2023-02-14
		4	external dimension	Refrigerators for conserved blood GB/T 21278-2007 4.1.3		2023-02-14
		5	inside Mechanical facilities	Refrigerators for conserved blood GB/T 21278-2007 4.1.4		2023-02-14
		6	illumination	Refrigerators for conserved blood GB/T 21278-2007 4.1.5		2023-02-14
		7	relative running time	Refrigerators for conserved blood GB/T 21278-2007 4.1.6		2023-02-14
		8	Mechanical facilities	Refrigerators for conserved blood GB/T 21278-2007 4.2.1		2023-02-14
		9	Stability	Refrigerators for conserved blood GB/T 21278-2007 4.2.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Power display	Refrigerators for conserved blood GB/T 21278-2007 4.2.3		2023-02-14
		11	Product centigrade	Refrigerators for conserved blood GB/T 21278-2007 4.2.4		2023-02-14
		12	Centigrade control	Refrigerators for conserved blood GB/T 21278-2007 4.2.5		2023-02-14
		13	Centigrade monitor	Refrigerators for conserved blood GB/T 21278-2007 4.2.6		2023-02-14
		14	Interruption of power supply	Refrigerators for conserved blood GB/T 21278-2007 4.2.7		2023-02-14
		15	Noise test	Refrigerators for conserved blood GB/T 21278-2007 4.2.8		2023-02-14
		16	Nominal energy consumption	Refrigerators for conserved blood GB/T 21278-2007 4.2.9		2023-02-14
		17	Defrost	Refrigerators for conserved blood GB/T 21278-2007 4.2.10		2023-02-14
		18	Health Requirement	Refrigerators for conserved blood GB/T 21278-2007 4.3		2023-02-14
98	Medical electrical equipment	1	All Parameters	Medical electrical equipment Recurrent test and after repair of medical electrical equipment YY/T 0841-2011 IEC 62353：2007		2023-02-14
		2	General requirements	Medical electrical equipment Recurrent test and after repair of medical electrical equipment YY/T 0841-2011 IEC 62353：2007 4.1		2023-02-14
		3	test before deliver or after modify orafterrepairing	Medical electrical equipment Recurrent test and after repair of medical electrical equipment YY/T 0841-2011 IEC 62353：2007 4.2		2023-02-14
		4	Periodicity test	Medical electrical equipment Recurrent test and after repair of medical electrical equipment YY/T 0841-2011 IEC 62353：2007 4.3		2023-02-14
		5	Summary	Medical electrical equipment Recurrent test and after repair of medical electrical equipment YY/T 0841-2011 IEC 62353：2007		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				5.1		
		6	Visual check	Medical electrical equipment Recurrent test and after repair of medical electrical equipment YY/T 0841-2011 IEC 62353：2007 5.2		2023-02-14
		7	Summary	Medical electrical equipment Recurrent test and after repair of medical electrical equipment YY/T 0841-2011 IEC 62353：2007 5.3.1		2023-02-14
		8	testing protective earth resistance	Medical electrical equipment Recurrent test and after repair of medical electrical equipment YY/T 0841-2011 IEC 62353：2007 5.3.2		2023-02-14
		9	Leakage current	Medical electrical equipment Recurrent test and after repair of medical electrical equipment YY/T 0841-2011 IEC 62353：2007 5.3.3		2023-02-14
		10	Testing insulation resistance	Medical electrical equipment Recurrent test and after repair of medical electrical equipment YY/T 0841-2011 IEC 62353：2007 5.3.4		2023-02-14
99	Electrical potential therapy equipment	1	All Parameters	Electrical potential therapy equipment YY 0649-2016		2023-02-14
		2	Apprarance	Electrical potential therapy equipment YY 0649-2016 4.2		2023-02-14
		3	Output voltage	Electrical potential therapy equipment YY 0649-2016 4.3		2023-02-14
		4	Output frequency	Electrical potential therapy equipment YY 0649-2016 4.4		2023-02-14
		5	Output voltage stability	Electrical potential therapy equipment YY 0649-2016 4.5		2023-02-14
		6	Short current	Electrical potential therapy equipment YY 0649-2016 4.6		2023-02-14
		7	Output overcurrent	Electrical potential therapy equipment YY 0649-2016 4.7		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			ptotection			
		8		Electrical potential therapy equipment YY 0649-2016 4.8		2023-02-14
		9		Electrical potential therapy equipment YY 0649-2016 4.9		2023-02-14
		10		Electrical potential therapy equipment YY 0649-2016 4.10		2023-02-14
		11		Electrical potential therapy equipment YY 0649-2016 4.11		2023-02-14
		12		Electrical potential therapy equipment YY 0649-2016 4.12		2023-02-14
		13	function	Electrical potential therapy equipment YY 0649-2016 4.13		2023-02-14
		14	safty require	Electrical potential therapy equipment YY 0649-2016 4.14		2023-02-14
		15	EMC	Electrical potential therapy equipment YY 0649-2016 4.15		2023-02-14
		16		Electrical potential therapy equipment YY 0649-2016 4.16		2023-02-14
100	Medical Low temperature freezer	1	All Parameters	Low temperature freezer GB/T 20154-2014		2023-02-14
		2	Total Volume	Low temperature freezer GB/T 20154-2014 5.2		2023-02-14
		3	Feature point temperature	Low temperature freezer GB/T 20154-2014 5.3.1		2023-02-14
		4	Cooling rate	Low temperature freezer GB/T 20154-2014 5.3.2		2023-02-14
		5	Declining temperature time	Low temperature freezer GB/T 20154-2014 5.3.3		2023-02-14
		6	Power consumption	Low temperature freezer GB/T 20154-2014 5.3.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Temperature display and recording	Low temperature freezer GB/T 20154-2014 5.3.5		2023-02-14
		8	Door	Low temperature freezer GB/T 20154-2014 5.4.1		2023-02-14
		9	testing hole	Low temperature freezer GB/T 20154-2014 5.4.2		2023-02-14
		10	Heat-insulating property and preventing dew	Low temperature freezer GB/T 20154-2014 5.4.3		2023-02-14
		11	Durability of door hinges and handle	Low temperature freezer GB/T 20154-2014 5.4.4		2023-02-14
		12	Inside material	Low temperature freezer GB/T 20154-2014 5.4.5		2023-02-14
		13	Cooling system tightness	Low temperature freezer GB/T 20154-2014 5.4.6		2023-02-14
		14	Noise and vibration	Low temperature freezer GB/T 20154-2014 5.4.7		2023-02-14
		15	Door of tightness	Low temperature freezer GB/T 20154-2014 5.4.8		2023-02-14
		16	Mechanical strength of shelf and similar component	Low temperature freezer GB/T 20154-2014 5.4.9		2023-02-14
		17	electroplating component	Low temperature freezer GB/T 20154-2014 5.4.10		2023-02-14
		18	Surface paintcoat	Low temperature freezer GB/T 20154-2014 5.4.11		2023-02-14
		19	surface requirement	Low temperature freezer GB/T 20154-2014 5.4.12		2023-02-14
		20	safty requirement	Low temperature freezer GB/T 20154-2014 5.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
101	Positron emission tomograph	1	All Parameters	Radionuclide imaging device-characteristics and test conditions-Part 1:Positron emission tomograph GB/T 18988.1-2013 IEC 61675:1998		2023-02-14
		2	Spatial resolution	Radionuclide imaging device-characteristics and test conditions-Part 1:Positron emission tomograph GB/T 18988.1-2013 IEC 61675:1998 3.1		2023-02-14
		3	recovery coefficient	Radionuclide imaging device-characteristics and test conditions-Part 1:Positron emission tomograph GB/T 18988.1-2013 IEC 61675:1998 3.2		2023-02-14
		4	tomographic sensitivity	Radionuclide imaging device-characteristics and test conditions-Part 1:Positron emission tomograph GB/T 18988.1-2013 IEC 61675:1998 3.3		2023-02-14
		5	Uniformity	Radionuclide imaging device-characteristics and test conditions-Part 1:Positron emission tomograph GB/T 18988.1-2013 IEC 61675:1998 3.4		2023-02-14
		6	count rate characteristic	Radionuclide imaging device-characteristics and test conditions-Part 1:Positron emission tomograph GB/T 18988.1-2013 IEC 61675:1998 3.5		2023-02-14
		7	scatter measurement	Radionuclide imaging device-characteristics and test conditions-Part 1:Positron emission tomograph GB/T 18988.1-2013 IEC 61675:1998 3.6		2023-02-14
		8	attenuation correction	Radionuclide imaging device-characteristics and test conditions-Part 1:Positron emission tomograph GB/T 18988.1-2013 IEC 61675:1998 3.7		2023-02-14
102	Anaesthetic systems	1	All Parameters	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD		2023-02-14
		2	Marking on the outside of equipment or	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 6.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			equipment parts			
		3	Marking on the inside of equipment or equipment parts	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 6.2		2023-02-14
		4	marking of controls and instruments	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 6.3		2023-02-14
		5	symbols	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 6.4		2023-02-14
		6	accompanying documents	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 6.8		2023-02-14
		7	source of suppl	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 10.2.101		2023-02-14
		8	Oxygen enriched atmospheres	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 43.2*		2023-02-14
		9	spillage	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 44.3		2023-02-14
		10	cleaning, sterilisation and disinfection	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 44.7		2023-02-14
		11	interruption of the power supply	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 49		2023-02-14
		12	power supply	Medical electrical equipment—Part 2: Particular requirements for		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 49.101		
		13	gas supply	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 49.102		2023-02-14
		14	general	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.101		2023-02-14
		15	pressure limitation	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.101.1		2023-02-14
		16	carbon dioxide monitor	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.101.2		2023-02-14
		17	oxygen monitor	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.101.3		2023-02-14
		18	expiratory volume monitor	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.101.4		2023-02-14
		19	ventilation system integrity alarm	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.101.5		2023-02-14
		20	continuing pressure alarm	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.101.6		2023-02-14
		21	anaesthetic gas scaveing systems transfer and receiving systems	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.101.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	anaesthetic systems withanaesthetic vapour delivery devices	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.101.8		2023-02-14
		23	oxygen supply failure alarm systems	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.102.1		2023-02-14
		24	Oxygen failure protection	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.102.2		2023-02-14
		25	prevent selection of the oxygen concentration lower than the atmospheric oxygen concentration	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.102.3		2023-02-14
		26	general requirements for alarm systems	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.103		2023-02-14
		27	highest priority alarm condition	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.104		2023-02-14
		28	medium priority alarm condition	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 51.105		2023-02-14
		29	general	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 54		2023-02-14
		30	components and general assembly	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				GB9706.29-2006 IEC60601-2-13:2003,MOD 56		
		31	mains parts components and layout	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 57		2023-02-14
		32	medical gas pipeline	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 101		2023-02-14
		33	medical gas pipeline input port connection	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 102		2023-02-14
		34	medical gas supply pressure monitoring	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 103		2023-02-14
		35	medical gas supply pressure regulator	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 104		2023-02-14
		36	anesthetic gas delivery system pipeline	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 105		2023-02-14
		37	gas flowmeter	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 106		2023-02-14
		38	gas mixer	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 107		2023-02-14
		39	oxygen flush valve	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 108		2023-02-14
		40	fresh gas outlet	Medical electrical equipment—Part 2: Particular requirements for		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 109		
		41	Checklist	Medical electrical equipment—Part 2: Particular requirements for the safety and essential performance of anaesthetic systems GB9706.29-2006 IEC60601-2-13:2003,MOD 110		2023-02-14
103	Anaesthetic and respiratory equipment—Conical connectorsCones and sockets	1	All Parameters	Anaesthetic and respiratory equipment—Conical connectors—Part 1:Cones and sockets YY/T1040.1-2015 ISO5356-1:2004		2023-02-14
		2	Conical connectors made of metal	Anaesthetic and respiratory equipment—Conical connectors—Part 1:Cones and sockets YY/T1040.1-2015 ISO5356-1:2004 4		2023-02-14
		3	Additional requirements for male conical connectors of 22mm size	Anaesthetic and respiratory equipment—Conical connectors—Part 1:Cones and sockets YY/T1040.1-2015 ISO5356-1:2004 4.2		2023-02-14
		4	Conical connectors made of materials other than metal	Anaesthetic and respiratory equipment—Conical connectors—Part 1:Cones and sockets YY/T1040.1-2015 ISO5356-1:2004 5		2023-02-14
		5	Additional requirements for conical connectors of 22mm size	Anaesthetic and respiratory equipment—Conical connectors—Part 1:Cones and sockets YY/T1040.1-2015 ISO5356-1:2004 5.2		2023-02-14
		6	22mm latching connrctors	Anaesthetic and respiratory equipment—Conical connectors—Part 1:Cones and sockets YY/T1040.1-2015 ISO5356-1:2004 6		2023-02-14
104	Anaesthetic and respiratory equipment-Conical connectors-Screw-threaded	1	All Parameters	Anaesthetic and respiratory equipment-Conical connectors-Part 2:Screw-threaded weight-bearing connectors YY/T1040.2-2008 ISO5356-2:2006		2023-02-14
		2	Design	Anaesthetic and respiratory equipment-Conical connectors-Part 3:Screw-threaded weight-bearing connectors YY/T1040.2-2008 ISO5356-2:2006 4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	weight-bearing connectors					
105	Breathing tubes intended for use with aneasthetic apparatus and ventilators	1	All Parameters	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003		2023-02-14
		2	Re-usable breathing tubes	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 4.1		2023-02-14
		3	Materials	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 4.2		2023-02-14
		4	Design	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 4.3		2023-02-14
		5	Length	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 4.4		2023-02-14
		6	Resistance to flow	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 4. 5		2023-02-14
		7	Means of connection	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 4. 6		2023-02-14
		8	Leakage	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 4.7		2023-02-14
		9	Increase in flow resistance with bending	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 4.8		2023-02-14
		10	Compliance	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 4.9		2023-02-14
		11	Prevention of electrostatic charges	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 5		2023-02-14
		12	Requirements for breathing tubes supplied sterile	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 6		2023-02-14
		13	Marking	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Information to be supplied by the manufacturer	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003 8		2023-02-14
106	Anaesthetic breathing system for adults	1	All Parameters	Inhalational anaesthesia systems-Part 1: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007		2023-02-14
		2	Connectors	Inhalational anaesthesia systems-Part 2: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 4.1		2023-02-14
		3	Bag/ventilator selector switch	Inhalational anaesthesia systems-Part 3: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 4.2		2023-02-14
		4	Electrical conductivity	Inhalational anaesthesia systems-Part 4: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 4.3		2023-02-14
		5	Recommendations on materials	Inhalational anaesthesia systems-Part 5: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 4.4		2023-02-14
		6	Leakage	Inhalational anaesthesia systems-Part 6: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 5.1		2023-02-14
		7	Resistance to flow	Inhalational anaesthesia systems-Part 7: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 5.2		2023-02-14
		8	Cleaning and disinfection or sterilization	Inhalational anaesthesia systems-Part 8: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 5.3		2023-02-14
		9	Direction of movement of controls	Inhalational anaesthesia systems-Part 9: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 6.1		2023-02-14
		10	Resistance to flow	Inhalational anaesthesia systems-Part 10: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 6.2		2023-02-14
		11	Leakage	Inhalational anaesthesia systems-Part 11: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 6.3		2023-02-14
		12	Non-rebreathing exhaust valves supplied separately	Inhalational anaesthesia systems-Part 12: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 6.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Construction	Inhalational anaesthesia systems-Part 13: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 7.1		2023-02-14
		14	Absorbent-bypass mechanism	Inhalational anaesthesia systems-Part 14: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 7.2		2023-02-14
		15	Leakage	Inhalational anaesthesia systems-Part 15: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 7.3		2023-02-14
		16	Resistance to flow	Inhalational anaesthesia systems-Part 16: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 7.4		2023-02-14
		17	Inspiratory and expiratory ports	Inhalational anaesthesia systems-Part 17: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 7.5		2023-02-14
		18	Inspiratory and expiratory valves	Inhalational anaesthesia systems-Part 18: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 7.6		2023-02-14
		19	Pressure monitoring	Inhalational anaesthesia systems-Part 19: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 8.1		2023-02-14
		20	Pressure limitation	Inhalational anaesthesia systems-Part 20: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 8.2		2023-02-14
		21	Exhaust valve	Inhalational anaesthesia systems-Part 21: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 9.1		2023-02-14
		22	Port for connection to a reservoir bag	Inhalational anaesthesia systems-Part 22: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 9.2		2023-02-14
		23	Fresh-gas inlet	Inhalational anaesthesia systems-Part 23: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 9.3		2023-02-14
		24	Inspiratory and expiratory valves	Inhalational anaesthesia systems-Part 24: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 9.4		2023-02-14
		25	Marking of breathing systems supplied complete	Inhalational anaesthesia systems-Part 25: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 10.1		2023-02-14
		26	Marking of breathing attachments	Inhalational anaesthesia systems-Part 26: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 10.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		27	Marking of packages	Inhalational anaesthesia systems-Part 27: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 10.3		2023-02-14
		28	Information to be provided by the manufacturer	Inhalational anaesthesia systems-Part 28: Anaesthetic breathing system for adults YY 0635.1-2013 ISO8835-2:2007 11		2023-02-14
107	Anaesthetic gas scavenging systems transfer and receiving systems	1	All Parameters	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997		2023-02-14
		2	Normal operating conditions	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 4.1		2023-02-14
		3	Single fault conditions	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 4.2		2023-02-14
		4	Materials	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 4.3		2023-02-14
		5	Means of pressure relief	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 5		2023-02-14
		6	Inlet of transfer systems	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 6.1		2023-02-14
		7	not interchangeable inlet of transfer systems	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 6.2		2023-02-14
		8	Outlet of transfer systems	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 6.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Receiving systems	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 7		2023-02-14
		10	Connectors	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 8		2023-02-14
		11	Extract flow resistance	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 9		2023-02-14
		12	Information to be supplied by the manufacturer	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 11		2023-02-14
		13	Marking	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 12		2023-02-14
		14	Recognized	Inhalational anaesthesia systems—Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009 ISO8835-3:1997 13		2023-02-14
108	Anaesthetic vapour delivery devices	1	All Parameters	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD		2023-02-14
		2	General requirements and general requirements for tests	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 4		2023-02-14
		3	Classification	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 5		2023-02-14
		4	Identification, marking and documents	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Marking of controls and instruments	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 6.3		2023-02-14
		6	Instructions for use	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 6.8.2		2023-02-14
		7	test method for legibility	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 6.101		2023-02-14
		8	fire prevention	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 43		2023-02-14
		9	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization,disinfection and compatibility	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 44		2023-02-14
		10	Spillage	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 44.3		2023-02-14
		11	Compatibility with substances used with the equipment	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 44.8		2023-02-14
		12	Delivered vapour concentration	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 51.101		2023-02-14
		13	Vapour output during and after oxygen flush	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 51.103		2023-02-14
		14	Determination of delivered vapour output during and after oxygen flush	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 51.104		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Connectors	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 101.1		2023-02-14
		16	Controls	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 101.2		2023-02-14
		17	Rotary control	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 101.3		2023-02-14
		18	Contamination	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 101.4		2023-02-14
		19	Agent-specific keyed filling systems	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 101.5		2023-02-14
		20	Overfilling	Inhalational anaesthesia systems—Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009 ISO8835-4:2004,MOD 101.6		2023-02-14
109	Requirements for anaesthetic ventilators	1	All Parameters	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD		2023-02-14
		2	General requirements and general requirement for tests	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 4		2023-02-14
		3	Classification	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 5		2023-02-14
		4	Identification, marking and documents	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 6		2023-02-14
		5	Instructions for use	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 6.8.2		2023-02-14
		6	Technical description	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 6.8.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Test method for legibility	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 6.101		2023-02-14
		8	Overflow,spillage,leakage,humidity,ingress of liquids,cleaning,sterilization	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 44		2023-02-14
		9	spillage	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 44.3		2023-02-14
		10	cleaning,sterilization and disinfection	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 44.7		2023-02-14
		11	Compatibility with substances used with the equipment	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 44.8		2023-02-14
		12	Interruption of the power supply	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 49		2023-02-14
		13	Operator-adjustable pressure limitation	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 51.101		2023-02-14
		14	Failure-to-cycle alarm	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 51.102		2023-02-14
		15	Operator-adjustable pressure alarm	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 51.103		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Medical gas supply	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 101.1		2023-02-14
		17	Medical gas pipeline inlet connections	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 101.2		2023-02-14
		18	Driving gas inlet port	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 101.3		2023-02-14
		19	Inflating gas inlet port	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 101.4		2023-02-14
		20	Controls) to change from automatic ventilation to spontaneous/manually assisted breathing or vice versa	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 101.5		2023-02-14
		21	Breathing system connection port	Inhalational anaesthesia systems—Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009 ISO8835-5:2004,MOD 101.6		2023-02-14
110	Respiratory gas monitors	1	All Parameters	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors YY0601-2009 ISO21647:2004,IDT		2023-02-14
		2	General requirements and general requirement for tests	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors YY0601-2009 ISO21647:2004,IDT 4		2023-02-14
		3	Classification	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				YY0601-2009 ISO21647:2004,IDT 5		
		4	Identification, marking and documents	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors YY0601-2009 ISO21647:2004,IDT 6		2023-02-14
		5	Environmental conditions	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors YY0601-2009 ISO21647:2004,IDT 10		2023-02-14
		6	Mechanical strength	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors YY0601-2009 ISO21647:2004,IDT 21		2023-02-14
		7	Fire prevention	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors YY0601-2009 ISO21647:2004,IDT 43		2023-02-14
		8	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization,disinfection and compatibility	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors YY0601-2009 ISO21647:2004,IDT 44		2023-02-14
		9	Interruption of the power supply	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors YY0601-2009 ISO21647:2004,IDT 49		2023-02-14
		10	Protection against hazardous output	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors YY0601-2009 ISO21647:2004,IDT 51		2023-02-14
		11	Mains parts, components and layout	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors YY0601-2009 ISO21647:2004,IDT 57		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Additional requirements for specifically related to respiratory gas monitors	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors YY0601-2009 ISO21647:2004,IDT 101		2023-02-14
		13	Alarm systems	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors YY0601-2009 ISO21647:2004,IDT 102		2023-02-14
111	Electrocardiographic monitors	1	All Parameters	Electrocardiographic monitors YY1079-2008		2023-02-14
		2	Labeling requirements	Electrocardiographic monitors YY1079-2008 4.1		2023-02-14
		3	Device markings	Electrocardiographic monitors YY1079-2008 4.1.1		2023-02-14
		4	Operator manual	Electrocardiographic monitors YY1079-2008 4.1.2		2023-02-14
		5	Disclosure of performance specifications	Electrocardiographic monitors YY1079-2008 4.1.2.1		2023-02-14
		6	Electro surgery protection	Electrocardiographic monitors YY1079-2008 4.1.2.1a)		2023-02-14
		7	Respiration, leads-off sensing, and active noise suppression	Electrocardiographic monitors YY1079-2008 4.1.2.1b)		2023-02-14
		8	Tall T-wave rejection capability	Electrocardiographic monitors YY1079-2008 4.1.2.1c)		2023-02-14
		9	Heart rate averaging	Electrocardiographic monitors YY1079-2008 4.1.2.1d)		2023-02-14
		10	Heart rate meter accuracy and	Electrocardiographic monitors YY1079-2008 4.1.2.1e)		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			response to irregular rhythm			
		11	Response time of heart rate meter to change in heart rate	Electrocardiographic monitors YY1079-2008 4.1.2.1f)		2023-02-14
		12	Time to alarm for tachycardia	Electrocardiographic monitors YY1079-2008 4.1.2.1g)		2023-02-14
		13	Pacemaker pulse rejection warning label	Electrocardiographic monitors YY1079-2008 4.1.2.1h)		2023-02-14
		14	Audible alarm disclosure	Electrocardiographic monitors YY1079-2008 4.1.2.1i)		2023-02-14
		15	Visual alarm disclosure	Electrocardiographic monitors YY1079-2008 4.1.2.1j)		2023-02-14
		16	Battery-powered monitors	Electrocardiographic monitors YY1079-2008 4.1.2.1k)		2023-02-14
		17	Telemetry.	Electrocardiographic monitors YY1079-2008 4.1.2.1l)		2023-02-14
		18	Line isolation monitor transients	Electrocardiographic monitors YY1079-2008 4.1.2.1m)		2023-02-14
		19	Special disclosure requirements for monitors with nonpermanent ECG waveform display	Electrocardiographic monitors YY1079-2008 4.1.2.1n)		2023-02-14
		20	Electrode polarization	Electrocardiographic monitors YY1079-2008 4.1.2.1o)		2023-02-14
		21	Auxiliary output.	Electrocardiographic monitors YY1079-2008 4.1.2.1p)		2023-02-14
		22	Alarm silencing	Electrocardiographic monitors YY1079-2008 4.1.2.1q)		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Battery disposal	Electrocardiographic monitors YY1079-2008 4.1.2.1r)		2023-02-14
		24	Application notes	Electrocardiographic monitors YY1079-2008 4.1.2.2		2023-02-14
		25	Service manual	Electrocardiographic monitors YY1079-2008 4.1.3		2023-02-14
		26	Pacemaker pulse rejection capability	Electrocardiographic monitors YY1079-2008 4.1.4		2023-02-14
		27	Pacemaker pulse rejection without overshoot	Electrocardiographic monitors YY1079-2008 4.1.4.1		2023-02-14
		28	Pacemaker pulse rejection with overshoot	Electrocardiographic monitors YY1079-2008 4.1.4.2		2023-02-14
		29	Pacer pulse detector rejection of fast ECG signals	Electrocardiographic monitors YY1079-2008 4.1.4.3		2023-02-14
		30	Pacemaker pulse appearance in auxiliary output	Electrocardiographic monitors YY1079-2008 4.1.4.4		2023-02-14
		31	Pacer pulse detector disabling	Electrocardiographic monitors YY1079-2008 4.1.4.5		2023-02-14
		32	Summary	Electrocardiographic monitors YY1079-2008 4.1.5		2023-02-14
		33	Performance requirements	Electrocardiographic monitors YY1079-2008 4.2		2023-02-14
		34	Operating conditions	Electrocardiographic monitors YY1079-2008 4.2.1		2023-02-14
		35	Overload protection	Electrocardiographic monitors YY1079-2008 4.2.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		36	Auxiliary output	Electrocardiographic monitors YY1079-2008 4.2.3		2023-02-14
		37	Respiration, leads-off sensing, and active noise suppression	Electrocardiographic monitors YY1079-2008 4.2.4		2023-02-14
		38	QRS detection	Electrocardiographic monitors YY1079-2008 4.2.5		2023-02-14
		39	Range of QRS wave amplitude and duration	Electrocardiographic monitors YY1079-2008 4.2.5.1		2023-02-14
		40	Line frequency voltage tolerance	Electrocardiographic monitors YY1079-2008 4.2.5.2		2023-02-14
		41	Drift tolerance	Electrocardiographic monitors YY1079-2008 4.2.5.3		2023-02-14
		42	Range and accuracy of heart rate meter	Electrocardiographic monitors YY1079-2008 4.2.6		2023-02-14
		43	Alarm system	Electrocardiographic monitors YY1079-2008 4.2.7		2023-02-14
		44	Alarm limit range	Electrocardiographic monitors YY1079-2008 4.2.7.1		2023-02-14
		45	Resolution of alarm limit settings	Electrocardiographic monitors YY1079-2008 4.2.7.2		2023-02-14
		46	Alarm limit accuracy	Electrocardiographic monitors YY1079-2008 4.2.7.3		2023-02-14
		47	Time to alarm for cardiac standstill	Electrocardiographic monitors YY1079-2008 4.2.7.4		2023-02-14
		48	Time to alarm for low heart rate	Electrocardiographic monitors YY1079-2008 4.2.7.5		2023-02-14
		49	Time to alarm for high heart rate	Electrocardiographic monitors YY1079-2008 4.2.7.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		50	Alarm silencing	Electrocardiographic monitors YY1079-2008 4.2.7.7		2023-02-14
		51	Alarm disabling	Electrocardiographic monitors YY1079-2008 4.2.7.8		2023-02-14
		52	Special requirements for monitors with ECG waveform display capability	Electrocardiographic monitors YY1079-2008 4.2.8		2023-02-14
		53	Input dynamic range	Electrocardiographic monitors YY1079-2008 4.2.8.1		2023-02-14
		54	Input impedance	Electrocardiographic monitors YY1079-2008 4.2.8.2		2023-02-14
		55	System noise	Electrocardiographic monitors YY1079-2008 4.2.8.3		2023-02-14
		56	Multichannel crosstalk	Electrocardiographic monitors YY1079-2008 4.2.8.4		2023-02-14
		57	Gain control and stability	Electrocardiographic monitors YY1079-2008 4.2.8.5		2023-02-14
		58	Time base selection and accuracy	Electrocardiographic monitors YY1079-2008 4.2.8.6		2023-02-14
		59	Output display	Electrocardiographic monitors YY1079-2008 4.2.8.7		2023-02-14
		60	Accuracy of input signal reproduction	Electrocardiographic monitors YY1079-2008 4.2.8.8		2023-02-14
		61	Standardizing voltage	Electrocardiographic monitors YY1079-2008 4.2.8.9		2023-02-14
		62	Common mode rejection	Electrocardiographic monitors YY1079-2008 4.2.8.10		2023-02-14
		63	Baseline control and stability	Electrocardiographic monitors YY1079-2008 4.2.8.11		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		64	Pacemaker pulse display capability	Electrocardiographic monitors YY1079-2008 4.2.8.12		2023-02-14
		65	Synchronizing pulse for cardioversion	Electrocardiographic monitors YY1079-2008 4.2.8.13		2023-02-14
		66	Electrosurgical interference suppression	Electrocardiographic monitors YY1079-2008 4.2.8.14		2023-02-14
		67	Electromagnetic compatibility	Electrocardiographic monitors YY1079-2008 4.2.10		2023-02-14
		68	Summary	Electrocardiographic monitors YY1079-2008 4.2.11		2023-02-14
112	Electrocardiographic monitoring equipment	1	All Parameters	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994		2023-02-14
		2		Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 4		2023-02-14
		3	Classification	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 5		2023-02-14
		4	Identification, marking and documents	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 6		2023-02-14
		5	Requirement related to classification	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 14		2023-02-14
		6	Separation	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 17		2023-02-14
		7	Continuous leakage	Medical electrical equipment. Part 2:Particular requirements for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			currents and patient auxiliary currents	the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 19		
		8	Dielectric strength	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 20		2023-02-14
		9	Mechanical strength	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 21		2023-02-14
		10	Excessive temperatures	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 42		2023-02-14
		11	Guards	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 42.5		2023-02-14
		12	Overflow,spillage,leskage,humidity,ingress of liquids,cleaning,sterilization and disinfection	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 44		2023-02-14
		13	spillage	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 44.3		2023-02-14
		14	Protection against hazardous output	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 51		2023-02-14
		15	Components and general assembly	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 56		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Connections – General	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 56.3		2023-02-14
		17	Battery	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 56.7		2023-02-14
		18	Mains parts, components and lay-out	Medical electrical equipment. Part 2:Particular requirements for the safety of electrocardiographic monitoring equipment GB9706.25-2005 IEC60601-2-27:1994 57		2023-02-14
113	Alarm systems in medical electrical equipment and medical electrical systems	1	All Parameters	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003		2023-02-14
		2	Identification, marking and documents	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 6		2023-02-14
		3	Alarm condition	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.1		2023-02-14
		4	Disclosures for intelligent alarm system	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.2		2023-02-14
		5	Generation of alarm signals	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.3		
		6	Visual alarm signals	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.3.2		2023-02-14
		7	Characteristics of visual alarm signals	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.3.2.2		2023-02-14
		8	Characteristics of auditory alarm signals	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.3.3		2023-02-14
		9	Volume of auditory alarm signals and information signals	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.3.3.2		2023-02-14
		10	Alarm system delays	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.4.1		2023-02-14
		11	Delay to or from a distributed alarm system	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.4.2		
		12	Alarm presets	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.5		2023-02-14
		13	Manufacturer configured alarm presets	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.5.2		2023-02-14
		14	User and operator configured alarm presets	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.5.3		2023-02-14
		15	Default alarm preset	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.5.4		2023-02-14
		16	Interruption of less than or equal to 30s	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.5.5		2023-02-14
		17	Alarm linit	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.6		
		18	Alarm system security	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.7		2023-02-14
		19	Alarm signal inactivation states	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.8		2023-02-14
		20	Alarm reset	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.9		2023-02-14
		21	Non-latching and latching alarm signals	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.1		2023-02-14
		22	Distributed alarm system	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.11		2023-02-14
		23	Alarm condition logging	medical electrical equipment—Part 1-8:General requirements for safety—Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipment and		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				medical electrical systems YY0709-2009 IEC60601-1-8:2003 201.12		
114	Home-care ventilatory support devices	1	All Parameters	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part 1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004		2023-02-14
		2	Marking on the outside of equipment or equipment parts	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 6		2023-02-14
		3	Pneumatic power	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 10. 101		2023-02-14
		4	Electromagnetic compatibility	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 36		2023-02-14
		5	Compatibility with pressurized oxygen	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 43.101		2023-02-14
		6	Internal electrical power source	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 49.101*		2023-02-14
		7	Spontaneous breathing during power failure	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 49.102		2023-02-14
		8	Maximum ventilator breathing system	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			pressure limitation	ventilatory support devices YY0600.1-2007 ISO10651-6:2004 51.101		
		9	Measurement of airway pressure	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 51.102		2023-02-14
		10	High-inspiratory pressure alarm condition	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 51.103*		2023-02-14
		11	Expiratory monitoring	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 51.104		2023-02-14
		12	Respiration rate alarm condition	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 51.105		2023-02-14
		13	Connections-General	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 56.3 aa)		2023-02-14
		14	Reservoir bags and breathing tubes	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 56.101		2023-02-14
		15	Power supply cords	Lung ventilation for medical use-Particular requirements for basic safety and essential performance Part1:Home-care ventilatory support devices YY0600.1-2007 ISO10651-6:2004 57. 3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
115	Home care ventilators for ventilator-dependent patients	1	All Parameters	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004		2023-02-14
		2	Marking on the outside of equipment or equipment parts	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 6		2023-02-14
		3	Pneumatic power	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 10. 101		2023-02-14
		4	Electromagnetic compatibility	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 36		2023-02-14
		5	Compatibility with pressurized oxygen	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 43.101		2023-02-14
		6	Spontaneous breathing during power failure	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 49.103		2023-02-14
		7	Accidental operation of the on/off-switch	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 49.104		2023-02-14
		8	Failure of air and oxyge supply	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			systems	ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 51.101		
		9	Adjustable ventilator breathing system pressure limitation	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 51.102		2023-02-14
		10	Maximum ventilator breathing system pressure limitation	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 51.103		2023-02-14
		11	Measurement of airway pressure	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 51.104		2023-02-14
		12	High-inspiratory pressure alarm condition	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 51.105		2023-02-14
		13	Continuing pressure alarm condition	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 51. 108		2023-02-14
		14	Expiratory monitoring	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 51.106		2023-02-14
		15	Hypoventilation alarm condition	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 51.107		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Respiration rate alarm condition	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 51.109		2023-02-14
		17	Connections-General	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2004 56.3aa)		2023-02-14
		18	Power supply cords	Lung ventilation for medical use-Particular requirements for basic safety and essential performance. Part 2:Home care ventilators for ventilator-dependent patients YY0600.2-2007 ISO10651-2:2005 57. 3		2023-02-14
116	Sleep apnoea breathing therapy devices	1	part Parameters	Sleep apnoea breathing therapy. Prat 1:Sleep apnoea breathing therapy devices YY/T0671.1-2009 ISO17510-1:2002	not for noise	2023-02-14
		2	Marking on the outside of equipment or equipment parts	Sleep apnoea breathing therapy. Prat 1:Sleep apnoea breathing therapy devices YY/T0671.1-2009 ISO17510-1:2002 6		2023-02-14
		3	Electromagnetic compatibility	Sleep apnoea breathing therapy. Prat 1:Sleep apnoea breathing therapy devices YY/T0671.1-2009 ISO17510-1:2002 36		2023-02-14
		4	Spontaneous breathing during power failure	Sleep apnoea breathing therapy. Prat 1:Sleep apnoea breathing therapy devices YY/T0671.1-2009 ISO17510-1:2002 49. 101		2023-02-14
		5	Maximum pressure limitation	Sleep apnoea breathing therapy. Prat 1:Sleep apnoea breathing therapy devices YY/T0671.1-2009 ISO17510-1:2002 51. 101		2023-02-14
		6	Measuring divice for respiratory pressure	Sleep apnoea breathing therapy. Prat 1:Sleep apnoea breathing therapy devices YY/T0671.1-2009 ISO17510-1:2002 51. 102		2023-02-14
		7	Measuring divice for expiratory	Sleep apnoea breathing therapy. Prat 1:Sleep apnoea breathing therapy devices YY/T0671.1-2009 ISO17510-1:2002 51.103		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			volume			
		8	Protection against carbon dioxide rebreathing	Sleep apnoea breathing therapy. Prat 1:Sleep apnoea breathing therapy devices YY/T0671.1-2009 ISO17510-1:2002 51. 104		2023-02-14
		9	Respiratory gas-conducting components(packaging and decontamination)	Sleep apnoea breathing therapy. Prat 1:Sleep apnoea breathing therapy devices YY/T0671.1-2009 ISO17510-1:2002 56. 101		2023-02-14
		10	Humidifiers and heat and moisture exchangers	Sleep apnoea breathing therapy. Prat 1:Sleep apnoea breathing therapy devices YY/T0671.1-2009 ISO17510-1:2002 56.102		2023-02-14
		11	Test for the pressure/volume curve and response time	Sleep apnoea breathing therapy. Prat 1:Sleep apnoea breathing therapy devices YY/T0671.1-2009 ISO17510-1:2002 56. 103		2023-02-14
117	Masks and application accessories	1	All Parameters	Sleep apnoea breathing therapy-Part2:Masks and application accessories YY 0671.2-2011 ISO17510-2:2007		2023-02-14
		2	Information to be supplied by the manufacture	Sleep apnoea breathing therapy-Part2:Masks and application accessories YY 0671.2-2011 ISO17510-2:2007 4		2023-02-14
		3	Construction requirements	Sleep apnoea breathing therapy-Part2:Masks and application accessories YY 0671.2-2011 ISO17510-2:2007 5		2023-02-14
		4	Mask connectors	Sleep apnoea breathing therapy-Part2:Masks and application accessories YY 0671.2-2011 ISO17510-2:2007 5.1		2023-02-14
		5	Biocompatibility	Sleep apnoea breathing therapy-Part2:Masks and application accessories YY 0671.2-2011 ISO17510-2:2007 5.2	See GB/T 16886	2023-02-14
		6	Protection against rebreathing	Sleep apnoea breathing therapy-Part2:Masks and application accessories YY 0671.2-2011 ISO17510-2:2007 5.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Cleaning,disinfection and sterilization	Sleep apnoea breathing therapy-Part2:Masks and application accessories YY 0671.2-2011 ISO17510-2:2007 5.4		2023-02-14
		8	Breathing during single fault condition	Sleep apnoea breathing therapy-Part2:Masks and application accessories YY 0671.2-2011 ISO17510-2:2007 5.5		2023-02-14
		9	Breathing system filter	Sleep apnoea breathing therapy-Part2:Masks and application accessories YY 0671.2-2011 ISO17510-2:2007 5.6		2023-02-14
		10	Vibration and noise	Sleep apnoea breathing therapy-Part2:Masks and application accessories YY 0671.2-2011 ISO17510-2:2007 6		2023-02-14
118	Respiratory tract humidifiers for medical use	1	All Parameters	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007		2023-02-14
		2	General requirements and general requirements for tests	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 4		2023-02-14
		3		Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 4.1		2023-02-14
		4	Identification, marking and documents	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 6.1		2023-02-14
		5	Instruction for use	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 6.8.2		2023-02-14
		6	Environment	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 10.2.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Pneumatic power supply	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 10.2.101		2023-02-14
		8	Acoustical energy(including ultrasonics)	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 35		2023-02-14
		9	Electromagnetic compatibility	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 36		2023-02-14
		10	Excessive temperatures	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 42		2023-02-14
		11	fire prevention	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 43		2023-02-14
		12	Overflow,spillage,leskage,humidity,ingress of liquids,cleaning,sterilization and disinfection	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 44		2023-02-14
		13	Overflow	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 44.2		2023-02-14
		14	Marking on controls and instruments	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 50.1		2023-02-14
		15	Accuracy of controls and instruments	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 50.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Protection against hazardous output	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 51		2023-02-14
		17	Connections-General	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 56.3		2023-02-14
		18	Breathing tubes	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 56.101		2023-02-14
		19	Temperature sensors and temperature sensor ports	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 56.102		2023-02-14
		20	Humidification system output	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 101		2023-02-14
		21	Liquid container	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 102		2023-02-14
		22	Alarm system	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems YY0786-2010 ISO8185-2007 103		2023-02-14
119	Lung ventilators. Critical care ventilators	1	All Parameters	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001		2023-02-14
		2	Identification, marking and documents	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 6		2023-02-14
		3	gas supply	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 10.101		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Oxygen enriched atmospheres	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 43.2*		2023-02-14
		5	spillage	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 44.3		2023-02-14
		6	cleaning, sterilisation and disinfection	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 44.7		2023-02-14
		7	interruption of the power supply	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 49		2023-02-14
		8	power supply	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 49.101		2023-02-14
		9	Internal electrical power source	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 49.102		2023-02-14
		10	Spontaneous breathing during power failure	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 49.103		2023-02-14
		11	Accidental operation of the on/off-switch	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 49.104		2023-02-14
		12	Alarm categories	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 50.101.1		2023-02-14
		13	Alarm system structures	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 50.101.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Priority	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 50.101.3		2023-02-14
		15	Inhibition	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 50.101.4		2023-02-14
		16	Sliencing and suspended alarm systems	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 50.101.5		2023-02-14
		17	alarm setting	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 50.101.6		2023-02-14
		18	High priority alarm signals	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 50.101.7		2023-02-14
		19	Medium- priority alarm signals	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 50.101.8		2023-02-14
		20	Remote alarm signal capability	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 50.101.9		2023-02-14
		21	Failure of one gas in an air oxygen mixing systems	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 51.101		2023-02-14
		22	Protection against inadvertent adjustments	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 51.102		2023-02-14
		23	Pneumatic pressure relief devices(maximum	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 51.103		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			pressure limitation)			
		24	Measurement of respiratory pressure	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 51.104		2023-02-14
		25	Adjustable pressure limitation	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 51.105		2023-02-14
		26	High-pressure alarm condition	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 51.106		2023-02-14
		27	Messurement of expratory volume and low-volume alarm condition	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 51.107		2023-02-14
		28	Continuing pressure alarm condition	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 51.108		2023-02-14
		29	Abnormal operation and fault conditions	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 52		2023-02-14
		30	Connections-General	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.3		2023-02-14
		31	Gas leakage from connections	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.3aa)		2023-02-14
		32	High oressure gas input ports	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.3bb)		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		33	Connection to the medical gas supply system	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.3cc)		2023-02-14
		34	VBS connectors	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.3dd)		2023-02-14
		35	Indicators	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.8		2023-02-14
		36	Reservoir bags and breathing tubes	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.101		2023-02-14
		37	Humidifiers and heat and moisture exchangers	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.102		2023-02-14
		38	Pulse oximeters and capnometers	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.103		2023-02-14
		39	Oxygen monitor and alarm condition	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.104		2023-02-14
		40	Integrated monitoring	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.105		2023-02-14
		41	Gas leakage from connections	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.106		2023-02-14
		42	Gas mixing system	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 56.107		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		43	Mains connectors,appliance lnlets and the like	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2001 57.2		2023-02-14
		44	Power supply cords	Medical electrical equipment. Part 2:Particular requirements for the safety of lung ventilators. Critical care ventilators GB9706.28-2006 IEC60601-2-12:2002 57.3		2023-02-14
120	Oxygen concentrators for medical use	1	All Parameters	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996		2023-02-14
		2	Identification, marking and documents	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996 1.7		2023-02-14
		3	Vibration and noise	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996 4.6		2023-02-14
		4	Flpw indicator	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996 50.3		2023-02-14
		5	Oxygen concentration	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996 50.4		2023-02-14
		6	Mean oxygen concentration	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996 50.5		2023-02-14
		7	Tolerance on flowrate	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996 50.6		2023-02-14
		8	Backpressure effect	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996 50.7		2023-02-14
		9	Outlet pressure	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996 50.8		2023-02-14
		10	Oxygen concentration	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996 51.5		2023-02-14
		11	Components and general assembly	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996 10.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Auditory indicators	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996 11.1		2023-02-14
		13	Indicators of loss of mains power	Oxygen concentrators for medical use. Safety requirements YY0732-2009 ISO8359-1996 11.2		2023-02-14
121	Non-invasive automated sphygmomanometer	1	All Parameters	Non-invasive automated sphygmomanometer YY 0670-2008		2023-02-14
		2	Requirements	Non-invasive automated sphygmomanometer YY 0670-2008 4		2023-02-14
		3	Working conditions	Non-invasive automated sphygmomanometer YY 0670-2008 4.1		2023-02-14
		4	Labeling requirements	Non-invasive automated sphygmomanometer YY 0670-2008 4.2		2023-02-14
		5	Life-time	Non-invasive automated sphygmomanometer YY 0670-2008 4.3		2023-02-14
		6	Safety requirement	Non-invasive automated sphygmomanometer YY 0670-2008 4.4		2023-02-14
		7	Devices incorporating automatic inflation systems	Non-invasive automated sphygmomanometer YY 0670-2008 4.4.1		2023-02-14
		8	Maximum cuff pressure	Non-invasive automated sphygmomanometer YY 0670-2008 4.4.1.1		2023-02-14
		9	Release rate	Non-invasive automated sphygmomanometer YY 0670-2008 4.4.1.2		2023-02-14
		10	Performance requirements	Non-invasive automated sphygmomanometer YY 0670-2008 4.5		2023-02-14
		11	Range	Non-invasive automated sphygmomanometer YY 0670-2008 4.5.1		2023-02-14
		12	Resolution	Non-invasive automated sphygmomanometer YY 0670-2008 4.5.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Repeatability	Non-invasive automated sphygmomanometer YY 0670-2008 4.5.3		2023-02-14
		14	Accuracy of pressure measurement	Non-invasive automated sphygmomanometer YY 0670-2008 4.5.4		2023-02-14
		15	Overall system efficacy	Non-invasive automated sphygmomanometer YY 0670-2008 4.5.5		2023-02-14
		16	Requirements for inflation source and pressure control valves	Non-invasive automated sphygmomanometer YY 0670-2008 4.6		2023-02-14
		17	Requirements for the inflatable bladder and cuff	Non-invasive automated sphygmomanometer YY 0670-2008 4.7		2023-02-14
		18	System leakagee	Non-invasive automated sphygmomanometer YY 0670-2008 4.8		2023-02-14
		19	Electromagnetic compatibility	Non-invasive automated sphygmomanometer YY 0670-2008 4.11		2023-02-14
122	Roller irrigation and suction equipment	1	All Parameters	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011		2023-02-14
		2	Requirements	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4		2023-02-14
		3	Structural requirements	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.1		2023-02-14
		4	Pressure limit	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.2		2023-02-14
		5	Adjustment range of preset pressure limit	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.2.1		2023-02-14
		6	The accuracy of the pressure limit	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.2.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Flow	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.3		2023-02-14
		8	Accuracy of flow preset	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.3.1		2023-02-14
		9	Applied part	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.4		2023-02-14
		10	Biocompatibility of pipeline	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.4.1	See GB/T 16886	2023-02-14
		11	Application of disinfection tolerance	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.4.2		2023-02-14
		12	The durability of the pipeline is affected by the roller extrusion part	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.4.3		2023-02-14
		13	Connection fastness of pipe line	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.4.4		2023-02-14
		14	Inner diameter tolerance of rolling line	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.4.5		2023-02-14
		15	Control switch	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.5		2023-02-14
		16	Electrical safety	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.6	See GB 9706.1-2007	2023-02-14
		17	Environmental test	Medical endoscopes. Endoscope functional supply units. Roller irrigation and suction equipment YY/T 0863-2011 4.7	See GB 9706.1-2007	2023-02-14
123	Automatic cycling non-	1	All Parameters	Medical electrical equipment. Part 2-30:Particular requirements for the safety,including essential performance,of automatic		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	invasive blood pressure monitoring equipment			cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999		
		2	Classification	Medical electrical equipment. Part 2-30:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 5		2023-02-14
		3	Identification, marking and documents	Medical electrical equipment. Part 2-30:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 6		2023-02-14
		4	Requirements related to classification	Medical electrical equipment. Part 2-30:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 14		2023-02-14
		5	Types B, BF and Cfapplied parts	Medical electrical equipment. Part 2-30:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 14.6		2023-02-14
		6	Separation	Medical electrical equipment. Part 2-30:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 17		2023-02-14
		7	Continuous leakage currents and patient auxiliary currents	Medical electrical equipment. Part 2-30:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 19		2023-02-14
		8	Dielectric strength	Medical electrical equipment. Part 2-31:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 20		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Mechanical strength	Medical electrical equipment. Part 2-32:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 21		2023-02-14
		10	Moving parts	Medical electrical equipment. Part 2-33:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 22		2023-02-14
		11	Cuff pressure	Medical electrical equipment. Part 2-34:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 22.4		2023-02-14
		12	Electromagnetic compatibility	Medical electrical equipment. Part 2-35:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 36		2023-02-14
		13	Electrosurgery interference	Medical electrical equipment. Part 2-36:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 36.202.15		2023-02-14
		14	Excessive temperatures	Medical electrical equipment. Part 2-37:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 42		2023-02-14
		15	Duty cycle	Medical electrical equipment. Part 2-38:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 42.3		2023-02-14
		16	Guards	Medical electrical equipment. Part 2-39:Particular requirements for the safety,including essential performance,of automatic		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 42.5		
		17	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning,sterilization and disinfection, and compatibility	Medical electrical equipment. Part 2-40:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 44		2023-02-14
		18	Spillage	Medical electrical equipment. Part 2-41:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 44.3		2023-02-14
		19	Pressure vessels and parts subject to pressure	Medical electrical equipment. Part 2-42:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 45		2023-02-14
		20	Toxic and flammable fluids and gases	Medical electrical equipment. Part 2-43:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 45.101		2023-02-14
		21	Interruption of the power supply	Medical electrical equipment. Part 2-44:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 49		2023-02-14
		22	Accuracy of operating data	Medical electrical equipment. Part 2-45:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 50		2023-02-14
		23	Protection against hazardous output	Medical electrical equipment. Part 2-46:Particular requirements for the safety,including essential performance,of automatic		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 51		
		24	Alarms	Medical electrical equipment. Part 2-47:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 51.101		2023-02-14
		25	Physiological alarm	Medical electrical equipment. Part 2-48:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 51.102		2023-02-14
		26	Technical alarm	Medical electrical equipment. Part 2-49:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 51.103		2023-02-14
		27	Remote equipment	Medical electrical equipment. Part 2-50:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 51.104		2023-02-14
		28	Sound level of the auditory ALARM manifestation	Medical electrical equipment. Part 2-51:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 51.105		2023-02-14
		29	Recovery from DEFIBRILLATOR discharge	Medical electrical equipment. Part 2-52:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 51.106		2023-02-14
		30	Components and general assembly	Medical electrical equipment. Part 2-53:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 56		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		31	Connections – General	Medical electrical equipment. Part 2-54:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 56.3		2023-02-14
		32	Battery	Medical electrical equipment. Part 2-55:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 56.7		2023-02-14
		33	Mains parts, components and lay-out	Medical electrical equipment. Part 2-56:Particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY0667-2008 IEC60601-2-30:1999 57		2023-02-14
124	Multifunction patient monitoring equipment	1	All Parameters	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001		2023-02-14
		2	Classification	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 5		2023-02-14
		3	Identification, marking and documents	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 6		2023-02-14
		4	Requirements related to classification	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 14		2023-02-14
		5	Separation	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 17		2023-02-14
		6	Continuous leakage currents and patient auxiliary currents	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 19		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Dielectric strength	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 20		2023-02-14
		8	Electromagnetic compatibility	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 36		2023-02-14
		9	Spillage	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 44.3		2023-02-14
		10	Interruption of the power supply	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 49		2023-02-14
		11	Accuracy of operating data	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 50		2023-02-14
		12	Protection against hazardous output	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 51		2023-02-14
		13	Alarms	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 51.101		2023-02-14
		14	Physiological alarm	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 51.102		2023-02-14
		15	Technical alarm	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 51.103		2023-02-14
		16	Remote equipment	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 51.104		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	Sound level of the auditory alarm manifestation	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 51.105		2023-02-14
		18	Components and general assembly	Medical electrical equipment. Part 2-49:Particular requiremens for the safety of multifunction patient monitoring equipment YY0668-2008 IEC60601-2-49:2001 56		2023-02-14
125	Pulse oximeter equipment for medical use	1	All Parameters	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005		2023-02-14
		2	Classification	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 5		2023-02-14
		3	Identification, marking and documents	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 6		2023-02-14
		4	Power input	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 7		2023-02-14
		5	Basic safety categories	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 8		2023-02-14
		6	Environmental conditions	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 10		2023-02-14
		7	Transport and storage	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 10.1		2023-02-14
		8	General	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 13		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Requirements related to classification	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 14		2023-02-14
		10	Limitation of voltage and/or energy	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 15		2023-02-14
		11	Encloseures and protective covers	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 16		2023-02-14
		12	Separation	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 17		2023-02-14
		13	Protective earthing, functional earthing and potential equalisation	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 18		2023-02-14
		14	Continuous leakage currents and patient auxiliary currents	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 19		2023-02-14
		15	Dielectric strength	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 20		2023-02-14
		16	Mechanical strength	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 21		2023-02-14
		17	Shock and vibration	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 21.101		2023-02-14
		18	Shock and vibration for transport	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				equipment for medical use YY0784-2010 ISO9919:2005 21.102		
		19	Mechanical strength	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 22		2023-02-14
		20	Surfaces, corners and edges	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 23		2023-02-14
		21	Stability in normal use	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 24		2023-02-14
		22	Electromagnetic compatibility	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 36		2023-02-14
		23	Locations and basic requirements	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 37		2023-02-14
		24	Marking, accompanying documents	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 38		2023-02-14
		25	Common requirements for category AP and category APG equipment	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 39		2023-02-14
		26	Requirements and tests for category AP equipment, parts and components thereof	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 40		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		27	Requirements and tests for category APG equipment, parts and components thereof	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 41		2023-02-14
		28	Excessive temperatures	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 42		2023-02-14
		29	Fire prevention	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 43		2023-02-14
		30	Pulse oximeter equipment used in conjunction with oxidants	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 43.101		2023-02-14
		31	Sparking	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 43.102		2023-02-14
		32	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilisation,disinfection and compatibility	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 44		2023-02-14
		33	lngress of liquids	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 44.6		2023-02-14
		34	Cleaning, sterilisation and	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			disinfection	equipment for medical use YY0784-2010 ISO9919:2005 44.7		
		35	Biocompatibility	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 48	SeeGB/T 16886	2023-02-14
		36	Interruption of the power supply	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 49		2023-02-14
		37	Power failure alarm condition	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 49.101		2023-02-14
		38	Pulse oximeter equipment operation following interruption of the power supply	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 49.102		2023-02-14
		39	Accuracy of operating data	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 50		2023-02-14
		40	Protection against hazardous output	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 51		2023-02-14
		41	Data update period	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 51.101		2023-02-14
		42	Detection of pulse oximeter probe and probe cable extender fault	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 51.102		2023-02-14
		43	Abnormal operation	Medical electrical equipment. Particular requirements for the		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			and fault conditions	basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 52		
		44	Environmental test	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 53	See GB 9706.1-2007	2023-02-14
		45	General	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 54		2023-02-14
		46	Enclosures and covers	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 55		2023-02-14
		47	components and general assembly	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 56		2023-02-14
		48	mains parts components and layout	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 57		2023-02-14
		49	Protective earthing--Terminals and connections	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 58		2023-02-14
		50	Construction and layout	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 59		2023-02-14
		51	Signal inadequacy	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 101		2023-02-14
		52	Pulse oximeter probes and probe cable extenders	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 102		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		53	General	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 102.1		2023-02-14
		54	Labelling	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 102.2		2023-02-14
		55	Saturation pluse information signal	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 103		2023-02-14
		56	Alarm systems	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 104		2023-02-14
		57	Assignment of priority	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 201.1.2		2023-02-14
		58	Default alarm preset	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 201.5.4		2023-02-14
		59	Alarm signal inactivation states	Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use YY0784-2010 ISO9919:2005 201.8		2023-02-14
126	Electrical thermometers for continuous measurement	1	All Parameters	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001		2023-02-14
		2	Unit	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 4		2023-02-14
		3	Types of thermometers	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 5		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	requirements	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6		2023-02-14
		5	General	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.1		2023-02-14
		6	Measuring range	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.2		2023-02-14
		7	Maximum permissible error	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.3		2023-02-14
		8	Time response	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.4		2023-02-14
		9	Enviromental operating range	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.5		2023-02-14
		10	Effect of storage	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.6		2023-02-14
		11	Humidity	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.7		2023-02-14
		12	Electromagnetic compatibility	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.8		2023-02-14
		13	General requirements for safety	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Additional requirements for the indicating unit	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.10		2023-02-14
		15	Digital increment	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.10.1		2023-02-14
		16	Display	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.10.2		2023-02-14
		17	Maximum energy dissipation	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.10.3		2023-02-14
		18	Auxiliary device	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.10.4		2023-02-14
		19	Self checking device	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.10.5		2023-02-14
		20	Variation of the voltage supply	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.10.6		2023-02-14
		21	Additional requirements for the temperature probe	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.11		2023-02-14
		22	Maximum energy dissipation	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.11.1		2023-02-14
		23	Long-term stability	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.11.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		24	protection against human liquids	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.11.3		2023-02-14
		25	Cleaning, disinfection and sterilisation	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.11.4		2023-02-14
		26	Biocompatibility	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.11.5	SeeGB/T 16886	2023-02-14
		27	Mechanical safety	Clinical thermometers. Performance of electrical thermometers for continuous measurement YY0785-2010 BS EN2470-4:2001 6.11.6		2023-02-14
127	blankets,pads and mattresses,intended for heating in medical use	1	All Parameters	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996		2023-02-14
		2	classification	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 5		2023-02-14
		3	Identification, marking and documentation	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 6		2023-02-14
		4	isolation	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 17		2023-02-14
		5	Continuous leakage currents and patient auxiliary current	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 19		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Mechanical strength	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 21		2023-02-14
		7	Electromagnetic Compatibility	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 36		2023-02-14
		8	Overtemperature	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 42		2023-02-14
		9	Overflow, crossing the body spill, leak, damp, into the liquid, wash, sterilization, disinfection and compatibility	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 44		2023-02-14
		10	Human error	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 46		2023-02-14
		11	Power supply interruption	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 49		2023-02-14
		12	The accuracy of the data work	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				50		
		13	Prevent the risk of output	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 51		2023-02-14
		14	Abnormal operation and fault status	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 52		2023-02-14
		15	Outline	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 54		2023-02-14
		16	Components and assemblies	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 56		2023-02-14
		17	Net power supply section, components and wiring	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 57		2023-02-14
		18	Structure and cabling	Medical electrical equipment-Part 2-35:Particular requirements for the safety of blankets,pads and mattresses,intended for heating in medical use YY 0834-2011 IEC 60601-2-35:1996 59		2023-02-14
128	programmable electrical medical systems	1	All Parameters	Medical electrical equipment-Part 1-4: General requirements for safety-coIlateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000		2023-02-14
		2	accompany	Medical electrical equipment-Part 1-4: General requirements for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			document	safety-collateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 6.8		
		3	file	Medical electrical equipment-Part 1-4: General requirements for safety-collateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 52.201		2023-02-14
		4	Risk Management Plan	Medical electrical equipment-Part 1-4: General requirements for safety-collateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 52.202		2023-02-14
		5	Development life cycle	Medical electrical equipment-Part 1-4: General requirements for safety-collateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 52.203		2023-02-14
		6	Risk management process	Medical electrical equipment-Part 1-4: General requirements for safety-collateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 52.204		2023-02-14
		7	Qualified person	Medical electrical equipment-Part 1-4: General requirements for safety-collateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 52.205		2023-02-14
		8	Requirements Specification	Medical electrical equipment-Part 1-4: General requirements for safety-collateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 52.206		2023-02-14
		9	Architecture	Medical electrical equipment-Part 1-4: General requirements for safety-collateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 52.207		2023-02-14
		10	Design and Implementation	Medical electrical equipment-Part 1-4: General requirements for safety-collateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 52.208		2023-02-14
		11	verification	Medical electrical equipment-Part 1-4: General requirements for safety-collateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 52.209		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	confirm	Medical electrical equipment-Part 1-4: General requirements for safety-coIlateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 52.21		2023-02-14
		13	modify	Medical electrical equipment-Part 1-4: General requirements for safety-coIlateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 52.211		2023-02-14
		14	assessment	Medical electrical equipment-Part 1-4: General requirements for safety-coIlateral standard : programmable electrical medical systems YY/T0708-2009 IEC 60601-1-4：2000 52.212		2023-02-14
129	Clinical electronic thermometer	1	All Parameters	Clinical electronic thermometer GB/T 21416-2008		2023-02-14
		2	Appearance and structure	Clinical electronic thermometer GB/T 21416-2008 4.2		2023-02-14
		3	Display Range	Clinical electronic thermometer GB/T 21416-2008 4.3.1		2023-02-14
		4	Resolution	Clinical electronic thermometer GB/T 21416-2008 4.3.2		2023-02-14
		5	The maximum permissible error	Clinical electronic thermometer GB/T 21416-2008 4.3.3		2023-02-14
		6	Repeatability	Clinical electronic thermometer GB/T 21416-2008 4.3.4		2023-02-14
		7	Measurement complete prompts	Clinical electronic thermometer GB/T 21416-2008 4.4.1		2023-02-14
		8	Over-temperature and low-temperature prompts	Clinical electronic thermometer GB/T 21416-2008 4.4.2		2023-02-14
		9	Low-voltage prompts	Clinical electronic thermometer GB/T 21416-2008 4.4.3		2023-02-14
		10	measure time	Clinical electronic thermometer GB/T 21416-2008 4.5		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	memory function	Clinical electronic thermometer GB/T 21416-2008 4.6		2023-02-14
		12	Automatic shutdown	Clinical electronic thermometer GB/T 21416-2008 4.7		2023-02-14
		13	Contact with the patient probe	Clinical electronic thermometer GB/T 21416-2008 4.9		2023-02-14
		14	Biological Evaluation	Clinical electronic thermometer GB/T 21416-2008 4.11	SeeGB/T 16886	2023-02-14
		15	material	Clinical electronic thermometer GB/T 21416-2008 4.12		2023-02-14
		16	technical instructions	Clinical electronic thermometer GB/T 21416-2008 4.13		2023-02-14
		17	Safety requirements	Clinical electronic thermometer GB/T 21416-2008 4.14	SeeGB 9706.1-2007	2023-02-14
		18	Environmental Testing	Clinical electronic thermometer GB/T 21416-2008 4.15	SeeGB/T 14710	2023-02-14
130	compression physiotherapy equipment for limbs	1	All Parameters	General technical requirements for compression physiotherapy equipment for limbs YY/T0833-2020		2023-02-14
		2	Appearance	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.2		2023-02-14
		3	Pressure indication	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.3		2023-02-14
		4	Treatment pressure adjustment range	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.4		2023-02-14
		5	Ultimate pressure	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.5		2023-02-14
		6	Overvoltage Protection	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.6		2023-02-14
		7	Timing means	Compression physiotherapy equipment for limbs YY/T0833-		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				2020 5.7		
		8	Function switch	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.8		2023-02-14
		9	Manual pressure release	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.9		2023-02-14
		10	Tightness	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.1		2023-02-14
		11	Pressure resistance	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.11		2023-02-14
		12	Fatigue Test	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.12		2023-02-14
		13	Biocompatibility	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.13	SeeGB/T 16886	2023-02-14
		14	connection	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.14		2023-02-14
		15	Working noise	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.15		2023-02-14
		16	Safety requirements	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.16	See GB 9706.1-2007	2023-02-14
		17	Environmental experimental requirements	General technical requirem for compression physiotherapy equipment for limbs YY/T0833-2020 5.17	SeeGB/T 14710	2023-02-14
131	Irrigation pump	1	All Parameters	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011		2023-02-14
		2	Preset pressure adjustment range limit	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.1.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	The accuracy of the preset pressure limit	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.1.2		2023-02-14
		4	Overvoltage decompression functions	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.1.3		2023-02-14
		5	Overvoltage alarm	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.1.4		2023-02-14
		6	Preset flow rate adjustment range	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.2.1		2023-02-14
		7	Traffic preset accuracy	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.2.2		2023-02-14
		8	Line biocompatibility	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.3.1	SeeGB/T 16886	2023-02-14
		9	Disinfection tolerance Application Part	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.3.2		2023-02-14
		10	Line roller by squeezing tolerance parts	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.3.3		2023-02-14
		11	Pipe connections firmness	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.3.4		2023-02-14
		12	Rolling pipe inner diameter tolerance	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.3.5		2023-02-14
		13	Electrical Safety	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.4	See GB 9706.1-2007	2023-02-14
		14	Environmental testing requirements	Medical endoscopes-Endoscope functional supply units-Irrigation pump YY/T 0864-2011 4.5	SeeGB/T 14710	2023-02-14
132	Medical Software	1	All parameters	Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Requirements for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				quality of Ready to Use Software Product (RUSP) and instructions for testing GB/T 25000.51-2016		
		2	Product description requirements	Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing GB/T 25000.51-2016 5.1		2023-02-14
		3	Requirements for user documentation	Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing GB/T 25000.51-2016 5.2		2023-02-14
		4	Product quality - Functionality	Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing GB/T 25000.51-2016 5.3.1		2023-02-14
		5	Product quality – Performance efficiency	Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing GB/T 25000.51-2016 5.3.2		2023-02-14
		6	Product quality – Compatibility	Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing GB/T 25000.51-2016 5.3.3		2023-02-14
		7	Product quality – Usability	Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing GB/T 25000.51-2016 5.3.4		2023-02-14
		8	Product quality – Reliability	Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing GB/T 25000.51-2016 5.3.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Product quality – Security	Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing GB/T 25000.51-2016 5.3.6		2023-02-14
		10	Product quality – Maintainability	Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing GB/T 25000.51-2016 5.3.7		2023-02-14
		11	Product quality – Portability	Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing GB/T 25000.51-2016 5.3.8		2023-02-14
133	Electrical surgical equipment for osseous tissue	1	All Parameters	Electrical surgical equipment for osseous tissue YY/T 0752-2016		2023-02-14
		2	working status instructions	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.1.1		2023-02-14
		3	rotation speed/ frequency with no-load rotation speed/ frequency of permissible error	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.1.2		2023-02-14
		4	tolerance of the rotation speed of point of a particular work load and measured rotation speed of that point	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.1.3		2023-02-14
		5	Corrosion Resistance	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.1.4		2023-02-14
		6	noise	Electrical surgical equipment for osseous tissue YY/T 0752-2016		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				5.1.5		
		7	cutter clamping with handpiece a)	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.1 a）		2023-02-14
		8	cutter clamping with handpiece b)	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.1 b）		2023-02-14
		9	Handing cutter	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.2		2023-02-14
		10	Radial circle run-out	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.3		2023-02-14
		11	Axial movement	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.4		2023-02-14
		12	Housing surface temperature	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.5		2023-02-14
		13	Surface roughness	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.2.6		2023-02-14
		14	Shaft and connector performance requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.3.1		2023-02-14
		15	Shaft and connector performance requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.3.2		2023-02-14
		16	Shaft and connector performance requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.3.3		2023-02-14
		17	Cable and connector performance requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.4.1		2023-02-14
		18	Cable and connector performance	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			requirements			
		19	Cable and connector performance requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.4.3		2023-02-14
		20	Foot Controller Requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.5	SeeYY 91057	2023-02-14
		21	Environmental testing requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.6	SeeGB/T 14710	2023-02-14
		22	Safety requirements	Electrical surgical equipment for osseous tissue YY/T 0752-2016 5.7	SeeGB 9706.1-2007, YY 0505	2023-02-14
134	electrically operated hospital beds	1	All Parameters	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013		2023-02-14
		2	Specific functions of risk assessment	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 3.101		2023-02-14
		3	classification	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 5		2023-02-14
		4	Identification, marking and documents	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 6.1		2023-02-14
		5	Instructions for use	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 6.8.2		2023-02-14
		6	isolation	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 17c)		2023-02-14
		7	Protective earthing,	Medical electrical equipment-Part 2 : Particular requirements for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			functional earthing and potential equalization	the safety of electrically operated hospital beds YY 0571-2013 18		
		8	Acting as a support and / or support quality patient or fixed bed member	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 21.3		2023-02-14
		9	Safe working load bed	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 21.3.101		2023-02-14
		10	Safe working load lever pulled	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 21.3.102		2023-02-14
		11	Sidebar	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 21.4		2023-02-14
		12	Impact test	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 21.6		2023-02-14
		13	Head / foot group	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 21.6.101		2023-02-14
		14	Threshold Test	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 21.6.102		2023-02-14
		15	Moving parts	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 22		2023-02-14
		16	Patient jammed protection	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 23.101		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	Castors and stability test bed sidebar	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 24.3 aa）		2023-02-14
		18	Stability test lever pulled	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 24.3 bb）		2023-02-14
		19	Means any movement of their own to prevent the transport state	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 24.4		2023-02-14
		20	Sound and vibration exposure	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 26.101		2023-02-14
		21	No safety devices metal suspension system	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 28.4		2023-02-14
		22	Accessories and their connection points and fasteners	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 28.4.101		2023-02-14
		23	Sidebar force status when normal use	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 28.4.102		2023-02-14
		24	Design Sidebar	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 28.4.103		2023-02-14
		25	Immunity	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 36.202	See YY 0505	2023-02-14
		26	Inlet	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				44.6.101		
		27	Inlet	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 44.6.102		2023-02-14
		28	Inlet	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 44.6.103		2023-02-14
		29	Unexpected movement of the application part	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 54.4.101		2023-02-14
		30	Failure element portion of the motion control application in the normal state	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 52.5.9		2023-02-14
		31	Means patients can reach the stop bed function control	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 52.5.101		2023-02-14
		32	Grid voltage interruption emergencies	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 52.5.102		2023-02-14
		33	Programmable system or subsystem failure	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 52.5.103		2023-02-14
		34	Trendelenburg position	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 54.101		2023-02-14
		35	Outline	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				56.1 aa）		
		36	Head plate assembly	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 56.1.101		2023-02-14
		37	Indicator	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 56.8		2023-02-14
		38	Limited mobile	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 56.10 c)		2023-02-14
		39	Power cable length	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 57.3 a）		2023-02-14
		40	Power cable insulation and sheathing	Medical electrical equipment-Part 2 : Particular requirements for the safety of electrically operated hospital beds YY 0571-2013 57.3 a）		2023-02-14
135	Operating table	1	All Parameters	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998		2023-02-14
		2	Accessory	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 4.6 aa)		2023-02-14
		3	External marking device or piece of equipment	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 6.1		2023-02-14
		4	accompany document	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 6.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	isolation	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 17		2023-02-14
		6	Protective earthing, functional earthing and potential equalization	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 18		2023-02-14
		7	Continuous leakage currents and patient auxiliary current	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 19		2023-02-14
		8	Dielectric strength	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 20		2023-02-14
		9	Mechanical strength	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 21		2023-02-14
		10	Moving parts	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 22		2023-02-14
		11	Stability in normal use	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 24		2023-02-14
		12	Electromagnetic Compatibility	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 36.101		2023-02-14
		13	Electrostatic Prevention	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 39.3b)		2023-02-14
		14	Overflow, liquid spill, leak, damp,	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			into the liquid, cleaning, disinfection, sterilization and compatibility	60601-2-46:1998 44.101		
		15	Interrupt the power supply	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 49.101		2023-02-14
		16	The accuracy of the data work	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 50.101		2023-02-14
		17	Components and assemblies	Medical electrical equipment-Part 2:Particular requirements for the safety of operating tables YY 0570-2013 IEC 60601-2-46:1998 56.11		2023-02-14
136	Electric cervical and lumbar traction therapy device	1	All Parameters	Electric cervical and lumbar traction therapy device YY/T 0697-2016		2023-02-14
		2	Traction mode	Dynamoelectric traction-table YY/T 0697-2016 4.2		2023-02-14
		3	Tolerance range and maximum traction	Dynamoelectric traction-table YY/T 0697-2016 4.3		2023-02-14
		4	Traction bed and traction treatment time and intermittent time tolerance	Dynamoelectric traction-table YY/T 0697-2016 4.4		2023-02-14
		5	protection	Dynamoelectric traction-table YY/T 0697-2016 4.5		2023-02-14
		6	Angle range and tolerance	Dynamoelectric traction-table YY/T 0697-2016 4.6		2023-02-14
		7	Having a quick pull function traction	Dynamoelectric traction-table YY/T 0697-2016 4.7.1		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			bed traction			
		8	Having a quick pull function traction bed traction stroke	Dynamoelectric traction-table YY/T 0697-2016 4.7.2		2023-02-14
		9	Exterior	Dynamoelectric traction-table YY/T 0697-2016 4.8.1		2023-02-14
		10	Text logo	Dynamoelectric traction-table YY/T 0697-2016 4.8.2		2023-02-14
		11	structure	Dynamoelectric traction-table YY/T 0697-2016 4.8.3		2023-02-14
		12	noise	Dynamoelectric traction-table YY/T 0697-2016 4.9		2023-02-14
		13	Safety requirements	Dynamoelectric traction-table YY/T 0697-2016 4.1	See GB 9706.1-2007	2023-02-14
		14	Environmental Testing	Dynamoelectric traction-table YY/T 0697-2016 4.11	SeeGB/T 14710	2023-02-14
137	Medical electrical device	1	All Parameters	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012		2023-02-14
		2	Conditions for application to ME EQUIPMENT or ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.1		2023-02-14
		3	General requirement for RISK MANAGEMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.2.2		2023-02-14
		4	HAZARDS identified in the IEC 60601-series	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.2.3.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	HAZARDS not identified in the IEC 60601 series	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.2.3.2		2023-02-14
		6	ESSENTIAL PERFORMANCE	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.3		2023-02-14
		7	EXPECTED SERVICE LIFE	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.4		2023-02-14
		8	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.5		2023-02-14
		9	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.6		2023-02-14
		10	SINGLE FAULT CONDITION for ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.7		2023-02-14
		11	Components of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.8		2023-02-14
		12	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Source of power for ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.10.1		2023-02-14
		14	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.10.2		2023-02-14
		15	Power input	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 4.11		2023-02-14
		16	Protection against electric shock	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 6.2		2023-02-14
		17	Protection against harmful ingress of water or particulate matter	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 6.3		2023-02-14
		18	Method(s) of sterilization	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 6.4		2023-02-14
		19	Suitability for use in an OXYGEN RICH ENVIRONMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 6.5		2023-02-14
		20	Mode of operation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 6.6		2023-02-14
		21	Legibility of markings	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.1.2		2023-02-14
		22	Durability of markings	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.1.3		2023-02-14
		23	Minimum requirements for marking on ME EQUIPMENT and on interchangeable	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			parts			
		24	Identification	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.2		2023-02-14
		25	Consult ACCOMPANYING DOCUMENTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.3		2023-02-14
		26	ACCESSORIES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.4		2023-02-14
		27	ME EQUIPMENT intended to receive power from other equipment	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.5		2023-02-14
		28	Connection to the SUPPLY MAINS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.6		2023-02-14
		29	Electrical input power from the SUPPLY MAINS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.7		2023-02-14
		30	Output connectors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.8		2023-02-14
		31	IP classification	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.9		2023-02-14
		32	APPLIED PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.10		2023-02-14
		33	Mode of operation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.11		2023-02-14
		34	Fuses	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.12		2023-02-14
		35	Physiological effects (safety signs	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.13		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			and warning statements)			
		36	HIGH VOLTAGE TERMINAL DEVICES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.14		2023-02-14
		37	Cooling conditions	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.15		2023-02-14
		38	Mechanical stability	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.16		2023-02-14
		39	Protective packaging	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.17		2023-02-14
		40	External pressure source	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.18		2023-02-14
		41	FUNCTIONAL EARTH TERMINALS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.19		2023-02-14
		42	Removable protective means	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.20		2023-02-14
		43	Mass of MOBILE ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.2.21		2023-02-14
		44	Heating elements or lampholders	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.3.1		2023-02-14
		45	HIGH VOLTAGE parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.3.2		2023-02-14
		46	Batteries	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.3.3		2023-02-14
		47	Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.3.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		48	PROTECTIVE EARTH TERMINALS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.3.5		2023-02-14
		49	FUNCTIONAL EARTH TERMINALS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.3.6		2023-02-14
		50	Supply terminals	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.3.7		2023-02-14
		51	Temperature of supply terminals	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.3.8		2023-02-14
		52	Power switches	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.4.1		2023-02-14
		53	Control devices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.4.2		2023-02-14
		54	Units of measurement	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.4.3		2023-02-14
		55	Safety signs	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.5		2023-02-14
		56	Explanation of symbols	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.6.1		2023-02-14
		57	Symbols from Annex D	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.6.2		2023-02-14
		58	Symbols for controls and performance	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.6.3		2023-02-14
		59	PROTECTIVE EARTH CONDUCTOR	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.7.1		2023-02-14
		60	PROTECTIVE EARTH	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.7.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			CONNECTIONS			
		61	Green and yellow insulation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.7.3		2023-02-14
		62	Neutral conductor	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.7.4		2023-02-14
		63	POWER SUPPLY CORD conductors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.7.5		2023-02-14
		64	Colours of indicator lights	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.8.1		2023-02-14
		65	Colours of controls	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.8.2		2023-02-14
		66	General	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.1		2023-02-14
		67	General	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.1		2023-02-14
		68	Warning and safety notices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.2		2023-02-14
		69	ME EQUIPMENT specified for connection to a separate power supply	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.3		2023-02-14
		70	Electrical power source	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.4		2023-02-14
		71	ME EQUIPMENT description	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.5		2023-02-14
		72	Installation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		73	Isolation from the SUPPLY MAINS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.7		2023-02-14
		74	Start-up PROCEDURE	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.8		2023-02-14
		75	Operating instructions	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.9		2023-02-14
		76	Messages	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.10		2023-02-14
		77	Shutdown PROCEDURE	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.11		2023-02-14
		78	Cleaning, disinfection and sterilization	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.12		2023-02-14
		79	Maintenance	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.13		2023-02-14
		80	ACCESSORIES, supplementary equipment, used material	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.14		2023-02-14
		81	Environmental protection	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.15		2023-02-14
		82	Reference to the technical description	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.16		2023-02-14
		83	ME EQUIPMENT emitting radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				7.9.2.17		
		84	ME EQUIPMENT and ACCESSORIES supplied sterile	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.18		2023-02-14
		85	Unique version identifier	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.2.19		2023-02-14
		86	General	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.3.1		2023-02-14
		87	Replacement of fuses, POWER SUPPLY CORDS and other parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.3.2		2023-02-14
		88	Circuit diagrams, component part lists, etc.	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.3.3		2023-02-14
		89	Mains isolation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 7.9.3.4		2023-02-14
		90	Connection to a separate power source	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.2.1		2023-02-14
		91	Connection to an external d.c. power source	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.2.2		2023-02-14
		92	Classification of APPLIED PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.3		2023-02-14
		93	PATIENT CONNECTIONS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			intended to deliver current			
		94	ACCESSIBLE PARTS including and APPLIED PARTS a)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.4.2 a		2023-02-14
		95	ACCESSIBLE PARTS including and APPLIED PARTS b)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.4.2 b		2023-02-14
		96	ACCESSIBLE PARTS including and APPLIED PARTS c)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.4.2 c		2023-02-14
		97	ACCESSIBLE PARTS including and APPLIED PARTS d)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.4.2 d		2023-02-14
		98	ACCESSIBLE PARTS including and APPLIED PARTS e)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.4.2 e		2023-02-14
		99	ME EQUIPMENT intended to be connected to a power source by a plug	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.4.3		2023-02-14
		100	Internal capacitive circuits	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		101	MEANS OF PATIENT PROTECTION (MOPP)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.5.1.2		2023-02-14
		102	MEANS OF OPERATOR PROTECTION (MOOP)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.5.1.3		2023-02-14
		103	F-TYPE APPLIED PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.5.2.1		2023-02-14
		104	TYPE B APPLIED PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.5.2.2		2023-02-14
		105	PATIENT leads or PATIENT cables	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.5.2.3		2023-02-14
		106	DEFIBRILLATION -PROOF APPLIED PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.5.5		2023-02-14
		107	PROTECTIVE EARTH TERMINAL	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.6.2		2023-02-14
		108	Protective earthing of moving parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.6.3		2023-02-14
		109	Impedance and current-carrying capability	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.6.4		2023-02-14
		110	Surface coatings	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.6.5		2023-02-14
		111	Plugs and sockets	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.6.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		112	POTENTIAL EQUALIZATION CONDUCTOR	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.6.7		2023-02-14
		113	FUNCTIONAL EARTH TERMINAL	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.6.8		2023-02-14
		114	CLASS II ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.6.9		2023-02-14
		115	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.7		2023-02-14
		116	Distance through solid insulation or use of thin sheet material	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.8.2		2023-02-14
		117	Dielectric strength	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.8.3		2023-02-14
		118	Mechanical strength and resistance to heat	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.8.4.1		2023-02-14
		119	Resistance to environmental stress	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.8.4.2		2023-02-14
		120	General	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.1		2023-02-14
		121	CREEPAGE DISTANCES and AIR CLEARANCES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			complying with IEC 60950-1			
		122	CREEPAGE DISTANCES across glass, mica, ceramic and similar materials	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.3		2023-02-14
		123	ME EQUIPMENT RATED for high altitudes	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.5		2023-02-14
		124	Material groups classification	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.7		2023-02-14
		125	Pollution degree classification	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.8		2023-02-14
		126	Overvoltage category classification	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.9		2023-02-14
		127	AIR CLEARANCE for MAINS PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.10		2023-02-14
		128	SUPPLY MAINS overvoltage	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.11		2023-02-14
		129	SECONDARY CIRCUITS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.12		2023-02-14
		130	PEAK WORKING VOLTAGES above 1 400 V peak or d.c.	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.13		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		131	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.14		2023-02-14
		132	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION -PROOF APPLIED PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.1.15		2023-02-14
		133	Application	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.2		2023-02-14
		134	Insulating compound forming solid insulation between conductive parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.3.2		2023-02-14
		135	Insulating compound forming a cemented joint with other insulating parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.9.3.3		2023-02-14
		136	Fixing of components	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.10.1		2023-02-14
		137	Fixing of wiring	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.10.2		2023-02-14
		138	Connections	Medical electrical equipment –Part 1: General requirements for		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			between different parts of ME EQUIPMENT	basic safety and essential performance IEC 60601-1:2012 8.10.3		
		139	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.10.4		2023-02-14
		140	Mechanical protection of wiring	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.10.5		2023-02-14
		141	Guiding rollers for insulated conductors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.10.6		2023-02-14
		142	Insulation of internal wiring	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.10.7		2023-02-14
		143	Isolation from the SUPPLY MAINS a)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.1 a		2023-02-14
		144	Isolation from the SUPPLY MAINS b)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.1 b		2023-02-14
		145	Isolation from the SUPPLY MAINS c)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.1 c		2023-02-14
		146	Isolation from the SUPPLY MAINS d)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.1 d		2023-02-14
		147	Isolation from the SUPPLY MAINS e)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.1 e		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		148	Isolation from the SUPPLY MAINS f)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.3 f		2023-02-14
		149	Isolation from the SUPPLY MAINS g)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.4 g		2023-02-14
		150	Isolation from the SUPPLY MAINS h)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.4 h		2023-02-14
		151	Isolation from the SUPPLY MAINS i)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.5 i		2023-02-14
		152	MULTIPLE SOCKET-OUTLETS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.2		2023-02-14
		153	Application	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.3.1		2023-02-14
		154	Types	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.3.2		2023-02-14
		155	Cross-sectional area of POWER SUPPLY CORD conductors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.3.3		2023-02-14
		156	APPLIANCE COUPLERS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.3.4		2023-02-14
		157	Cord anchorage	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.3.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		158	Cord guards	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.3.6		2023-02-14
		159	General requirements for MAINS TERMINAL DEVICES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.4.1		2023-02-14
		160	Arrangement of MAINS TERMINAL DEVICES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.4.2		2023-02-14
		161	Fixing of mains terminals	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.4.3		2023-02-14
		162	Connections to mains terminals	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.4.4		2023-02-14
		163	Accessibility of the connection	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.4.5		2023-02-14
		164	Mains fuses and OVER-CURRENT RELEASES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.5		2023-02-14
		165	Internal wiring of the MAINS PART	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 8.11.6		2023-02-14
		166	General	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.2.1		2023-02-14
		167	TRAPPING ZONE	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.2.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		168	Other MECHANICAL HAZARDS associated with moving parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.2.3		2023-02-14
		169	Emergency stopping devices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.2.4		2023-02-14
		170	Release of PATIENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.2.5		2023-02-14
		171	MECHANICAL HAZARD associated with surfaces, corners and edges	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.3		2023-02-14
		172	Instability – overbalance	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.4.2		2023-02-14
		173	Instability from unwanted lateral movement (including sliding)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.4.3		2023-02-14
		174	Grips and other handling devices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.4.4		2023-02-14
		175	Protective means	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.5.1		2023-02-14
		176	Cathode ray tubes	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.5.2		2023-02-14
		177	Audible acoustic energy	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.6.2.1		2023-02-14
		178	Infrasound and ultrasound energy	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.6.2.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		179	Hand-transmitted vibration	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.6.3		2023-02-14
		180	Pneumatic and hydraulic parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.7.2		2023-02-14
		181	Maximum pressure	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.7.3		2023-02-14
		182	Pressure rating of ME EQUIPMENT parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.7.4		2023-02-14
		183	Pressure vessels	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.7.5		2023-02-14
		184	Pressure-control device	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.7.6		2023-02-14
		185	Pressure-relief device	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.7.7		2023-02-14
		186	RATED maximum supply pressure	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.7.8		2023-02-14
		187	General	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.8.1		2023-02-14
		188	TENSILE SAFETY FACTOR	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.8.2		2023-02-14
		189	Strength of PATIENT or OPERATOR support or suspension systems	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.8.3		2023-02-14
		190	Systems with MECHANICAL PROTECTIVE DEVICES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.8.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		191	Systems without MECHANICAL PROTECTIVE DEVICES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 9.8.5		2023-02-14
		192	ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 10.1.1		2023-02-14
		193	ME EQUIPMENT Intended to produce diagnostic or therapeutic X-radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 10.1.2		2023-02-14
		194	Alpha, beta, gamma, neutron and other particle radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 10.2		2023-02-14
		195	Microwave radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 10.3		2023-02-14
		196	Lasers	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 10.4	SeeGB 7247.1-2012	2023-02-14
		197	Other visible electromagnetic radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 10.5		2023-02-14
		198	Infrared radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 10.6		2023-02-14
		199	Ultraviolet radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 10.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		200	Maximum temperature during NORMAL USE	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.1.1		2023-02-14
		201	APPLIED PARTS intended to supply heat to a PATIENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.1.2.1		2023-02-14
		202	APPLIED PARTS not intended to supply heat to a PATIENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.1.2.2		2023-02-14
		203	GUARDS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.1.4		2023-02-14
		204	Fire prevention	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.2		2023-02-14
		205	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.3		2023-02-14
		206	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.4		2023-02-14
		207	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.5		2023-02-14
		208	Overflow in ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.6.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		209	Spillage on ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.6.3		2023-02-14
		210	Leakage	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.6.4	see 13.2.6	2023-02-14
		211	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.6.5		2023-02-14
		212	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.6.6		2023-02-14
		213	Sterilization of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.6.7	see 7.9.2.12	2023-02-14
		214	Compatibility with substances used with the ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.6.8		2023-02-14
		215	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.7		2023-02-14
		216	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 11.8		2023-02-14
		217	Accuracy of controls and	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 12.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			instruments			
		218	USABILITY of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 12.2		2023-02-14
		219	ALARM SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 12.3	seeYY 0709	2023-02-14
		220	Intentional exceeding of safety limits	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 12.4.1		2023-02-14
		221	Indication relevant to safety	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 12.4.2		2023-02-14
		222	Accidental selection of excessive output values	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 12.4.3		2023-02-14
		223	Incorrect output	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 12.4.4		2023-02-14
		224	Limits	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 12.4.5.1		2023-02-14
		225	Diagnostic X-ray equipment	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 12.4.5.2		2023-02-14
		226	Radiotherapy equipment	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 12.4.5.3		2023-02-14
		227	Other ME EQUIPMENT producing diagnostic or therapeutic radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 12.4.5.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		228	Diagnostic or therapeutic acoustic pressure	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 12.4.6		2023-02-14
		229	Emissions, deformation of ENCLOSURE or exceeding maximum temperature	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.1.2		2023-02-14
		230	Exceeding LEAKAGE CURRENT or voltage limits	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.1.3		2023-02-14
		231	Specific MECHANICAL HAZARDS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.1.4	see 9.1 to 9.8	2023-02-14
		232	Electrical SINGLE FAULT CONDITION	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.2	see 8.1	2023-02-14
		233	Overheating of transformers in ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.3	see 15.5	2023-02-14
		234	Failure of THERMOSTATS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.4	see 13.2.13 and 15.4.2	2023-02-14
		235	Failure of temperature limiting devices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.5	see 13.2.13 and 15.4.2	2023-02-14
		236	Leakage of liquid	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		237	Impairment of cooling that could result in a HAZARDOUS SITUATION	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.7		2023-02-14
		238	Locking of moving parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.8		2023-02-14
		239	Interruption and short circuiting of motor capacitors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.9		2023-02-14
		240	Additional test criteria for motor operated ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.10		2023-02-14
		241	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.11	see 11.2.2	2023-02-14
		242	Failure of parts that might result in a MECHANICAL HAZARD	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.12	see cl.9 & 15.3	2023-02-14
		243	ME EQUIPMENT with heating elements	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.13.2		2023-02-14
		244	ME EQUIPMENT with motors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.13.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		245	ME EQUIPMENT RATED for non-CONTINUOUS OPERATION	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 13.2.13.4		2023-02-14
		246	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 14		2023-02-14
		247	Arrangements of controls and indicators of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.1		2023-02-14
		248	Serviceability	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.2		2023-02-14
		249	Push test	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.3.2		2023-02-14
		250	Impact test	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.3.3		2023-02-14
		251	HAND-HELD ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.3.4.1		2023-02-14
		252	PORTABLE ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.3.4.2		2023-02-14
		253	Rough handling test	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.3.5		2023-02-14
		254	Mould stress relief test	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.3.6		2023-02-14
		255	Environmental influences	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.3.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		256	Construction of connectors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.1		2023-02-14
		257	Temperature and overload control devices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.2		2023-02-14
		258	Housing	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.3.1		2023-02-14
		259	Connection	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.3.2		2023-02-14
		260	Protection against overcharging	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.3.3		2023-02-14
		261	Lithium batteries	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.3.4		2023-02-14
		262	Excessive current and voltage protection	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.3.5		2023-02-14
		263	Indicators	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.4		2023-02-14
		264	Pre-set controls	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.5		2023-02-14
		265	Fixing, prevention of maladjustment	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.6.1		2023-02-14
		266	Limitation of movement	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.6.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		267	Mechanical strength	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.7.1		2023-02-14
		268	Accidental operation of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.7.2		2023-02-14
		269	Entry of liquids	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.7.3		2023-02-14
		270	Internal wiring of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.8		2023-02-14
		271	Oil containers	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.4.9		2023-02-14
		272	Short-circuit test	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.5.1.2		2023-02-14
		273	Overload test	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.5.1.3		2023-02-14
		274	Dielectric strength	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.5.2		2023-02-14
		275	Construction of transformers used to provide separation as required by 8.5	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 15.5.3		2023-02-14
		276	General requirements for the ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 16.1		2023-02-14
		277	ACCOMPANYING DOCUMENTS of	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 16.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			an ME SYSTEM			
		278	Power supply	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 16.3		2023-02-14
		279	ENCLOSURES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 16.4		2023-02-14
		280	SEPARATION DEVICES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 16.5		2023-02-14
		281	TOUCH CURRENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 16.6.1		2023-02-14
		282	EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 16.6.2		2023-02-14
		283	PATIENT LEAKAGE CURRENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 16.6.3		2023-02-14
		284	Protection against MECHANICAL HAZARDS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 16.7		2023-02-14
		285	Interruption of the power supply to parts of an ME SYSTEM	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 16.8		2023-02-14
		286	Connection terminals and connectors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 16.9.1		2023-02-14
		287	MAINS PARTS, components and layout	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 16.9.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		288	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 17		2023-02-14
138	portable mode steam sterilizers	1	All Parameters	portable mode steam sterilizers YY0504-2016		2023-02-14
		2	Appearance and Structure	portable mode steam sterilizers YY0504-2016 5.2		2023-02-14
		3	Pressurised parts of sterilizers	portable mode steam sterilizers YY0504-2016 5.3		2023-02-14
		4	material	portable mode steam sterilizers YY0504-2016 5.4		2023-02-14
		5	Pressure thermometer	portable mode steam sterilizers YY0504-2016 5.5		2023-02-14
		6	Safety valve	portable mode steam sterilizers YY0504-2016 5.6		2023-02-14
		7	Exhaust valve	portable mode steam sterilizers YY0504-2016 5.7		2023-02-14
		8	Sealed gaskets	portable mode steam sterilizers YY0504-2016 5.8		2023-02-14
		9	timer	portable mode steam sterilizers YY0504-2016 5.9		2023-02-14
		10	Load Attachments	portable mode steam sterilizers YY0504-2016 5.10		2023-02-14
		11	Heating time	portable mode steam sterilizers YY0504-2016 5.11		2023-02-14
		12	Sterilizing temperature range	portable mode steam sterilizers YY0504-2016 5.12		2023-02-14
		13	Sealing performance	portable mode steam sterilizers YY0504-2016 5.13		2023-02-14
		14	Warning	portable mode steam sterilizers YY0504-2016 5.14		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			instructions			
		15	Dry burning function	portable mode steam sterilizers YY0504-2016 5.15		2023-02-14
		16	Sterilizing effect	portable mode steam sterilizers YY0504-2016 5.16		2023-02-14
		17	Hydraulic test of sterilizer	portable mode steam sterilizers YY0504-2016 5.17		2023-02-14
		18	Safety performance	portable mode steam sterilizers YY0504-2016 5.18		2023-02-14
		19	Environmental testing	portable mode steam sterilizers YY0504-2016 5.19		2023-02-14
139	intensity-modulated radiation treatment planning system-functional performance characteristics and test methods	1	All Parameters	intensity-modulated radiation treatment planning system-functional performance characteristics and test methods YY/T0889-2013		2023-02-14
		2	Accuracy of point dose calculations	intensity-modulated radiation treatment planning system-functional performance characteristics and test methods YY/T0889-2013 4.1		2023-02-14
		3	Accuracy of dose distribution calculations	intensity-modulated radiation treatment planning system-functional performance characteristics and test methods YY/T0889-2013 4.2		2023-02-14
		4	Treatment plan dose target	intensity-modulated radiation treatment planning system-functional performance characteristics and test methods YY/T0889-2013 4.3		2023-02-14
140	teleradiotherapy treatment planning system accurcay of dosimetric	1	All Parameters	teleradiotherapy treatment planning system accurcay of dosimetric calculation and test methods foe high energy X(γ) beam YY 0775-2010		2023-02-14
		2	Simple geometric conditions	teleradiotherapy treatment planning system accurcay of dosimetric calculation and test methods foe high energy X(γ) beam YY 0775-2010 4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	calculation and test methods foe high energy X(γ) beam	3	Complex geometric conditions	teleradiotherapy treatment planning system accurcay of dosimetric calculation and test methods foe high energy X(γ) beam YY 0775-2010 4.2		2023-02-14
		4	Composite complex geometric conditions	teleradiotherapy treatment planning system accurcay of dosimetric calculation and test methods foe high energy X(γ) beam YY 0775-2010 4.3		2023-02-14
		5	Outside the field edge	teleradiotherapy treatment planning system accurcay of dosimetric calculation and test methods foe high energy X(γ) beam YY 0775-2010 4.4		2023-02-14
		6	Extracorporeal, complex geometric conditions and occluded central axis	teleradiotherapy treatment planning system accurcay of dosimetric calculation and test methods foe high energy X(γ) beam YY 0775-2010 4.5		2023-02-14
141	functional performance characteristics and test methods for multi-element beam limiting device used in radiotherapy	1	All Parameters	functional performance characteristics and test methods for multi-element beam limiting device used in radiotherapy YY/T0971-2016		2023-02-14
		2	Random files	functional performance characteristics and test methods for multi-element beam limiting device used in radiotherapy YY/T0971-2016 4.1		2023-02-14
		3	Number indicator for radiation field	functional performance characteristics and test methods for multi-element beam limiting device used in radiotherapy YY/T0971-2016 4.2		2023-02-14
		4	Radiant field light field indication	functional performance characteristics and test methods for multi-element beam limiting device used in radiotherapy YY/T0971-2016 4.3		2023-02-14
		5	Repetition of radiation fields	functional performance characteristics and test methods for multi-element beam limiting device used in radiotherapy YY/T0971-2016 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	The shadow of the radiation field	functional performance characteristics and test methods for multi-element beam limiting device used in radiotherapy YY/T0971-2016 4.5		2023-02-14
		7	Consistency between radiation field center and radiation beam axis of treatment machine in beam limiting device	functional performance characteristics and test methods for multi-element beam limiting device used in radiotherapy YY/T0971-2016 4.6		2023-02-14
		8	Motion performance of the restraint device	functional performance characteristics and test methods for multi-element beam limiting device used in radiotherapy YY/T0971-2016 4.7		2023-02-14
		9	The deviation of the radiation field	functional performance characteristics and test methods for multi-element beam limiting device used in radiotherapy YY/T0971-2016 4.8		2023-02-14
		10	Leakage radiation	functional performance characteristics and test methods for multi-element beam limiting device used in radiotherapy YY/T0971-2016 4.9		2023-02-14
		11	Control Software Function of Blocking Device	functional performance characteristics and test methods for multi-element beam limiting device used in radiotherapy YY/T0971-2016 4.10		2023-02-14
142	electronic portal imaging device using in radiotherapy - functional performance characteristics and test	1	All Parameters	electronic portal imaging device using in radiotherapy -functional performance characteristics and test methods YY/T 0890-2013		2023-02-14
		2	Generic requirements	electronic portal imaging device using in radiotherapy -functional performance characteristics and test methods YY/T 0890-2013 4.1		2023-02-14
		3	Mechanical support structure	electronic portal imaging device using in radiotherapy -functional performance characteristics and test methods YY/T 0890-2013 4.2		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	methods	4	Imaging performance requirements	electronic portal imaging device using in radiotherapy -functional performance characteristics and test methods YY/T 0890-2013 4.3		2023-02-14
143	Fumigationtherapeutic equipment	1	All Parameters	Fumigationtherapeutic equipment YY/T1306-2016		2023-02-14
		2	working conditions	Fumigationtherapeutic equipment YY/T1306-2016 5.1		2023-02-14
		3	requirement of therapeutic equipment ofopen type	Fumigationtherapeutic equipment YY/T1306-2016 5.2.1		2023-02-14
		4	requirement of therapeutic equipment ofclosed type	Fumigationtherapeutic equipment YY/T1306-2016 5.2.2		2023-02-14
		5	Fumigation time	Fumigationtherapeutic equipment YY/T1306-2016 5.3		2023-02-14
		6	Anti dry burning function	Fumigationtherapeutic equipment YY/T1306-2016 5.4		2023-02-14
		7	Safety protection function	Fumigationtherapeutic equipment YY/T1306-2016 5.5		2023-02-14
		8	Biocompatibility	Fumigationtherapeutic equipment YY/T1306-2016 5.6		2023-02-14
		9	Appearance	Fumigationtherapeutic equipment YY/T1306-2016 5.7		2023-02-14
		10	operating manual	Fumigationtherapeutic equipment YY/T1306-2016 5.8		2023-02-14
		11	security	Fumigationtherapeutic equipment YY/T1306-2016 5.9		2023-02-14
		12	electromagnetic compatibility	Fumigationtherapeutic equipment YY/T1306-2016 5.10		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Environmental test requirements	Fumigationtherapeutic equipment YY/T1306-2016 5.11		2023-02-14
144	Clinicalinfrared thermometers ear	1	part Parameters	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008	no do maximum allowable clinical reproducibility	2023-02-14
		2	General	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.2		2023-02-14
		3	Temperature display range	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.3		2023-02-14
		4	Maximum allowable error within the specified temperature display range	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.4.1		2023-02-14
		5	Maximum allowable error outside the specified temperature display range	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.4.2		2023-02-14
		6	Maximum permissible error under changing environmental conditions	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.4.3		2023-02-14
		7	Drop resistance	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Resolution	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.6.1		2023-02-14
		9	display	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.6.2		2023-02-14
		10	Prompt / alarm function	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.6.3		2023-02-14
		11	Low voltage prompt function	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.6.4		2023-02-14
		12	pattern	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.6.5		2023-02-14
		13	safety requirements	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.8		2023-02-14
		14	The thermometer	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.9.1		2023-02-14
		15	Multi purpose detector protective cover	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.9.2		2023-02-14
		16	Health protection function of protective cover	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.10.1		2023-02-14
		17	Prompt function of protective cover	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.10.2		2023-02-14
		18	Self check function	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.11		2023-02-14
		19	Auto Power Off	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.12		2023-02-14
		20	Appearance and mechanism	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.13		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		21	Technical / operation instruction	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.14		2023-02-14
		22	Environmental test requirements	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.15		2023-02-14
		23	Biocompatibility	Clinicalinfrared thermometers-Part 1：Ear GB/T 21417.1-2008 4.7		2023-02-14
145	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer	1	All Parameters	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T 1155- 2019		2023-02-14
		2	Accuracy and repeatability of sampling	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T 1155- 2019 4.1		2023-02-14
		3	Accuracy and fluctuation of temperature control in reaction zone	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T1155-2019 4.2		2023-02-14
		4	Instrument noise	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T 1155- 2019 4.3.1		2023-02-14
		5	Linearity of luminous value	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T 1155- 2019 4.3.2		2023-02-14
		6	Repeatability of luminous value	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T 1155- 2019 4.3.3		2023-02-14
		7	Carrying pollution	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T1155-2019 4.4		2023-02-14
		8	In-lot precision of clinical items	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T1155-2019 4.5		2023-02-14
		9	Main function of analyzer	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T1155-2019 4.6		2023-02-14
		10	Appearance	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T1155-2019 4.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Environmental test requirements	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T 1155- 2019 4.8		2023-02-14
		12	Safety requirements	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T 1155- 2019 4.9		2023-02-14
		13	Electromagnetic compatibility	FULL-AUTOMATIC IMMUNOFLUORESCENCE immunoassay analyzer YY/T 1155- 2019 4.10		2023-02-14
146	Functional and compatibility test methods for remote medical imaging equipment	1	All Parameters	Functional and compatibility test methods for remote medical imaging equipment YY/T1643-2018		2023-02-14
		2	Test Condition	Functional and compatibility test methods for remote medical imaging equipment YY/T1643-2018 4		2023-02-14
		3	Patient Management	Functional and compatibility test methods for remote medical imaging equipment YY/T1643-2018 5.1		2023-02-14
		4	2D Viewer	Functional and compatibility test methods for remote medical imaging equipment YY/T1643-2018 5.2		2023-02-14
		5	Print	Functional and compatibility test methods for remote medical imaging equipment YY/T1643-2018 5.3		2023-02-14
		6	Test Method of DICOM File Compatibility	Functional and compatibility test methods for remote medical imaging equipment YY/T1643-2018 6		2023-02-14
		7	Image Storage	Functional and compatibility test methods for remote medical imaging equipment YY/T1643-2018 7.1		2023-02-14
		8	Image Storage Commitment	Functional and compatibility test methods for remote medical imaging equipment YY/T1643-2018 7.2		2023-02-14
		9	Image Query/Retrieve	Functional and compatibility test methods for remote medical imaging equipment YY/T1643-2018 7.3		2023-02-14
147	Beds, chairs and accessories for electric traction of the	1	All Parameters	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016		2023-02-14
		2	Traction bed	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	cervical and lumbar spine	3	Dimensions	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.2.1		2023-02-14
		4	Angle of motion	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.2.2		2023-02-14
		5	Velocity of motion	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.2.3		2023-02-14
		6	Leg Board	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.2.4		2023-02-14
		7	Head plate	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.2.5		2023-02-14
		8	Stability	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.2.6		2023-02-14
		9	Load bearing	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.2.7		2023-02-14
		10	Degree of fastening	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.2.8		2023-02-14
		11	Traction Chair	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.3		2023-02-14
		12	Angle	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.3.1		2023-02-14
		13	Stability	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.3.2		2023-02-14
		14	Load bearing	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.3.3		2023-02-14
		15	Degree of fastening	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.3.4		2023-02-14
		16	Appendices	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.4		2023-02-14
		17	Fixed band	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	Load bearing	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.4.1.1		2023-02-14
		19	Durability	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.4.1.2		2023-02-14
		20	Reliability	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.4.1.3		2023-02-14
		21	Fastening degree of lock	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.4.1.4		2023-02-14
		22	Connecting piece	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.4.1.5		2023-02-14
		23	Fixing frame	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.4.2		2023-02-14
		24	Pulleys	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.4.3		2023-02-14
		25	Stability	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.4.3.1		2023-02-14
		26	Protective device	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.4.3.2		2023-02-14
		27	Inspection and maintenance	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.4.4		2023-02-14
		28	Appearance	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.5		2023-02-14
		29	Traction bed, chair	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.5.1		2023-02-14
		30	Fixed band	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.5.2		2023-02-14
		31	Soft Pack	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.5.3		2023-02-14
		32	Protrusions	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.5.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		33	Environmental Requirements	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.6		2023-02-14
		34	Safety requirements	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.7		2023-02-14
		35	Electromagnetic compatibility	Beds, chairs and accessories for electric traction of the cervical and lumbar spine YY/T1491-2016 4.8		2023-02-14
148	"the safety of radiotherapy treatment planning systems "	1	All Parameters	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009		2023-02-14
		2	outline	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 4		2023-02-14
		3	exploitation	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 4.1		2023-02-14
		4	Installation period test	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 4.2		2023-02-14
		5	Accompanying documents	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 5		2023-02-14
		6	General requirements for operation safety	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 6		2023-02-14
		7	Distance and linearity、Angular dimension	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 6.1		2023-02-14
		8	radiant quantity	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 6.2		2023-02-14
		9	Date and time format	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 6.3		2023-02-14
		10	Prevent unauthorized use	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 6.4		2023-02-14
		11	scope of data	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 6.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Protection of unauthorized modification	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 6.6		2023-02-14
		13	The correctness of data transmission	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 6.7		2023-02-14
		14	Coordinate system and scale	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 6.8		2023-02-14
		15	Preservation and archiving of data	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 6.9		2023-02-14
		16	Data configuration of radiotherapy equipment and data configuration of brachytherapy source	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 7		2023-02-14
		17	Equipment data	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 7.1		2023-02-14
		18	Source data of brachytherapy	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 7.2		2023-02-14
		19	Dosimetric parameters	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 7.3		2023-02-14
		20	Equipment data、Acceptance of brachytherapy source data	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 7.4		2023-02-14
		21	Equipment data、Delete of brachytherapy source data	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 7.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	Virtual patient building	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 8		2023-02-14
		23	data procurement	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 8.1		2023-02-14
		24	Coordinate system and scale	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 8.2		2023-02-14
		25	Outline of region of interest	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 8.3		2023-02-14
		26	Acceptance of patient anatomical data	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 8.4		2023-02-14
		27	Delete of patient anatomical data	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 8.5		2023-02-14
		28	Treatment plan design	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 9		2023-02-14
		29	General requirements	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 9.1		2023-02-14
		30	Preparation of treatment plan	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 9.2		2023-02-14
		31	Identification of treatment plan	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 9.3		2023-02-14
		32	Delete of treatment plan	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 9.4		2023-02-14
		33	Electronic signature	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 9.5		2023-02-14
		34	Calculation of absorbed dose distribution	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 10		2023-02-14
		35	The algorithm used	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 10.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		36	Accuracy of algorithm	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 10.2		2023-02-14
		37	Treatment plan report	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 11		2023-02-14
		38	Incomplete treatment plan report	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 11.1		2023-02-14
		39	Treatment plan report content	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 11.2		2023-02-14
		40	Transmission of treatment plan information	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 11.3		2023-02-14
		41	General hardware diagnostic requirements	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 12		2023-02-14
		42	Data and code	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 13		2023-02-14
		43	Human error in software design	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 14		2023-02-14
		44	Change of software version	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 15		2023-02-14
		45	Human error in use	Medical electrical equipment-Requirements for the safety of radiotherapy lEC62083:2009 16		2023-02-14
149	Radiotherapy simulator	1	All Parameters	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016		2023-02-14
		2	Performance of simulator image system using X-ray image intensifier	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Useful incident field size	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.1.1		2023-02-14
		4	Image distortion	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.1.2		2023-02-14
		5	Line pair resolution	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.1.3		2023-02-14
		6	Low contrast resolution	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.1.4		2023-02-14
		7	Image gray discrimination level	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.1.5		2023-02-14
		8	Image brightness stability	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.1.6		2023-02-14
		9	Image response time	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.1.7		2023-02-14
		10	Specific kinetic energy rate of perspective air on the incident surface of X ray image intensifier	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.1.8		2023-02-14
		11	Specific kinetic energy rate of perspective incident air of X-ray image intensifier	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.1.9		2023-02-14
		12	Performance of image system of simulator using digital flat panel detector	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Pixel matrix and pixel spacing	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.2.1		2023-02-14
		14	frame frequency	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.2.2		2023-02-14
		15	Line pair resolution	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.2.3		2023-02-14
		16	Low contrast resolution	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.2.4		2023-02-14
		17	Image gray discrimination level	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.2.5		2023-02-14
		18	Image brightness stability	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.2.6		2023-02-14
		19	Image uniformity	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.2.7		2023-02-14
		20	Effective imaging area	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.2.8		2023-02-14
		21	image geometric distortion	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.2.9		2023-02-14
		22	Image format	performance characteristics and test methods of image system for radiotherapy simulator YY/T1407-2016 5.3		2023-02-14
150	Optical positioning device for radiation	1	All Parameters	Optical positioning device for radiation therapy—Performance and test methods YY/T1694-2020		2023-02-14
		2	Accompanying documents	Optical positioning device for radiation therapy—Performance and test methods YY/T1694-2020 4.1		2023-02-14
		3	Field of view	Optical positioning device for radiation therapy—Performance and test methods YY/T1694-2020 4.2		2023-02-14
		4	Positioning accuracy	Optical positioning device for radiation therapy—Performance and test methods YY/T1694-2020 4.3		2023-02-14
		5	Positioning repeatability	Optical positioning device for radiation therapy—Performance and test methods YY/T1694-2020 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Refresh frequency of system data	Optical positioning device for radiation therapy—Performance and test methods YY/T1694-2020 4.5		2023-02-14
		7	drift	Optical positioning device for radiation therapy—Performance and test methods YY/T1694-2020 4.6		2023-02-14
		8	Device functions	Optical positioning device for radiation therapy—Performance and test methods YY/T1694-2020 4.7		2023-02-14
151	ECG cables and leadwires	1	All Parameters	ECG cables and leadwires YY0828-2011		2023-02-14
		2	General test conditions	ECG cables and leadwires YY0828-2011 4.1		2023-02-14
		3	Label requirements	ECG cables and leadwires YY0828-2011 4.2		2023-02-14
		4	Packaging label (applicable to two types of lead wires)	ECG cables and leadwires YY0828-2011 4.2.1		2023-02-14
		5	Label of junction box of main cable (applicable to two types of lead wires)	ECG cables and leadwires YY0828-2011 4.2.2		2023-02-14
		6	Label of patient lead wire terminal (applicable to two types of lead wires)	ECG cables and leadwires YY0828-2011 4.2.3		2023-02-14
		7	Requirements for cleaning, disinfection and chemical resistance	ECG cables and leadwires YY0828-2011 4.3		2023-02-14
		8	Cleaning and disinfection (for reusable lead wires)	ECG cables and leadwires YY0828-2011 4.3.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Exposure sterilization requirements	ECG cables and leadwires YY0828-2011 4.4		2023-02-14
		10	Ethylene oxide (EO) exposure sterilization (for reusable lead wires)	ECG cables and leadwires YY0828-2011 4.4.1		2023-02-14
		11	Performance requirements-main cable and patient lead	ECG cables and leadwires YY0828-2011 4.5		2023-02-14
		12	Dielectric strength (applicable to two types of lead wires)	ECG cables and leadwires YY0828-2011 4.5.1		2023-02-14
		13	Sink current (applicable to two types of lead wires)	ECG cables and leadwires YY0828-2011 4.5.2		2023-02-14
		14	Defibrillation protection (for two types of leads)	ECG cables and leadwires YY0828-2011 4.5.3		2023-02-14
		15	Cable and lead line noise (applicable to two types of lead lines)	ECG cables and leadwires YY0828-2011 4.5.4		2023-02-14
		16	Equipment connector、cable head、Bending life of patient lead wire connector and patient terminal	ECG cables and leadwires YY0828-2011 4.5.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			bending net tail (applicable to reusable lead wires)			
		17	Tensile strength of cable connection (applicable to two types of lead wires)	ECG cables and leadwires YY0828-2011 4.5.6		2023-02-14
		18	Plugging and unplugging times of connectors (applicable to two types of lead wires)	ECG cables and leadwires YY0828-2011 4.5.7		2023-02-14
		19	contact resistance	ECG cables and leadwires YY0828-2011 4.5.8		2023-02-14
		20	Retaining force of connector (applicable to two types of lead wires)	ECG cables and leadwires YY0828-2011 4.5.9		2023-02-14
152	Measuring methods for optical radiation safety classification of medical LED equipment	1	All Parameters	Measuring methods for optical radiation safety classification of medical LED equipment YY/T1534-2017		2023-02-14
		2	Measuring condition	Measuring methods for optical radiation safety classification of medical LED equipment YY/T1534-2017 5		2023-02-14
		3	Preheat	Measuring methods for optical radiation safety classification of medical LED equipment YY/T1534-2017 5.1		2023-02-14
		4	Environmental conditions	Measuring methods for optical radiation safety classification of medical LED equipment YY/T1534-2017 5.2		2023-02-14
		5	Power supply	Measuring methods for optical radiation safety classification of medical LED equipment YY/T1534-2017 5.3		2023-02-14
		6	Safety Protection	Measuring methods for optical radiation safety classification of medical LED equipment YY/T1534-2017 5.4		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Requirements for testing equipment	Measuring methods for optical radiation safety classification of medical LED equipment YY/T1534-2017 5.5		2023-02-14
		8	Measuring position	Measuring methods for optical radiation safety classification of medical LED equipment YY/T1534-2017 5.6		2023-02-14
		9	measuring procedure	Measuring methods for optical radiation safety classification of medical LED equipment YY/T1534-2017 6.1		2023-02-14
		10	irradiance measurements	Measuring methods for optical radiation safety classification of medical LED equipment YY/T1534-2017 6.2		2023-02-14
		11	radiance measurements	Measuring methods for optical radiation safety classification of medical LED equipment YY/T1534-2017 6.3		2023-02-14
		12	multiple source	Measuring methods for optical radiation safety classification of medical LED equipment YY/T1534-2017 6.4		2023-02-14
153	Rehabilitation training instrument--General safety requirements	1	All Parameters	Rehabilitation training instrument--General safety requirements GB24436-2009		2023-02-14
		2	Overall structural design requirements	Rehabilitation training instrument--General safety requirements GB24436-2009 5.1		2023-02-14
		3	Training position	Rehabilitation training instrument--General safety requirements GB24436-2009 5.1.1		2023-02-14
		4	Shearing, squeezing and rotating moving parts	Rehabilitation training instrument--General safety requirements GB24436-2009 5.1.2		2023-02-14
		5	Rigid collision sites and moving heavy blocks	Rehabilitation training instrument--General safety requirements GB24436-2009 5.1.3		2023-02-14
		6	Safety protection device	Rehabilitation training instrument--General safety requirements GB24436-2009 5.2		2023-02-14
		7	Structural design requirements for components	Rehabilitation training instrument--General safety requirements GB24436-2009 5.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Machine stability requirement	Rehabilitation training instrument--General safety requirements GB24436-2009 5.4		2023-02-14
		9	Mechanical strength requirement	Rehabilitation training instrument--General safety requirements GB24436-2009 5.5		2023-02-14
		10	Static load strength requirements	Rehabilitation training instrument--General safety requirements GB24436-2009 5.5.1		2023-02-14
		11	Fatigue strength requirement	Rehabilitation training instrument--General safety requirements GB24436-2009 5.5.2		2023-02-14
		12	Cosmetic requirements	Rehabilitation training instrument--General safety requirements GB24436-2009 5.6		2023-02-14
		13	Soft package requirements	Rehabilitation training instrument--General safety requirements GB24436-2009 5.7		2023-02-14
		14	The surface coating	Rehabilitation training instrument--General safety requirements GB24436-2009 5.8		2023-02-14
		15	Environmental requirements	Rehabilitation training instrument--General safety requirements GB24436-2009 5.9		2023-02-14
		16	The service life of the safe	Rehabilitation training instrument--General safety requirements GB24436-2009 5.11		2023-02-14
		17	Installation requirements for fixed installations on walls, floors, or tops	Rehabilitation training instrument--General safety requirements GB24436-2009 5.12		2023-02-14
154	General specification for motion rehabilitation training robot	1	All Parameters	General specification for motion rehabilitation training robot GB/T 37704-2019		2023-02-14
		2	Basic structure	General specification for motion rehabilitation training robot GB/T 37704-2019 6.1		2023-02-14
		3	General requirements	General specification for motion rehabilitation training robot GB/T 37704-2019 6.1.1		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Ontology	General specification for motion rehabilitation training robot GB/T 37704-2019 6.1.2		2023-02-14
		5	Sensor	General specification for motion rehabilitation training robot GB/T 37704-2019 6.1.3		2023-02-14
		6	Control system	General specification for motion rehabilitation training robot GB/T 37704-2019 6.1.4		2023-02-14
		7	Physiological parameter monitoring device	General specification for motion rehabilitation training robot GB/T 37704-2019 6.1.5		2023-02-14
		8	Application software	General specification for motion rehabilitation training robot GB/T 37704-2019 6.1.6		2023-02-14
		9	Function	General specification for motion rehabilitation training robot GB/T 37704-2019 6.2		2023-02-14
		10	Rehabilitation training function	General specification for motion rehabilitation training robot GB/T 37704-2019 6.2.1		2023-02-14
		11	Information detection function	General specification for motion rehabilitation training robot GB/T 37704-2019 6.2.2		2023-02-14
		12	Data analysis function	General specification for motion rehabilitation training robot GB/T 37704-2019 6.2.3		2023-02-14
		13	Safety protection function	General specification for motion rehabilitation training robot GB/T 37704-2019 6.2.4		2023-02-14
		14	Operation parameters	General specification for motion rehabilitation training robot GB/T 37704-2019 6.3		2023-02-14
		15	Motion resistance	General specification for motion rehabilitation training robot GB/T 37704-2019 6.3.1		2023-02-14
		16	Movement speed	General specification for motion rehabilitation training robot GB/T 37704-2019 6.3.2		2023-02-14
		17	Driving moment	General specification for motion rehabilitation training robot GB/T 37704-2019 6.3.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	Angle of joint motion	General specification for motion rehabilitation training robot GB/T 37704-2019 6.3.4		2023-02-14
		19	Training time	General specification for motion rehabilitation training robot GB/T 37704-2019 6.3.5		2023-02-14
		20	Static load strength	General specification for motion rehabilitation training robot GB/T 37704-2019 6.5		2023-02-14
		21	Static load strength of main supporting parts	General specification for motion rehabilitation training robot GB/T 37704-2019 6.5.1		2023-02-14
		22	Static load strength of handle and grip	General specification for motion rehabilitation training robot GB/T 37704-2019 6.5.2		2023-02-14
		23	Static load strength of protective belt	General specification for motion rehabilitation training robot GB/T 37704-2019 6.5.3		2023-02-14
		24	Fatigue strength	General specification for motion rehabilitation training robot GB/T 37704-2019 6.6		2023-02-14
		25	Working noise	General specification for motion rehabilitation training robot GB/T 37704-2019 6.7		2023-02-14
155	Testing method for SPECT imaging based on CT-attenuation correction	1	All Parameters	Testing method for SPECT imaging based on CT-attenuation correction YY/T1546-2017		2023-02-14
		2	Overviews	Testing method for SPECT imaging based on CT-attenuation correction YY/T1546-2017 4.3.1		2023-02-14
		3	radionuclide	Testing method for SPECT imaging based on CT-attenuation correction YY/T1546-2017 4.3.2		2023-02-14
		4	Data Acquisition	Testing method for SPECT imaging based on CT-attenuation correction YY/T1546-2017 4.3.3		2023-02-14
		5	Data processing	Testing method for SPECT imaging based on CT-attenuation correction YY/T1546-2017 4.3.4		2023-02-14
		6	Analysis	Testing method for SPECT imaging based on CT-attenuation correction YY/T1546-2017 4.3.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Report	Testing method for SPECT imaging based on CT-attenuation correction YY/T1546-2017 4.3.6		2023-02-14
156	Electric upper/lower limbs round exercise theray equipmen	1	All Parameters	Electric upper/lower limbs round exercise theray equipmen YY/T1626-2019		2023-02-14
		2	Passive mode	Electric upper/lower limbs round exercise theray equipmen YY/T1626-2019 5.2		2023-02-14
		3	Active mode	Electric upper/lower limbs round exercise theray equipmen YY/T1626-2019 5.3		2023-02-14
		4	Operational control	Electric upper/lower limbs round exercise theray equipmen YY/T1626-2019 5.4		2023-02-14
		5	Symmetry detection	Electric upper/lower limbs round exercise theray equipmen YY/T1626-2019 5.5		2023-02-14
		6	Spasm protection	Electric upper/lower limbs round exercise theray equipmen YY/T1626-2019 5.6		2023-02-14
		7	Structure and safety measures	Electric upper/lower limbs round exercise theray equipmen YY/T1626-2019 5.7		2023-02-14
		8	Stability	Electric upper/lower limbs round exercise theray equipmen YY/T1626-2019 5.8		2023-02-14
		9	Additional function	Electric upper/lower limbs round exercise theray equipmen YY/T1626-2019 5.9		2023-02-14
		10	Safety requirements	Electric upper/lower limbs round exercise theray equipmen YY/T1626-2019 5.10		2023-02-14
		11	Electromagnetic compatibility	Electric upper/lower limbs round exercise theray equipmen YY/T1626-2019 5.11		2023-02-14
		12	Environmental testing	Electric upper/lower limbs round exercise theray equipmen YY/T1626-2019 5.12		2023-02-14
157	Rigid rehabilitation training bed	1	Appearance	Rigid rehabilitation training bed GB/T 20403-2006 5.1		2023-02-14
		2	The performance requirements	Rigid rehabilitation training bed GB/T 20403-2006 5.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
158	Adjustable rehabilitation training bed	1	All Parameters	Adjustable rehabilitation training bed GB/T 26340-2010		2023-02-14
		2	General safety requirements for training beds	Adjustable rehabilitation training bed GB/T 26340-2010		2023-02-14
		3	Moving parts	Adjustable rehabilitation training bed GB/T 26340-2010 5.1		2023-02-14
		4	Surface、edges and pipe end	Adjustable rehabilitation training bed GB/T 26340-2010 5.2		2023-02-14
		5	Structure design	Adjustable rehabilitation training bed GB/T 26340-2010 5.3		2023-02-14
		6	Stability	Adjustable rehabilitation training bed GB/T 26340-2010 5.4		2023-02-14
		7	Mechanical strength	Adjustable rehabilitation training bed GB/T 26340-2010 5.5		2023-02-14
		8	Safe working load	Adjustable rehabilitation training bed GB/T 26340-2010 5.5.1		2023-02-14
		9	Static load test strength	Adjustable rehabilitation training bed GB/T 26340-2010 5.5.2		2023-02-14
		10	Durability test strength	Adjustable rehabilitation training bed GB/T 26340-2010 5.5.3		2023-02-14
		11	Impact test strength	Adjustable rehabilitation training bed GB/T 26340-2010 5.5.4		2023-02-14
		12	Bedside deviation requirement	Adjustable rehabilitation training bed GB/T 26340-2010 5.5.5		2023-02-14
		13	Height adjustment device requirements	Adjustable rehabilitation training bed GB/T 26340-2010 5.5.6		2023-02-14
		14	Linear dimension and Angle requirements	Adjustable rehabilitation training bed GB/T 26340-2010 5.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Height of bed	Adjustable rehabilitation training bed GB/T 26340-2010 5.6.1		2023-02-14
		16	Under the bed clearance	Adjustable rehabilitation training bed GB/T 26340-2010 5.6.2		2023-02-14
		17	Multiple position bed requirements	Adjustable rehabilitation training bed GB/T 26340-2010 5.6.3		2023-02-14
		18	Controller	Adjustable rehabilitation training bed GB/T 26340-2010 5.6.4		2023-02-14
		19	Operate handle and pedal	Adjustable rehabilitation training bed GB/T 26340-2010 5.6.5		2023-02-14
		20	Operating force	Adjustable rehabilitation training bed GB/T 26340-2010 5.7		2023-02-14
		21	Operation speed and time	Adjustable rehabilitation training bed GB/T 26340-2010 5.8		2023-02-14
		22	Castor localization	Adjustable rehabilitation training bed GB/T 26340-2010 5.9		2023-02-14
		23	Noise	Adjustable rehabilitation training bed GB/T 26340-2010 5.10		2023-02-14
		24	Specific safety requirements for upright beds	Adjustable rehabilitation training bed GB/T 26340-2010 6		2023-02-14
		25	Dimension and Angle requirements	Adjustable rehabilitation training bed GB/T 26340-2010 6.1		2023-02-14
		26	Accessories and strength requirements	Adjustable rehabilitation training bed GB/T 26340-2010 6.2		2023-02-14
		27	Accessory stability requirements	Adjustable rehabilitation training bed GB/T 26340-2010 6.3		2023-02-14
		28	Electrical technical requirements	Adjustable rehabilitation training bed GB/T 26340-2010 7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		29	Hand - held and pedal - operated controllers with wire connections	Adjustable rehabilitation training bed GB/T 26340-2010 7.1		2023-02-14
		30	Power cord	Adjustable rehabilitation training bed GB/T 26340-2010 7.2		2023-02-14
		31	Click on Hazard Protection	Adjustable rehabilitation training bed GB/T 26340-2010 7.3		2023-02-14
159	Elbow，knee joints passive motion equipment	1	All Parameters	Elbow，knee joints passive motion equipment YY/T0997-2015		2023-02-14
		2	Angle range and tolerance	Elbow，knee joints passive motion equipment YY/T0997-2015 4.2.1		2023-02-14
		3	The angular velocity	Elbow，knee joints passive motion equipment YY/T0997-2015 4.2.2		2023-02-14
		4	Treatment time	Elbow，knee joints passive motion equipment YY/T0997-2015 4.2.3		2023-02-14
		5	Handheld operator	Elbow，knee joints passive motion equipment YY/T0997-2015 4.3.1		2023-02-14
		6	A stent that holds a limb in place	Elbow，knee joints passive motion equipment YY/T0997-2015 4.3.2		2023-02-14
		7	Unexpected power outage	Elbow，knee joints passive motion equipment YY/T0997-2015 4.4		2023-02-14
		8	Bearing load	Elbow，knee joints passive motion equipment YY/T0997-2015 4.5		2023-02-14
		9	The warning information	Elbow，knee joints passive motion equipment YY/T0997-2015 4.6		2023-02-14
		10	Fatigue test	Elbow，knee joints passive motion equipment YY/T0997-2015 4.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Working noise	Elbow，knee joints passive motion equipment YY/T0997-2015 4.8		2023-02-14
		12	Appearance	Elbow，knee joints passive motion equipment YY/T0997-2015 4.9		2023-02-14
		13	Safety requirements	Elbow，knee joints passive motion equipment YY/T0997-2015 4.10		2023-02-14
		14	Environmental test requirements	Elbow，knee joints passive motion equipment YY/T0997-2015 4.11		2023-02-14
		15	Biocompatibility	Elbow，knee joints passive motion equipment YY/T0997-2015 4.12		2023-02-14
160	Hoists for the transfer of disabled persons-Requirements and test methods	1	All Parameters	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014		2023-02-14
		2	General requirements and test methods	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4		2023-02-14
		3	General requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.1		2023-02-14
		4	General test method	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.2		2023-02-14
		5	Safety requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.3		2023-02-14
		6	Safety and performance requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.3.1		2023-02-14
		7	General safety requirements test methods	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.3.2		2023-02-14
		8	Requirements for body support units	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Central suspension point	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.5		2023-02-14
		10	Upreader bar	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.6		2023-02-14
		11	Performance	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.7		2023-02-14
		12	Performance requirement	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.7.1		2023-02-14
		13	Performance test method	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.7.2		2023-02-14
		14	Rate of rise and fall	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.8		2023-02-14
		15	Operating force (torque)	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.9		2023-02-14
		16	Durability	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.10		2023-02-14
		17	Hydraulic components	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.11		2023-02-14
		18	Pneumatic components	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.12		2023-02-14
		19	Information provided by the manufacturer	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 4.13		2023-02-14
		20	Specific requirements and test methods for mobile hoist	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 5		2023-02-14
		21	General requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	Static strength	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 5.2		2023-02-14
		23	Static stability	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 5.3		2023-02-14
		24	Fixing device (brake device)	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 5.4		2023-02-14
		25	Power	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 5.5		2023-02-14
		26	Operating instruction	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 5.6		2023-02-14
		27	Specific requirements and test methods for standing and/or raising hoist	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 6		2023-02-14
		28	General requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 6.1		2023-02-14
		29	Static strength	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 6.2		2023-02-14
		30	Static stability	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 6.3		2023-02-14
		31	Fixing device (brake device)	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 6.4		2023-02-14
		32	Power	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 6.5		2023-02-14
		33	Durability	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 6.6		2023-02-14
		34	Operating instruction	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 6.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		35	Specific requirements and test methods for stationary hoist	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 7		2023-02-14
		36	General requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 7.1		2023-02-14
		37	Specific safety requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 7.2		2023-02-14
		38	Static strength	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 7.3		2023-02-14
		39	Static stability (only applicable to free-standing stationary hoist)	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 7.4		2023-02-14
		40	Static strength of other stationary hoist	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 7.5		2023-02-14
		41	Operating instruction	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 7.6		2023-02-14
		42	Specific requirements and test methods for non-rigid body support hoist	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 8		2023-02-14
		43	The general	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 8.1		2023-02-14
		44	Requirements for materials and sutures for non-rigid body support unit	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 8.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		45	Test Method for non-rigid body support unit	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 8.3		2023-02-14
		46	Information provided by the manufacturer	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 8.4		2023-02-14
		47	Specific requirements and test methods for rigid body support unit	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 9		2023-02-14
		48	General requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 9.1		2023-02-14
		49	Backrest requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 9.2		2023-02-14
		50	Durability requirements and test methods	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 9.3		2023-02-14
		51	Information provided by the manufacturer	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 9.4		2023-02-14
		52	Specific requirements and test methods for bathtub hoist	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10		2023-02-14
		53	General requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.1		2023-02-14
		54	General test method	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		55	Safety requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.3		2023-02-14
		56	Body support unit	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.4		2023-02-14
		57	Spreader part	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.5		2023-02-14
		58	Performance	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.6		2023-02-14
		59	Rate of rise and fall	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.7		2023-02-14
		60	Manipulation of the force	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.8		2023-02-14
		61	Durability	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.9		2023-02-14
		62	Static strength and stability	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.10		2023-02-14
		63	Hydraulic components	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.11		2023-02-14
		64	Pneumatic components	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.12		2023-02-14
		65	Specific safety requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.13 10.13		2023-02-14
		66	non-rigid body support unit	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.14		2023-02-14
		67	rigid body support unit requirements	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.15		2023-02-14
		68	Information provided by the manufacturer	Hoists for the transfer of disabled persons-Requirements and test methods GB/T 20404-2014 10.16		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
161	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators	1	All Parameters	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators GB/T 14728.2-2008		2023-02-14
		2	Wheel	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators GB/T 14728.2-2008 4.1		2023-02-14
		3	Stability	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators GB/T 14728.2-2008 4.2		2023-02-14
		4	Brake	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators GB/T 14728.2-2008 4.3		2023-02-14
		5	Handgrip	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators GB/T 14728.2-2008 4.4		2023-02-14
		6	Leg and foot pad	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators GB/T 14728.2-2008 4.5		2023-02-14
		7	Seat	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators GB/T 14728.2-2008 4.6		2023-02-14
		8	Mechanical durability	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators GB/T 14728.2-2008 4.7		2023-02-14
		9	Adjusting device	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators GB/T 14728.2-2008 4.8		2023-02-14
		10	Folding device	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators GB/T 14728.2-2008 4.9		2023-02-14
		11	Handle adjust	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators GB/T 14728.2-2008 4.10		2023-02-14
		12	Materials and finish	Walking aids manipulated by both arms-Requirements and test methods-Part 2：Rollators GB/T 14728.2-2008 4.11		2023-02-14
162	Walking aids manipulated by both arms-Requirements	1	All Parameters	Walking aids manipulated by both arms-Requirements and test methods-Part 1：Wanling frames GB/T 14728.1-2006		2023-02-14
		2	Mechanical strength	Walking aids manipulated by both arms-Requirements and test methods-Part 1：Wanling frames GB/T 14728.1-2006 4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	and test methods-Part 1：Wanling frames	3	Stability	Walking aids manipulated by both arms-Requirements and test methods-Part 1：Wanling frames GB/T 14728.1-2006 4.2		2023-02-14
		4	Parameters	Walking aids manipulated by both arms-Requirements and test methods-Part 1：Wanling frames GB/T 14728.1-2006 4.3		2023-02-14
		5	The handle set	Walking aids manipulated by both arms-Requirements and test methods-Part 1：Wanling frames GB/T 14728.1-2006 4.4		2023-02-14
		6	Leg pieces and footpads	Walking aids manipulated by both arms-Requirements and test methods-Part 1：Wanling frames GB/T 14728.1-2006 4.5		2023-02-14
		7	Adjusting device	Walking aids manipulated by both arms-Requirements and test methods-Part 1：Wanling frames GB/T 14728.1-2006 4.6		2023-02-14
		8	Materials and Finished Products	Walking aids manipulated by both arms-Requirements and test methods-Part 1：Wanling frames GB/T 14728.1-2006 4.7		2023-02-14
163	Walking aids manipulated by both arms-Requirements and test methods-Part 3：Wanling tables	1	All Parameters	Walking aids manipulated by both arms-Requirements and test methods-Part 3：Wanling tables GB/T 14728.3-2008		2023-02-14
		2	Stability	Walking aids manipulated by both arms-Requirements and test methods-Part 3：Wanling tables GB/T 14728.3-2008 4.1		2023-02-14
		3	Brake devices	Walking aids manipulated by both arms-Requirements and test methods-Part 3：Wanling tables GB/T 14728.3-2008 4.2		2023-02-14
		4	Mechanical durability	Walking aids manipulated by both arms-Requirements and test methods-Part 3：Wanling tables GB/T 14728.3-2008 4.3		2023-02-14
		5	The wheel	Walking aids manipulated by both arms-Requirements and test methods-Part 3：Wanling tables GB/T 14728.3-2008 4.4		2023-02-14
		6	The handle	Walking aids manipulated by both arms-Requirements and test methods-Part 3：Wanling tables GB/T 14728.3-2008 4.5		2023-02-14
		7	Legs and stabilizer blade	Walking aids manipulated by both arms-Requirements and test methods-Part 3：Wanling tables GB/T 14728.3-2008 4.6		2023-02-14
		8	Adjusting device	Walking aids manipulated by both arms-Requirements and test methods-Part 3：Wanling tables GB/T 14728.3-2008 4.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Seat	Walking aids manipulated by both arms-Requirements and test methods-Part 3：Wanling tables GB/T 14728.3-2008 4.8		2023-02-14
		10	Materials and degree of finish	Walking aids manipulated by both arms-Requirements and test methods-Part 3：Wanling tables GB/T 14728.3-2008 4.9		2023-02-14
		11	Signs and Labels	Walking aids manipulated by both arms-Requirements and test methods-Part 3：Wanling tables GB/T 14728.3-2008 4.10		2023-02-14
164	Rehabilitation trainingdevices -Standing frames	1	All Parameters	Rehabilitation trainingdevices-Standing frames GB/T 28919-2012		2023-02-14
		2	Basic parameters	Rehabilitation trainingdevices-Standing frames GB/T 28919-2012 5.1		2023-02-14
		3	Appearance quality	Rehabilitation trainingdevices-Standing frames GB/T 28919-2012 5.2		2023-02-14
		4	Adjusting and locking device	Rehabilitation trainingdevices-Standing frames GB/T 28919-2012 5.3		2023-02-14
		5	Stability	Rehabilitation trainingdevices-Standing frames GB/T 28919-2012 5.4		2023-02-14
		6	Intensity	Rehabilitation trainingdevices-Standing frames GB/T 28919-2012 5.5		2023-02-14
		7	Static load strength of the table	Rehabilitation trainingdevices-Standing frames GB/T 28919-2012 5.5.1		2023-02-14
		8	Handrail static load strength	Rehabilitation trainingdevices-Standing frames GB/T 28919-2012 5.5.2		2023-02-14
		9	Static strength of fixed belt	Rehabilitation trainingdevices-Standing frames GB/T 28919-2012 5.5.3		2023-02-14
		10	Pedal static load strength	Rehabilitation trainingdevices-Standing frames GB/T 28919-2012 5.5.4		2023-02-14
		11	Noise	Rehabilitation trainingdevices-Standing frames GB/T 28919-2012 5.6		2023-02-14
		12	Electrical safety	Rehabilitation trainingdevices-Standing frames GB/T 28919-2012 5.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
165	medical electricl equipement-part 2：particular requirments for the safety of electromyograohs and response equipment	1	All Parameters	medical electricl equipement-part 2：particular requirments for the safety of electromyograohs and response equipment YY 0896-2013		2023-02-14
		2	classification	medical electricl equipement-part 2：particular requirments for the safety of electromyograohs and response equipment YY 0896-2013 5		2023-02-14
		3	identification、marks and documents	medical electricl equipement-part 2：particular requirments for the safety of electromyograohs and response equipment YY 0896-2013 6		2023-02-14
		4	input power	medical electricl equipement-part 2：particular requirments for the safety of electromyograohs and response equipment YY 0896-2013 7		2023-02-14
		5	requirments of calssification	medical electricl equipement-part 2：particular requirments for the safety of electromyograohs and response equipment YY 0896-2013 14		2023-02-14
		6	dielectric strength	medical electricl equipement-part 2：particular requirments for the safety of electromyograohs and response equipment YY 0896-2013 20		2023-02-14
		7	Electromagnetic compatibility	medical electricl equipement-part 2：particular requirments for the safety of electromyograohs and response equipment YY 0896-2013 36		2023-02-14
		8	over-tempreture	medical electricl equipement-part 2：particular requirments for the safety of electromyograohs and response equipment YY 0896-2013 42		2023-02-14
		9	humen error	medical electricl equipement-part 2：particular requirments for the safety of electromyograohs and response equipment YY 0896-2013 46		2023-02-14
		10	Accuracy of workdata	medical electricl equipement-part 2：particular requirments for the safety of electromyograohs and response equipment YY		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				0896-2013 50		
		11	prevention of dangrous output	medical electricl equipement-part 2：particular requirments for the safety of electromyograohs and response equipment YY 0896-2013 51		2023-02-14
166	Anaesthetic and suction apparatus, medical oxygen humidifier	1	All Parameters	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018		2023-02-14
		2	Compatibility of materials used	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 4		2023-02-14
		3	appearance	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 5		2023-02-14
		4	Interface size	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 6		2023-02-14
		5	Humidification output	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 7.1		2023-02-14
		6	Overflows	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 7.2		2023-02-14
		7	Pressure release	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 7.3		2023-02-14
		8	Divulges	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 7.4		2023-02-14
		9	Compressive strength	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 8		2023-02-14
		10	Medical oxygen humidifier / water storage bottle with humidification liquid pre installed	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 9		2023-02-14
		11	sterile	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 10.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Packaging of sterile medical oxygen humidifier or accessories	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 10.2		2023-02-14
		13	Ethylene oxide residue	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 10.3		2023-02-14
		14	microbial limit	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 10.4		2023-02-14
		15	Cleaning, disinfection and sterilization	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 11		2023-02-14
		16	Marking of medical oxygen humidifier	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 12.1		2023-02-14
		17	Packaging mark of medical oxygen humidifier	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 12.2		2023-02-14
		18	Information provided by the manufacturer	Anaesthetic and suction apparatus, medical oxygen humidifier YY/T 1610- 2018 13		2023-02-14
167	hand-held probe Doppler fetal heartbeat detector	1	All Parameters	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009		2023-02-14
		2	Acoustic working frequency	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 6.1		2023-02-14
		3	Safety	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 7		2023-02-14
		4	Test Methods	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				reporting YY/T 0749-2009 8		
		5	Acoustic working frequency	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.1		2023-02-14
		6	Output Power	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.2		2023-02-14
		7	Spatial peak time peak sound pressure	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.3		2023-02-14
		8	Effective area of sensitive element of ultrasonic transducer	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.4		2023-02-14
		9	Comprehensive sensitivity	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.5		2023-02-14
		10	test facility	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.5.1		2023-02-14
		11	the reflective target	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.5.1.1		2023-02-14
		12	"Drive unit "	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.5.1.2		2023-02-14
		13	Test container	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.5.1.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	RMS signal measurement	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.5.1.4		2023-02-14
		15	Loudspeaker (audio output unit)	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.5.1.5		2023-02-14
		16	Sound attenuation sheet	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.5.1.6		2023-02-14
		17	Measuring step	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 8.5.2		2023-02-14
		18	The preferred method for reporting the performance of existing equipment	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 9		2023-02-14
		19	Technical requirements for marking	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 10		2023-02-14
		20	sampling	Ultrasonic hand-held probe Doppler fetal heartbeat detector performance requirements and methods of measurement and reporting YY/T 0749-2009 11		2023-02-14
168	Electrical equipment for measurement,control,and laboratory use	1	All Parameters	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008		2023-02-14
		2	test	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 4		2023-02-14

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		№	Item/ Parameter			
		3	device status	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 4.3.2		2023-02-14
		4	heating system	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 4.4.2.10		2023-02-14
		5	Compliance after application of fault conditions	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 4.4.4		2023-02-14
		6	Signs and documents	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 5		2023-02-14
		7	Power Supply	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 5.1.3		2023-02-14
		8	Switches and circuit breakers	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 5.1.6		2023-02-14
		9	Warning sign	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 5.2		2023-02-14
		10	Equipment with high contact current	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 5.2.101		2023-02-14
		11	equipment installation	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 5.4.3		2023-02-14
		12	Dry	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 5.4.3.101		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Operation of equipment	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 5.4.4		2023-02-14
		14	Maintenance of equipment	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 5.4.5		2023-02-14
		15	Cleaning and disinfection	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 5.4.4.101		2023-02-14
		16	Anti-shock	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 6		2023-02-14
		17	summarize	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 6.1		2023-02-14
		18	Exceptions to heating furnace	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 6.1.2.101		2023-02-14
		19	Permissible limits of accessible parts	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 6.3		2023-02-14
		20	Electric current	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 6.3.1b）1）		2023-02-14
		21	Electric current	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 6.3.2b）1）		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	Protection under normal conditions	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 6.4		2023-02-14
		23	Wet pretreatment	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 6.8.2		2023-02-14
		24	Implementation of the test	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 6.8.3		2023-02-14
		25	Power cord	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 6.10.1		2023-02-14
		26	Protection against mechanical hazards	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 7		2023-02-14
		27	Resistant to mechanical shock and impact	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 8		2023-02-14
		28	dynamic test	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 8.1.2		2023-02-14
		29	Dynamic test of horizontally heated surface of glass or ceramic materials	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 8.1.101		2023-02-14
		30	Prevent flame spread	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 9		2023-02-14
		31	Requirements for equipment	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			containing or using flammable liquids	equipment for the heating of materials GB4793.6-2008 9.4		
		32	Equipment temperature limits and heat resistance	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 10		2023-02-14
		33	Limit of surface temperature for preventing burns	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 10.1		2023-02-14
		34	Over temperature protection	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 10.101		2023-02-14
		35	Protection against fluid hazards	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 11		2023-02-14
		36	Radiation protection (including laser source), acoustic pressure and ultrasonic pressure	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 12		2023-02-14
		37	Protection against released gas, explosion and implosion	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 13		2023-02-14
		38	Components and heated materials	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 13.2.1		2023-02-14
		39	Internal explosion of vacuum furnace	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 13.2.101		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		40	Components	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 14		2023-02-14
		41	Over temperature protection device	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 14.3		2023-02-14
		42	Protection using interlock	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 15		2023-02-14
		43	Test and measurement equipment	Safety requirements for electrical for measurement, control, and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB4793.6-2008 16		2023-02-14
169	Medical carbon dioxide incubator	1	All Parameters	Medical carbon dioxide incubator YY/T 1621-2018		2023-02-14
		2	Appearance and structure	Medical carbon dioxide incubator YY/T 1621-2018 4.2		2023-02-14
		3	Temperature display and control function	Medical carbon dioxide incubator YY/T 1621-2018 4.3		2023-02-14
		4	Carbon dioxide concentration display and control function	Medical carbon dioxide incubator YY/T 1621-2018 4.4		2023-02-14
		5	Relative humidity control performance	Medical carbon dioxide incubator YY/T 1621-2018 4.5		2023-02-14
		6	noise	Medical carbon dioxide incubator YY/T 1621-2018 4.6		2023-02-14
		7	Call the police	Medical carbon dioxide incubator YY/T 1621-2018 4.7		2023-02-14
		8	Door recovery time	Medical carbon dioxide incubator YY/T 1621-2018 4.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Temperature recovery time	Medical carbon dioxide incubator YY/T 1621-2018 4.8.1		2023-02-14
		10	Recovery time of carbon dioxide concentration	Medical carbon dioxide incubator YY/T 1621-2018 4.8.2		2023-02-14
		11	Insulation performance	Medical carbon dioxide incubator YY/T 1621-2018 4.9		2023-02-14
		12	Prevent the generation of condensate	Medical carbon dioxide incubator YY/T 1621-2018 4.10		2023-02-14
		13	Over-temperature protection	Medical carbon dioxide incubator YY/T 1621-2018 4.11		2023-02-14
		14	Safety	Medical carbon dioxide incubator YY/T 1621-2018 4.12		2023-02-14
		15	Environmental test	Medical carbon dioxide incubator YY/T 1621-2018 4.13		2023-02-14
170	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods	1	All Parameters	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017		2023-02-14
		2	Random file	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.1		2023-02-14
		3	Coordinate System	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.2		2023-02-14
		4	Laser classification of laser localization system for radiotherapy	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.3		2023-02-14
		5	Alignment Line width of laser alignment system for radiotherapy	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Length of laser alignment line	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.5		2023-02-14
		7	Straightness of laser line	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.6		2023-02-14
		8	The verticality of the laser cross alignment line (if applicable)	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.7		2023-02-14
		9	Consistency with reference point	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.8.1		2023-02-14
		10	Consistency with reference plane (if applicable)	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.8.2		2023-02-14
		11	Projection accuracy	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.8.3.1		2023-02-14
		12	PROJECTIVE repeatability	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.8.3.2		2023-02-14
		13	Mobile Radiotherapy localizes the range of movement of laser system	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.9		2023-02-14
		14	Software functions (if applicable)	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017 4.10		2023-02-14
		15	MRI compatibility (if applicable)	Laser positioning system in radiation therapy—Functional-performance characteristics and test methods YY/T1537-2017		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				4.11		
171	Auto-scanning water phatom system in radiation therapy-Functional-performance	1	All Parameters	Auto-scanning water phatom system in radiation therapy-Functional-performance characteristics and test methods YY/T 1538-2017		2023-02-14
		2	Accompanying documents	Auto-scanning water phatom system in radiation therapy-Functional-performance characteristics and test methods YY/T 1538-2017 4.1		2023-02-14
		3	Positioning accuracy	Auto-scanning water phatom system in radiation therapy-Functional-performance characteristics and test methods YY/T 1538-2017 4.2		2023-02-14
		4	Positioning repeatability	Auto-scanning water phatom system in radiation therapy-Functional-performance characteristics and test methods YY/T 1538-2017 4.3		2023-02-14
		5	Perpendicularity of each axis	Auto-scanning water phatom system in radiation therapy-Functional-performance characteristics and test methods YY/T 1538-2017 4.4		2023-02-14
		6	Sampling point density	Auto-scanning water phatom system in radiation therapy-Functional-performance characteristics and test methods YY/T 1538-2017 4.5		2023-02-14
		7	Requirements of radiation measurement unit	Auto-scanning water phatom system in radiation therapy-Functional-performance characteristics and test methods YY/T 1538-2017 4.6		2023-02-14
		8	software function	Auto-scanning water phatom system in radiation therapy-Functional-performance characteristics and test methods YY/T 1538-2017 4.7		2023-02-14
172	Dosimeters with ionization chambers as used in	1	All Parameters	Medical electrical equipment-Dosimeters with ionization chambers as used in radiotherapy IEC 60731:2011		2023-02-14
		2	General requirements	Medical electrical equipment-Dosimeters with ionization chambers as used in radiotherapy IEC 60731:2011 4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	radiotherapy	3	Performance requirements of ionization chamber components	Medical electrical equipment-Dosimeters with ionization chambers as used in radiotherapy IEC 60731:2011 5		2023-02-14
		4	Performance requirements for measuring components	Medical electrical equipment-Dosimeters with ionization chambers as used in radiotherapy IEC 60731:2011 6		2023-02-14
		5	Performance requirements of stability testing device	Medical electrical equipment-Dosimeters with ionization chambers as used in radiotherapy IEC 60731:2011 7		2023-02-14
		6	Structural requirements for relevant performance characteristics	Medical electrical equipment-Dosimeters with ionization chambers as used in radiotherapy IEC 60731:2011 8		2023-02-14
		7	sign	Medical electrical equipment-Dosimeters with ionization chambers as used in radiotherapy IEC 60731:2011 9		2023-02-14
		8	Accompanying documents	Medical electrical equipment-Dosimeters with ionization chambers as used in radiotherapy IEC 60731:2011 10		2023-02-14
173	automatically-controlled brachytherapy afterloading equipment	1	All Parameters	Medical electrical equipment Part 2:Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2004		2023-02-14
		2	General requirements	Medical electrical equipment Part 2:Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2004 3		2023-02-14
		3	General requirements for testing	Medical electrical equipment Part 2:Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2004 4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	classification	Medical electrical equipment Part 2:Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2004 5		2023-02-14
		5	Identification, marking and documentation	Medical electrical equipment Part 2:Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2004 6		2023-02-14
		6	environment condition	Medical electrical equipment Part 2:Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2004 10		2023-02-14
		7	X-ray radiation	Medical electrical equipment Part 2:Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2004 29		2023-02-14
		8	α、β、γ Neutron radiation and other particle radiation	Medical electrical equipment Part 2:Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2004 30		2023-02-14
		9	Accuracy of working data	Medical electrical equipment Part 2:Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2004 50		2023-02-14
		10	Abnormal operation and fault conditions	Medical electrical equipment Part 2:Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2004 52		2023-02-14
174	Radiotherapy treatment planning system for automatically-controlled brachytherapy afterloading equipment	1	All Parameters	Radiotherapy treatment planning system for automatically-controlled brachytherapy afterloading equipment-Characteristics and test methods YY/T 0973-2016		2023-02-14
		2	Length reconstruction deviation	Radiotherapy treatment planning system for automatically-controlled brachytherapy afterloading equipment-Characteristics and test methods YY/T 0973-2016 6.1		2023-02-14
		3	Volume reconstruction deviation	Radiotherapy treatment planning system for automatically-controlled brachytherapy afterloading equipment-Characteristics and test methods YY/T 0973-2016 6.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Reconstruction geometric accuracy of applicator's length	Radiotherapy treatment planning system for automatically-controlled brachytherapy afterloading equipment-Characteristics and test methods YY/T 0973-2016 6.3		2023-02-14
		5	Dose calculation deviation	Radiotherapy treatment planning system for automatically-controlled brachytherapy afterloading equipment-Characteristics and test methods YY/T 0973-2016 6.4		2023-02-14
		6	Accuracy of dose distribution	Radiotherapy treatment planning system for automatically-controlled brachytherapy afterloading equipment-Characteristics and test methods YY/T 0973-2016 6.5		2023-02-14
		7	Accompanying documents	Radiotherapy treatment planning system for automatically-controlled brachytherapy afterloading equipment-Characteristics and test methods YY/T 0973-2016 6.6		2023-02-14
175	Automatically-controlled brachytherapy afterloading equipment	1	All Parameters	Automatically-controlled brachytherapy afterloading equipment YY/T 1308-2016		2023-02-14
		2	Accompanying documents	Automatically-controlled brachytherapy afterloading equipment YY/T 1308-2016 5.1		2023-02-14
		3	Maximum transmission distance of radioactive source	Automatically-controlled brachytherapy afterloading equipment YY/T 1308-2016 5.2		2023-02-14
		4	Positioning error of radioactive source	Automatically-controlled brachytherapy afterloading equipment YY/T 1308-2016 5.3		2023-02-14
		5	Reproducibility of location of radioactive sources	Automatically-controlled brachytherapy afterloading equipment YY/T 1308-2016 5.4		2023-02-14
		6	Accumulated location error of radioactive sources	Automatically-controlled brachytherapy afterloading equipment YY/T 1308-2016 5.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Transmission time	Automatically-controlled brachytherapy afterloading equipment YY/T 1308-2016 5.6		2023-02-14
		8	Dwell time range	Automatically-controlled brachytherapy afterloading equipment YY/T 1308-2016 5.7		2023-02-14
		9	Head lifting range	Automatically-controlled brachytherapy afterloading equipment YY/T 1308-2016 5.8		2023-02-14
		10	Minimum radius of curvature of the source combination	Automatically-controlled brachytherapy afterloading equipment YY/T 1308-2016 5.9		2023-02-14
		11	Applicator and related accessories	Automatically-controlled brachytherapy afterloading equipment YY/T 1308-2016 5.10		2023-02-14
		12	Radiation Therapy Planning System	Automatically-controlled brachytherapy afterloading equipment YY/T 1308-2016 5.11		2023-02-14
176	medical magnetic resonance imaging （MRI） equipment	1	All Parameters	Specification of image quality test and evaluation for medical magnetic resonance imaging（MRI）equipment WS/T 263-2006		2023-02-14
		2	Resonance frequence	Specification of image quality test and evaluation for medical magnetic resonance imaging（MRI）equipment WS/T 263-2006 7.1		2023-02-14
		3	SNR(signal-to-noise ratio)	Specification of image quality test and evaluation for medical magnetic resonance imaging（MRI）equipment WS/T 263-2006 7.1		2023-02-14
		4	Geometric distortion	Specification of image quality test and evaluation for medical magnetic resonance imaging（MRI）equipment WS/T 263-2006 7.1		2023-02-14
		5	High contrast spatial resolution	Specification of image quality test and evaluation for medical magnetic resonance imaging（MRI）equipment WS/T 263-2006 7.1		2023-02-14
		6	Image uniformity	Specification of image quality test and evaluation for medical		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				magnetic resonance imaging（MRI）equipment WS/T 263-2006 7.1		
		7	Slice Thickness	Specification of image quality test and evaluation for medical magnetic resonance imaging（MRI）equipment WS/T 263-2006 7.1		2023-02-14
		8	Slice ununiformity	Specification of image quality test and evaluation for medical magnetic resonance imaging（MRI）equipment WS/T 263-2006 7.1		2023-02-14
		9	Aspect ratio	Specification of image quality test and evaluation for medical magnetic resonance imaging（MRI）equipment WS/T 263-2006 7.1		2023-02-14
		10	Static magnetic field homogeneity	Specification of image quality test and evaluation for medical magnetic resonance imaging（MRI）equipment WS/T 263-2006 7.1		2023-02-14
		11	Instability of static magnetic field(B0)	Specification of image quality test and evaluation for medical magnetic resonance imaging（MRI）equipment WS/T 263-2006 7.1		2023-02-14
		12	Image artifacts	Specification of image quality test and evaluation for medical magnetic resonance imaging（MRI）equipment WS/T 263-2006 7.1		2023-02-14
		13	cryogen(liquid nitrogen、liquid helium)boiled-off ratio	Specification of image quality test and evaluation for medical magnetic resonance imaging（MRI）equipment WS/T 263-2006 7.1		2023-02-14
177	Thermoplastic	1	All Parameters	Immobilization device for body positioning used in radiation therapy-Part 1:Thermoplastic YY/T 1547.1-2017		2023-02-14
		2	External identification	Immobilization device for body positioning used in radiation therapy-Part 1:Thermoplastic YY/T 1547.1-2017 3.1		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Accompanying documents	Immobilization device for body positioning used in radiation therapy-Part 1:Thermoplastic YY/T 1547.1-2017 3.2		2023-02-14
		4	overall dimension	Immobilization device for body positioning used in radiation therapy-Part 1:Thermoplastic YY/T 1547.1-2017 3.3		2023-02-14
		5	Softening temperature	Immobilization device for body positioning used in radiation therapy-Part 1:Thermoplastic YY/T 1547.1-2017 3.4		2023-02-14
		6	tensile property	Immobilization device for body positioning used in radiation therapy-Part 1:Thermoplastic YY/T 1547.1-2017 3.5		2023-02-14
		7	Linear shrinkage	Immobilization device for body positioning used in radiation therapy-Part 1:Thermoplastic YY/T 1547.1-2017 3.6		2023-02-14
		8	viscosity	Immobilization device for body positioning used in radiation therapy-Part 1:Thermoplastic YY/T 1547.1-2017 3.7		2023-02-14
		9	hardness	Immobilization device for body positioning used in radiation therapy-Part 1:Thermoplastic YY/T 1547.1-2017 3.8		2023-02-14
		10	biocompatibility	Immobilization device for body positioning used in radiation therapy-Part 1:Thermoplastic YY/T 1547.1-2017 3.9		2023-02-14
		11	appearance	Immobilization device for body positioning used in radiation therapy-Part 1:Thermoplastic YY/T 1547.1-2017 3.10		2023-02-14
178	Vacuum cushion	1	All Parameters	Immobilization device for body positioning used in radiation therapy-Part 2:Vacuum cushion YY/T 1547.2-2017		2023-02-14
		2	External identification	Immobilization device for body positioning used in radiation therapy-Part 2:Vacuum cushion YY/T 1547.2-2017 3.1		2023-02-14
		3	Accompanying documents	Immobilization device for body positioning used in radiation therapy-Part 2:Vacuum cushion YY/T 1547.2-2017 3.2		2023-02-14
		4	overall dimension	Immobilization device for body positioning used in radiation therapy-Part 2:Vacuum cushion YY/T 1547.2-2017 3.3		2023-02-14
		5	Sealing performance	Immobilization device for body positioning used in radiation therapy-Part 2:Vacuum cushion YY/T 1547.2-2017 3.4		2023-02-14
		6	Compressive properties	Immobilization device for body positioning used in radiation therapy-Part 2:Vacuum cushion YY/T 1547.2-2017 3.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	biocompatibility	Immobilization device for body positioning used in radiation therapy-Part 2:Vacuum cushion YY/T 1547.2-2017 3.6		2023-02-14
		8	appearance	Immobilization device for body positioning used in radiation therapy-Part 2:Vacuum cushion YY/T 1547.2-2017 3.7		2023-02-14
179	Plasma thawing device	1	All Parameters	Plasma thawing device T/CSBME 023-2020		2023-02-14
		2	Comprehensive sensitivity	Plasma thawing device T/CSBME 023-2020 4.2		2023-02-14
		3	Maximum defrosting capacity	Plasma thawing device T/CSBME 023-2020 4.3.1		2023-02-14
		4	No-load heating time	Plasma thawing device T/CSBME 023-2020 4.3.2		2023-02-14
		5	DEFROSTING DEGREE	Plasma thawing device T/CSBME 023-2020 4.3.3		2023-02-14
		6	Thawing ability	Plasma thawing device T/CSBME 023-2020 4.3.4		2023-02-14
		7	time set	Plasma thawing device T/CSBME 023-2020 4.4		2023-02-14
		8	temperature display	Plasma thawing device T/CSBME 023-2020 4.5		2023-02-14
		9	Water level monitoring function	Plasma thawing device T/CSBME 023-2020 4.6		2023-02-14
		10	Temperature protection function	Plasma thawing device T/CSBME 023-2020 4.7		2023-02-14
		11	Defrost completion prompt function	Plasma thawing device T/CSBME 023-2020 4.8		2023-02-14
		12	Waterproof performance	Plasma thawing device T/CSBME 023-2020 4.9		2023-02-14
		13	Swing function	Plasma thawing device T/CSBME 023-2020 4.10		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	noise（dB）	Plasma thawing device T/CSBME 023-2020 4.11		2023-02-14
		15	Sink current (applicable to two types of lead wires)	Plasma thawing device T/CSBME 023-2020 4.12		2023-02-14
		16	Performance requirements-main cable and patient lead	Plasma thawing device T/CSBME 023-2020 4.13		2023-02-14
		17	Mark random document packaging transport storage	Plasma thawing device T/CSBME 023-2020 6		2023-02-14
180	Tongue features acquisition device	1	All Parameters	Tongue features acquisition device YY/T 1488-2016		2023-02-14
		2	Requirements	Tongue features acquisition device YY/T 1488-2016 4		2023-02-14
		3	Working condition	Tongue features acquisition device YY/T 1488-2016 4.1		2023-02-14
		4	Optical requirements	Tongue features acquisition device YY/T 1488-2016 4.2		2023-02-14
		5	The illuminance	Tongue features acquisition device YY/T 1488-2016 4.2.1		2023-02-14
		6	Correlated colour temperature	Tongue features acquisition device YY/T 1488-2016 4.2.2		2023-02-14
		7	Color rendering index (Ra)	Tongue features acquisition device YY/T 1488-2016 4.2.3		2023-02-14
		8	Irradiance	Tongue features acquisition device YY/T 1488-2016 4.2.4		2023-02-14
		9	Ultraviolet irradiance	Tongue features acquisition device YY/T 1488-2016 4.2.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Image quality	Tongue features acquisition device YY/T 1488-2016 4.3		2023-02-14
		11	Resolution ratio	Tongue features acquisition device YY/T 1488-2016 4.3.1		2023-02-14
		12	Colour reproduction	Tongue features acquisition device YY/T 1488-2016 4.3.2		2023-02-14
		13	relative distortion	Tongue features acquisition device YY/T 1488-2016 4.3.3		2023-02-14
		14	Structural requirement	Tongue features acquisition device YY/T 1488-2016 4.4		2023-02-14
		15	Function	Tongue features acquisition device YY/T 1488-2016 4.5		2023-02-14
		16	Biocompatibility	Tongue features acquisition device YY/T 1488-2016 4.6	See GB/T 16886.1	2023-02-14
		17	Operating instruction	Tongue features acquisition device YY/T 1488-2016 4.7		2023-02-14
		18	Security	Tongue features acquisition device YY/T 1488-2016 4.8	See 9706.1	2023-02-14
		19	Electromagnetic compatibility	Tongue features acquisition device YY/T 1488-2016 4.9	See 9706.102	2023-02-14
		20	Environmental testing	Tongue features acquisition device YY/T 1488-2016 4.10		2023-02-14
		21	Logo、 Label、 Instruction manual	Tongue features acquisition device YY/T 1488-2016 7		2023-02-14
		22	Logo	Tongue features acquisition device YY/T 1488-2016 7.1		2023-02-14
		23	Nameplate	Tongue features acquisition device YY/T 1488-2016 7.1.1		2023-02-14
		24	The outer packing	Tongue features acquisition device YY/T 1488-2016 7.1.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		25	Certificate of approval	Tongue features acquisition device YY/T 1488-2016 7.1.3		2023-02-14
		26	Labels, Markings, and symbols that provide information	Tongue features acquisition device YY/T 1488-2016 7.1.4		2023-02-14
		27	Operating instruction	Tongue features acquisition device YY/T 1488-2016 7.2		2023-02-14
		28	Packing, transportation and storage	Tongue features acquisition device YY/T 1488-2016 8		2023-02-14
		29	Packaging	Tongue features acquisition device YY/T 1488-2016 8.1		2023-02-14
		30	Transport	Tongue features acquisition device YY/T 1488-2016 8.2		2023-02-14
		31	Storage	Tongue features acquisition device YY/T 1488-2016 8.3		2023-02-14
181	Pulse graph acquisition device for traditional Chinese medicine	1	All Parameters	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016		2023-02-14
		2	Requirements	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		3	Working condition	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		4	The applied mechanical quantity applies the safety limit of the device	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		5	Accuracy of applied mechanical quantity	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Accuracy of pulse pressure	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		7	Pulse accuracy	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		8	Function of pressure	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		9	Effective sensor geometry	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		10	Time constant of dynamic amplifier	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		11	Working noise	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		12	Biocompatibility	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4	See GB/T 16886.1	2023-02-14
		13	Appearance	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		14	Operating instruction	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		15	Security	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4	See 9706.1	2023-02-14
		16	Electromagnetic compatibility	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4	See 9706.102	2023-02-14
		17	Environmental testing	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		18	Logo、 Label、 Instruction manual	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		19	Logo	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		20	Nameplate	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		21	The outer packing	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		22	Certificate of approval	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		23	Labels, Markings, and symbols that provide information	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		24	Operating instruction	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		25	Packing, transportation and storage	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		26	Packaging	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		27	Transport	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
		28	Storage	Pulse graph acquisition device for traditional Chinese medicine YY/T 1489-2016 4		2023-02-14
182	Electrical resistance detector at acupuncture points equipment	1	All Parameters	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019		2023-02-14
		2	Requirements	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5		2023-02-14
		3	Accuracy of impedance detection	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5		2023-02-14
		4	Detecting voltage	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5		2023-02-14
		5	The test current	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Energy limit of output signal	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5		2023-02-14
		7	Effective size of electrode	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5		2023-02-14
		8	Force control device for electrode	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5		2023-02-14
		9	Biocompatibility of materials	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5	See GB/T 16886.1	2023-02-14
		10	Appearance	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5		2023-02-14
		11	External marker	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5		2023-02-14
		12	Specification requirements	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5		2023-02-14
		13	Safety requirements	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5	See 9706.1	2023-02-14
		14	Electromagnetic compatibility	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5	See 9706.102	2023-02-14
		15	Environmental test requirements	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019 5		2023-02-14
183	Short-wave therapy equipment	1	All Parameters	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016		2023-02-14
		2	General requirements	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.4		2023-02-14
		3	General requirements for ME equipment testing	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.5		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Routine test	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.5.101		2023-02-14
		5	Classification of ME devices and ME systems	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.6		2023-02-14
		6	ME device identification, tags, and files	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.7		2023-02-14
		7	External markings for ME devices or parts of ME devices	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.7.2		2023-02-14
		8	The output	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.7.2.101		2023-02-14
		9	Internal markings for ME devices or parts of ME devices	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.7.3		2023-02-14
		10	Device or panel marking	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.7.3.101		2023-02-14
		11	Control device	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.7.4.2		2023-02-14
		12	Operating instruction	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.7.9.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Supplementary requirements for operating instructions	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.7.9.2.101		2023-02-14
		14	Technical specification	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.7.9.3		2023-02-14
		15	General requirements	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.7.9.3.1		2023-02-14
		16	ME equipment protection against electric shock hazard	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.8		2023-02-14
		17	Classification of application parts	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.8.3		2023-02-14
		18	General requirements	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.8.7.1		2023-02-14
		19	Dielectric strength	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.8.8.3		2023-02-14
		20	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.9		2023-02-14
		21	Protection against unwanted or	Medical electrical equipment — Part 2-3: Particular		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			excessive radiation hazards	requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.10		
		22	Protection against hyperthermia and other hazards	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.11		2023-02-14
		23	Control and instrument accuracy and hazard output protection	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.12		2023-02-14
		24	Accuracy of controller and instrument	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.12.1		2023-02-14
		25	Output controls the accuracy of Settings	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.12.1.101		2023-02-14
		26	Hazard output protection	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.12.4		2023-02-14
		27	Maximum allowable output power	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.12.4.101		2023-02-14
		28	Output reduction method	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.12.4.102		2023-02-14
		29	Incentive output	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.12.4.103		2023-02-14
		30	Adjustable timer	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				short-wave therapy equipment IEC 60601-2-3:2016 201.12.4.104		
		31	ME Device critical conditions and fault conditions	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.13		2023-02-14
		32	Programmable Medical Electrical System (PEMS)	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.14		2023-02-14
		33	ME device structure	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.15		2023-02-14
		34	The ME system	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.16		2023-02-14
		35	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment IEC 60601-2-3:2016 201.17	See 9706.102	2023-02-14
184	Haemodialysis, haemodiafiltration and haemofiltration equipment	1	All Parameters	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018		2023-02-14
		2	General requirements	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.4		2023-02-14
		3	Basic performance	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Supplement basic performance requirements	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.4.3.101		2023-02-14
		5	Blood flow	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.4.3.102		2023-02-14
		6	Dialysate flow	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.4.3.103		2023-02-14
		7	Net dehydration	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.4.3.104		2023-02-14
		8	Displacement fluid flow	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.4.3.105		2023-02-14
		9	Dialysis time	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.4.3.106		2023-02-14
		10	Dialysate composition	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.4.3.107		2023-02-14
		11	Dialysate	Medical electrical equipment-Part 2-16 : Particular		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			temperature	requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.4.3.108		
		12	Displacement fluid temperature	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.4.3.109		2023-02-14
		13	Single fault state of ME device	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.4.7		2023-02-14
		14	General requirements for ME equipment testing	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.5		2023-02-14
		15	Classification of ME devices and ME systems	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.6		2023-02-14
		16	ME Device identification, tags, and files	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.7		2023-02-14
		17	Unit of measure	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.7.4.3		2023-02-14
		18	Controller color	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.7.8.2		
		19	Operating instruction	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.7.9.2		2023-02-14
		20	Warnings and safety instructions	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.7.9.2.2		2023-02-14
		21	ME device description	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.7.9.2.5		2023-02-14
		22	The installation	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.7.9.2.6		2023-02-14
		23	Cleaning, disinfection and sterilization	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.7.9.2.12		2023-02-14
		24	Accessories, additional equipment, materials used	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.7.9.2.14		2023-02-14
		25	Technical specification	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				IEC 60601-2-16:2018 201.7.9.3		
		26	Overview	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.7.9.3.1		2023-02-14
		27	Protection of ME equipment against electric shock hazard (source)	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.8		2023-02-14
		28	Classification of application parts	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.8.3		2023-02-14
		29	Measurement of patient leakage current	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.8.7.4.7		2023-02-14
		30	A number of sockets	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.8.11.2		2023-02-14
		31	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.9		2023-02-14
		32	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.10		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		33	Protection against hyperthermia and other hazards (sources)	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.11		2023-02-14
		34	Liquid splashing in ME equipment and ME systems	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.11.6.3		2023-02-14
		35	ME equipment and ME system cleaning and disinfection	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.11.6.6		2023-02-14
		36	The power supply/power grid of the ME device is interrupted	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.11.8		2023-02-14
		37	Control and instrument accuracy and hazard output protection	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12		2023-02-14
		38	Incorrect output	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4		2023-02-14
		39	Dialysate composition	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.101		2023-02-14
		40	Dialysate and	Medical electrical equipment-Part 2-16 : Particular		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			replacement fluid temperature	requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.102		
		41	Net dehydration	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.103		2023-02-14
		42	In vitro blood loss	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.104		2023-02-14
		43	External blood loss to the environment	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.104.1		2023-02-14
		44	Leakage of blood to the dialysate	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.104.2		2023-02-14
		45	External blood loss caused by coagulation	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.104.3		2023-02-14
		46	Air injection	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.105		2023-02-14
		47	Alarm state override mode	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.106		
		48	Protection system	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.107		2023-02-14
		49	Protection against chemical pollution	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.108		2023-02-14
		50	Blood pumps and/or replacement fluid pumps reverse	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.109		2023-02-14
		51	Operation mode selection and change	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.110		2023-02-14
		52	On line HDF and on line HF	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.111		2023-02-14
		53	Anticoagulation	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.12.4.4.112		2023-02-14
		54	ME Device danger status and fault status	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				IEC 60601-2-16:2018 201.13		
		55	Liquid leakage	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.13.2.6		2023-02-14
		56	Programmable Medical Electrical System (PEMS)	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.14		2023-02-14
		57	PEMS expected to access the IT-network	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.14.13		2023-02-14
		58	ME device structure	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.15		2023-02-14
		59	Connector construction	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.5.4.1		2023-02-14
		60	Dialysate concentrate connector	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.15.4.1.101		2023-02-14
		61	Blood pressure sensor connector	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.15.4.1.102		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		62	The ME system	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.16		2023-02-14
		63	General requirements for ME systems	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.16.1		2023-02-14
		64	Documentation that comes with the ME system	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.16.2		2023-02-14
		65	Patient leakage current	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.16.6.3		2023-02-14
		66	Connect terminals and connectors	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.16.9.1		2023-02-14
		67	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 201.17	See 9706.102	2023-02-14
		68	Electromagnetic compatibility - Requirements and tests	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 202	See 9706.102	2023-02-14
		69	Life support ME	Medical electrical equipment-Part 2-16 : Particular	See	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			devices or ME systems	requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 202.3.18	9706.102	
		70	General requirements, guidelines for testing and testing of alarm systems in medical electrical equipment and medical electrical systems	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 208		2023-02-14
		71	General requirements	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 208.4		2023-02-14
		72	Operating instruction	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 208.5.2.1		2023-02-14
		73	Generation of alarm signal	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 208.6.3		2023-02-14
		74	Overview	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 208.6.3.1		2023-02-14
		75	Volume and characteristics of	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			auditory alarm signals and information signals	haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 208.6.3.3.2		
		76	Operator adjustable sound pressure level	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 208.6.3.3.3		2023-02-14
		77	Special features of aural alarm signals for hemodialysis equipment	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 208.6.3.3.101		2023-02-14
		78	Environmentally conscious design requirements	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 209		2023-02-14
		79	Physiological closed loop controller development requirements	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 210		2023-02-14
		80	Requirements for medical electrical equipment and medical electrical systems used in home care Settings	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 211		2023-02-14
		81	Classification of ME devices and ME systems	Medical electrical equipment-Part 2-16 : Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:2018 211.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
185	Peritoneal dialysis equipment	1	All Parameters	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018,		2023-02-14
		2	General requirements	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.4		2023-02-14
		3	Basic performance	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.4.3		2023-02-14
		4	Add basic performance requirements	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.4.3.101		2023-02-14
		5	Dialysate flow during perfusion/drainage	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.4.3.102		2023-02-14
		6	Dialysate volume balance (perfusion/drainage volume)	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.4.3.103		2023-02-14
		7	Peritoneal dialysis indwelling time	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.4.3.104		2023-02-14
		8	Dialysate composition	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.4.3.105		2023-02-14
		9	Dialysate temperature	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.4.3.106		2023-02-14
		10	Single fault state of ME device	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				equipment IEC 60601-2-39:2018 201.4.7		
		11	ME Normal and single fault status of the device	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.4.7.101		2023-02-14
		12	General requirements for ME equipment testing	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.5		2023-02-14
		13	Other conditions	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.5.4		2023-02-14
		14	Classification of ME devices and ME systems	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.6		2023-02-14
		15	ME Device identification, tags, and files	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.7		2023-02-14
		16	The attached file	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.7.9		2023-02-14
		17	Overview	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.7.9.1		2023-02-14
		18	Operating instruction	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.7.9.2		2023-02-14
		19	Supplementary requirements for PD devices	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.7.9.2.101		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		20	Technical specification	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.7.9.3		2023-02-14
		21	Supplementary requirements for PD devices	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.7.9.3.101		2023-02-14
		22	Protection of ME equipment against electric shock hazard (source)	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.8		2023-02-14
		23	Leakage current and patient auxiliary current	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.8.7		2023-02-14
		24	Measurement	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.8.7.4		2023-02-14
		25	Measurement of patient leakage current	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.8.7.4.7		2023-02-14
		26	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.9		2023-02-14
		27	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.10		2023-02-14
		28	Protection against hyperthermia and other hazards	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.11		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			(sources)			
		29	Overflow, liquid splashing, leakage, invasion of water or particulate matter, cleaning, disinfection, sterilization and compatibility of materials used in ME equipment	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.11.6		2023-02-14
		30	Overview	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.11.6.1		2023-02-14
		31	Liquid splashing in ME equipment and ME systems	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.11.6.3		2023-02-14
		32	The power supply/power grid of the ME device is interrupted	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.11.8		2023-02-14
		33	Control and instrument accuracy and hazard output protection	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.12		2023-02-14
		34	Incorrect output	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.12.4.4		2023-02-14
		35	Dialysate temperature	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				equipment IEC 60601-2-39:2018 201.12.4.4.101		
		36	Pressure	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.12.4.4.102		2023-02-14
		37	Air injection	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.12.4.4.103		2023-02-14
		38	Excessive infusion of dialysate	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.12.4.4.104		2023-02-14
		39	Dialysate composition	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.12.4.4.105		2023-02-14
		40	Protection system	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.12.4.4.106		2023-02-14
		41	ME Danger and fault status of the device	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.13		2023-02-14
		42	Programmable Medical Electrical System (PEMS)	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.14		2023-02-14
		43	ME device structure	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.15		2023-02-14
		44	ME device components and general purpose components	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.15.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		45	Guidelines for dialysate piping	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.15.4.101		2023-02-14
		46	The drainage	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.15.4.102		2023-02-14
		47	The ME system	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.16		2023-02-14
		48	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 201.17	See 9706.102	2023-02-14
		49	Electromagnetic compatibility - Requirements and tests	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 202	See 9706.102	2023-02-14
		50	General requirements, testing and guidance for ALARM systems in ME devices and ME systems	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 208		2023-02-14
		51	Alarm status determination and priority allocation	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 208.6.1.2		2023-02-14
		52	4M (remote) visual alarm signal	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 208.6.3.2.2.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		53	Auditory alarm signal	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 208.6.3.3		2023-02-14
		54	Auditory alarm signal characteristics	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 208.6.3.3.1		2023-02-14
		55	Volume and characteristics of auditory alarm signals and information signals	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 208.6.3.3.2		2023-02-14
		56	Operator adjustable sound pressure level	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 208.6.3.3.3		2023-02-14
		57	Special characteristics of PD device auditory alarm signal	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 208.6.3.3.101		2023-02-14
		58	Environmentally conscious design requirements	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 209		2023-02-14
		59	Requirements for ME devices and ME systems used in home care Settings	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 211		2023-02-14
		60	Classification of ME devices and ME systems	Medical electrical equipment-Part 2-39: Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2018 211.6		2023-02-14
186	Infant incubators	1	All Parameters	Medical electrical equipmentPart 2-19 ： Particular requirements for the basic safety and essential performance of		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				infant incubators IEC 60601-2-19:2016		
		2	General requirements	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.4		2023-02-14
		3	Application conditions of ME device or ME system	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.4.1		2023-02-14
		4	Basic performance	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.4.3		2023-02-14
		5	Basic performance of infant incubator	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.4.3.101		2023-02-14
		6	General requirements for ME equipment testing	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.5		2023-02-14
		7	Ambient temperature, humidity and atmospheric pressure	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.5.3		2023-02-14
		8	Other conditions	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.5.4		2023-02-14
		9	Classification of ME devices and ME systems	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	ME Device identification, tags, and files	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.7		2023-02-14
		11	External markings for ME devices or components of ME devices (see Table C.1 of the general standard)	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.7.2		2023-02-14
		12	Oxygen monitoring	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.7.2.101		2023-02-14
		13	Heater surface temperature	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.7.2.102		2023-02-14
		14	Marking of controllers and meters (see Table C.3 for general standards)	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.7.4		2023-02-14
		15	Control device	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.7.4.2		2023-02-14
		16	Warnings and safety instructions	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.7.9.2.2		2023-02-14
		17	Start the program	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.7.9.2.8		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	Operating instructions	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.7.9.2.9		2023-02-14
		19	Technical specification	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.7.9.3		2023-02-14
		20	Overview	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.7.9.3.1		2023-02-14
		21	ME equipment protection against electric shock hazard	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.8	See GB9706.1	2023-02-14
		22	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9		2023-02-14
		23	Mechanical hazards associated with moving parts	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.2		2023-02-14
		24	Overview	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.2.1		2023-02-14
		25	Sound energy	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.6.2		2023-02-14
		26	Audible sound energy	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.6.2.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		27	Sound pressure levels in the baby's cabin	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.6.2.1.101		2023-02-14
		28	Audible alarm sound pressure level	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.6.2.1.102		2023-02-14
		29	Baby cabin audible alarm sound pressure level	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.6.2.1.103		2023-02-14
		30	Mechanical hazards associated with supporting systems	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.8		2023-02-14
		31	Strength requirements for patient or operator support or suspension systems	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.8.3		2023-02-14
		32	Overview	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.8.3.1		2023-02-14
		33	File every thing	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.8.3.101		2023-02-14
		34	The mattress tray	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.8.3.102		2023-02-14
		35	Brackets and brackets for accessories	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.9.8.101		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		36	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.10		2023-02-14
		37	Protection against hyperthermia and other dangerous skin (source)	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.11		2023-02-14
		38	ME Device overtemperature	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.11.1		2023-02-14
		39	The portion of the application that does not provide heat to the patient	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.11.1.2.2		2023-02-14
		40	fire	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.11.2		2023-02-14
		41	Overflow in ME equipment	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.11.6.2		2023-02-14
		42	Liquid splashing in ME equipment and ME systems	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.11.6.3		2023-02-14
		43	ME equipment and ME system cleaning and disinfection	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.11.6.6		2023-02-14
		44	The power supply/power grid of the ME device is	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.11.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			interrupted			
		45	Control and instrument accuracy and hazard output protection	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12		2023-02-14
		46	Accuracy of controller and instrument	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.1		2023-02-14
		47	Stability of incubator temperature	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.1.101		2023-02-14
		48	Uniformity of incubator temperature	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.1.102		2023-02-14
		49	Accuracy of skin temperature sensor	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.1.103		2023-02-14
		50	Accuracy between skin temperature and control temperature	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.1.104		2023-02-14
		51	Accuracy of incubator temperature display	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.1.105		2023-02-14
		52	Accuracy of incubator temperature control	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.1.106		2023-02-14
		53	Heating up time	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				infant incubators IEC 60601-2-19:2016 201.12.1.107		
		54	Overshoot of incubator temperature	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.1.108		2023-02-14
		55	Accuracy of relative humidity display	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.1.109		2023-02-14
		56	Oxygen control	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.1.110		2023-02-14
		57	The air flow rate	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.1.111		2023-02-14
		58	The weight balance	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.1.112		2023-02-14
		59	Availability	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.2		2023-02-14
		60	Display of skin temperature	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.2.101		2023-02-14
		61	Display of operation mode	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.2.102		2023-02-14
		62	The temperature control	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.2.103		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		63	Alarm system	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.3		2023-02-14
		64	Air circulating fan	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.3.101		2023-02-14
		65	Connector for skin temperature sensor	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.3.102		2023-02-14
		66	Power supply interruption alarm	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.3.103		2023-02-14
		67	Alarm sound pause	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.3.104		2023-02-14
		68	Alarm function test	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.3.105		2023-02-14
		69	Indication of safety parameters	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.4.2		2023-02-14
		70	Carbon dioxide (CO2) concentration	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.12.4.2.101		2023-02-14
		71	ME Device danger status and fault status	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.13		2023-02-14
		72	Liquid leakage	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				infant incubators IEC 60601-2-19:2016 201.13.2.6		
		73	Programmable Medical Electrical System (PEMS)	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.14		2023-02-14
		74	ME device structure	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.15		2023-02-14
		75	Mechanical strength	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.15.3		2023-02-14
		76	Rough handling test	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.15.3.5		2023-02-14
		77	Baby channel	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.15.3.101		2023-02-14
		78	Connector construction	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.15.4.1		2023-02-14
		79	Temperature sensor	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.15.4.1.101		2023-02-14
		80	Temperature and overload control	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.15.4.2		2023-02-14
		81	Application	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.15.4.2.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		82	Temperature setting	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.15.4.2.2		2023-02-14
		83	Air temperature control range	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.15.4.2.2.101		2023-02-14
		84	Infant temperature control range	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.15.4.2.2.102		2023-02-14
		85	The ME system	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.16		2023-02-14
		86	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 201.17	See 9706.102	2023-02-14
		87	Electromagnetic compatibility requirements and testing	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 202	See 9706.102	2023-02-14
		88	Immunity test level	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 202.6.2.3	See 9706.102	2023-02-14
		89	Requirements	Medical electrical equipmentPart 2-19 : Particular requirements for the basic safety and essential performance of infant incubators IEC 60601-2-19:2016 202.6.2.3.1	See 9706.102	2023-02-14
187	Infant transport incubators	1	All Parameters	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	General requirements	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.4		2023-02-14
		3	Application conditions of ME device or ME system	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.4.1		2023-02-14
		4	Basic performance	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.4.3		2023-02-14
		5	Basic performance of infant transport incubator	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.4.3.101		2023-02-14
		6	The power supply	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.4.10		2023-02-14
		7	Different power supply operating capacity	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.4.10.101		2023-02-14
		8	The amount of electricity from a portable power source	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.4.10.102		2023-02-14
		9	Overcharging of	Medical electrical equipment—Part 2-20：Particular		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			removable power supply	requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.4.10.103		
		10	General requirements for ME equipment testing	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.5		2023-02-14
		11	Ambient temperature, humidity, atmospheric pressure	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.5.3		2023-02-14
		12	Other conditions	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.5.4		2023-02-14
		13	Classification of ME devices and ME systems	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.6		2023-02-14
		14	ME Device identification, tags, and files	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.7		2023-02-14
		15	External markings for ME devices or components of ME devices (see Table C.1 of the general standard)	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.7.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Oxygen monitoring	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.7.2.101		2023-02-14
		17	Heater surface temperature	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.7.2.102		2023-02-14
		18	Marking of controllers and meters (see Table C.3 for general standards)	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.7.4		2023-02-14
		19	Control device	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.7.4.2		2023-02-14
		20	Warnings and safety instructions	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.7.9.2.2		2023-02-14
		21	Start the program	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.7.9.2.8		2023-02-14
		22	Operating instructions	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.7.9.2.9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Technical specification	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.7.9.3		2023-02-14
		24	Overview	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.7.9.3.1		2023-02-14
		25	Protection of ME equipment against electric shock hazard (source)	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.8	See GB9706.1	2023-02-14
		26	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9		2023-02-14
		27	Mechanical hazards associated with moving parts	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.2		2023-02-14
		28	Overview	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.2.1		2023-02-14
		29	Instability in transport	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.4.2.1		2023-02-14
		30	Instability caused by	Medical electrical equipment—Part 2-20：Particular		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			unnecessary lateral movement (including sliding)	requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.4.3		
		31	Tilting force	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.4.3.101		2023-02-14
		32	To prevent the moving	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.4.3.102		2023-02-14
		33	Prevent baby from moving	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.4.3.103		2023-02-14
		34	To prevent vibration	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.4.3.104		2023-02-14
		35	Sound energy	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.6.2		2023-02-14
		36	Audible sound energy	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.6.2.1		2023-02-14
		37	Infant cabin sound pressure level	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.6.2.1.101		
		38	Audible alarm sound pressure level	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.6.2.1.102		2023-02-14
		39	Baby cabin audible alarm sound pressure level	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.6.103		2023-02-14
		40	Mechanical hazards associated with supporting systems	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.8		2023-02-14
		41	Strength requirements for patient or operator support or suspension systems	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.8.3		2023-02-14
		42	Overview	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.8.3.1		2023-02-14
		43	File every thing	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.8.3.101		2023-02-14
		44	The mattress tray	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				201.9.8.3.102		
		45	Brackets and brackets for accessories	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.9.8.101		2023-02-14
		46	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.10		2023-02-14
		47	Protection against hyperthermia and other hazards (sources)	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.11		2023-02-14
		48	The portion of the application that does not provide heat to the patient	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.11.1.2.2		2023-02-14
		49	Fireproofing	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.11.2		2023-02-14
		50	Overflow in ME equipment	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.11.6.2		2023-02-14
		51	Water level indicator	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.11.6.2.101		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		52	Liquid splashing in ME equipment and ME systems	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.11.6.3		2023-02-14
		53	ME equipment and ME system cleaning and disinfection	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.11.6.6		2023-02-14
		54	The power supply/power grid of the ME device is interrupted	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.11.8		2023-02-14
		55	Control and instrument accuracy and hazard output protection	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12		2023-02-14
		56	Accuracy of controller and instrument	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1		2023-02-14
		57	Temperature stability of transport incubator	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.101		2023-02-14
		58	Temperature uniformity of transport incubator	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.102		2023-02-14
		59	Accuracy of skin	Medical electrical equipment—Part 2-20：Particular		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			temperature sensor	requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.103		
		60	Accuracy between skin temperature and control temperature	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.104		2023-02-14
		61	Accuracy of temperature display in transport incubator	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.105		2023-02-14
		62	Accuracy of temperature control in transport incubator	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.106		2023-02-14
		63	Heating up time	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.107		2023-02-14
		64	Overshoot of transport incubator temperature	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.108		2023-02-14
		65	Accuracy of relative humidity display	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.109		2023-02-14
		66	Oxygen control	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.110		
		67	The air flow rate	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.111		2023-02-14
		68	Changes in ambient temperature	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.113		2023-02-14
		69	Oxygen supply	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.114		2023-02-14
		70	Overshoot of transport incubator temperature	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.115		2023-02-14
		71	The weight balance	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.1.116		2023-02-14
		72	availability	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.2		2023-02-14
		73	Display of skin temperature	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				201.12.2.101		
		74	Display of operation mode	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.2.102		2023-02-14
		75	The temperature control	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.2.103		2023-02-14
		76	Alarm system	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.3		2023-02-14
		77	Air circulating fan	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.3.101		2023-02-14
		78	Connector for skin temperature sensor	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.3.102		2023-02-14
		79	Power outage	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.3.103		2023-02-14
		80	Alarm sound pause	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.3.104		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		81	Alarm function test	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.3.105		2023-02-14
		82	Indication of safety parameters	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.4.2		2023-02-14
		83	Carbon dioxide (CO2) concentration	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.12.4.2.101		2023-02-14
		84	ME Device danger status and fault status	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.13		2023-02-14
		85	Electrical single fault state	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.13.2.2		2023-02-14
		86	Liquid leakage	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.13.2.6		2023-02-14
		87	Programmable Medical Electrical System (PEMS)	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.14		2023-02-14
		88	ME device structure	Medical electrical equipment—Part 2-20：Particular		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.15		
		89	Mechanical strength	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.15.3		2023-02-14
		90	Baby channel	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.15.3.101		2023-02-14
		91	Portable ME device	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.15.3.4.2		2023-02-14
		92	Connector construction	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.15.4.1		2023-02-14
		93	Connector for temperature sensor	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.15.4.1.101		2023-02-14
		94	Temperature and overload control	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.15.4.2		2023-02-14
		95	Application	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.15.4.2.1		
		96	Temperature setting	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.15.4.2.2		2023-02-14
		97	Fix and prevent mistune	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.15.4.6.1		2023-02-14
		98	The ME system	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.16		2023-02-14
		99	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 201.17	See 9706.102	2023-02-14
		100	Electromagnetic compatibility - Requirements and tests	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 202	See 9706.102	2023-02-14
		101	Immunity test level	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 202.6.2.3	See 9706.102	2023-02-14
		102	requirements	Medical electrical equipment—Part 2-20 : Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016	See 9706.102	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				202.6.2.3.1		
		103	Requirements for medical electrical equipment and medical electrical systems intended for use in emergency medical service Settings	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 212		2023-02-14
		104	Transportation and storage environmental conditions between uses	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 212.4.2.1		2023-02-14
		105	Continuous operating condition	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 212.4.2.2.1		2023-02-14
		106	Transient operating condition	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 212.4.2.2.2		2023-02-14
		107	Classification of ME devices and ME systems	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 212.5		2023-02-14
		108	Power supply added on request	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				212.6.3.2		
		109	Additional requirements for operating instructions	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 212.6.3.4		2023-02-14
		110	ME Device Description Added requirements	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 212.6.3.5		2023-02-14
		111	ME equipment electrical hazard (source) protection	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 212.7		2023-02-14
		112	Intrusion of water or particulate matter into ME equipment and ME systems increases requirements	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 212.8.1		2023-02-14
		113	Control and instrument accuracy and hazard output protection	Medical electrical equipment—Part 2-20：Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601-2-20:2009 + AMD1:2016 212.9		2023-02-14
188	Infant radiant warmers	1	All Parameters	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1：2016		2023-02-14
		2	General requirements	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1：2016 201.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Application conditions of ME device or ME system	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.4.1		2023-02-14
		4	Basic performance	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.4.3		2023-02-14
		5	Added basic performance requirements	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.4.3.101		2023-02-14
		6	General requirements for ME equipment testing	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.5		2023-02-14
		7	Ambient temperature, humidity and atmospheric pressure	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.5.3		2023-02-14
		8	Other conditions	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.5.4		2023-02-14
		9	Classification of ME devices and ME systems	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.6		2023-02-14
		10	ME device identification, tags, and files	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.7		2023-02-14
		11	External markings for ME devices or	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			parts of ME devices	warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.7.2		
		12	Oxygen monitor	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.7.2.101		2023-02-14
		13	Distance markers	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.7.2.102		2023-02-14
		14	Control device	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.7.4.2		2023-02-14
		15	Warnings and safety instructions	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.7.9.2.2		2023-02-14
		16	Operating instructions	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.7.9.2.9		2023-02-14
		17	Maintenance	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.7.9.2.13		2023-02-14
		18	Accessories, additional equipment, materials used	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.7.9.2.14		2023-02-14
		19	Technical specification	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.7.9.3		2023-02-14
		20	Overview	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.7.9.3.1		
		21	Protection of ME equipment against electric shock hazard (source)	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.8	See GB9706.1	2023-02-14
		22	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.9		2023-02-14
		23	Instability in transport	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.9.4.2.1		2023-02-14
		24	Sound energy	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.9.6.2		2023-02-14
		25	Audible sound energy	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.9.6.2.1		2023-02-14
		26	Audible alarm sound pressure level	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.9.6.2.1.101		2023-02-14
		27	Mechanical hazards associated with supporting systems	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.9.8		2023-02-14
		28	Brackets and brackets for accessories	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.9.8.101		2023-02-14
		29	Strength requirements for	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			patient or operator support or suspension systems	warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.9.8.3		
		30	Overview	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.9.8.3.1		2023-02-14
		31	File every thing	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.9.8.3.101		2023-02-14
		32	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.10		2023-02-14
		33	The infrared radiation	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.10.6		2023-02-14
		34	Protection against hyperthermia and other hazards (sources)	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.11		2023-02-14
		35	The portion of the application that is not intended to provide heat to the patient	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.11.1.2.2		2023-02-14
		36	Protection	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.11.1.4		2023-02-14
		37	Fireproofing	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.11.2		
		38	Liquid splashing in ME equipment and ME systems	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.11.6.3		2023-02-14
		39	The power supply/power grid of the ME device is interrupted	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.11.8		2023-02-14
		40	Control and instrument accuracy and hazard output protection	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12		2023-02-14
		41	Accuracy of controller and instrument	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.1		2023-02-14
		42	Accuracy of skin temperature sensor	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.1.101		2023-02-14
		43	The accuracy of the distribution of bed surface radiation	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.1.102		2023-02-14
		44	Infantile control mode radiation thermal unit operation accuracy	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.1.103		2023-02-14
		45	Oxygen control	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.1.104		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		46	The weight balance	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.1.105		2023-02-14
		47	availability	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.2		2023-02-14
		48	Availability of the controller	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.2.101		2023-02-14
		49	Availability of run mode	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.2.102		2023-02-14
		50	Time and irradiation limits in manual mode	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.2.103		2023-02-14
		51	Heat output level in preheating mode	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.2.104		2023-02-14
		52	Alarm system	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.3		2023-02-14
		53	Power outage	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.3.101		2023-02-14
		54	Open and short circuit operation of skin temperature sensor in infantile control mode	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.3.102		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			radiation thermal unit			
		55	Manual mode can listen to the sound of the alarm signal pause	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.3.103		2023-02-14
		56	Sound paused	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.3.104		2023-02-14
		57	Test the alarm function	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.3.105		2023-02-14
		58	Indication of safety parameters	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.4.2		2023-02-14
		59	Carbon dioxide (CO2) concentration	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.12.4.2.101		2023-02-14
		60	ME Device danger status and fault status	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.13		2023-02-14
		61	Programmable Medical Electrical System (PEMS)	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.14		2023-02-14
		62	ME device structure	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.15		2023-02-14
		63	Rough handling test	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.15.3.5		
		64	Connector construction	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.15.4.1		2023-02-14
		65	Connector for temperature sensor	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.15.4.1.101		2023-02-14
		66	Application	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.15.4.2.1		2023-02-14
		67	Temperature setting	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.15.4.2.2		2023-02-14
		68	Control temperature range	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.15.4.2.2.101		2023-02-14
		69	The ME system	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.16		2023-02-14
		70	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 201.17	See 9706.102	2023-02-14
		71	Electromagnetic compatibility - Requirements and tests	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 202	See 9706.102	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		72	Immunity test level	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 202.6.2.3	See 9706.102	2023-02-14
		73	Requirements	Medical electrical equipment—Part 2-21: Particular requirements for thebasic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009 + AMD1 ： 2016 202.6.2.3.1	See 9706.102	2023-02-14
189	Pneumatic impulse oscillation equipment for sputum excretion	1	All Parameters	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020		2023-02-14
		2	Pneumatic frequency setting upper limit and output accuracy	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.1		2023-02-14
		3	Pneumatic pressure safety and effective range and output accuracy	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.2		2023-02-14
		4	Working noise	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.3		2023-02-14
		5	Treatment time	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.4		2023-02-14
		6	Requirements for inflatable airbags and air delivery hoses	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.5		2023-02-14
		7	Specifications and dimensions of inflatable airbag	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.5.1		2023-02-14
		8	The maximum atmospheric pressure tolerance	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.5.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			of an inflatable air bag			
		9	Connection reliability of air hose	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.5.3		2023-02-14
		10	Fixed mode output	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.6		2023-02-14
		11	Equipment function	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.7		2023-02-14
		12	Power adaptability	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.8		2023-02-14
		13	Biocompatibility	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.9		2023-02-14
		14	Appearance	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.10		2023-02-14
		15	Specification requirements	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.11		2023-02-14
		16	Electrical safety	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.12		2023-02-14
		17	Electromagnetic compatibility	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.13		2023-02-14
		18	Environmental testing	Pneumatic impulse oscillation equipment for sputum excretion YY/T 1685-2020 5.14		2023-02-14
190	Class Ⅱ biological safety cabinets	1	All Parameters	Guide for the check of medical class Ⅱ biological safety cabinets YY/T 1540-2017		2023-02-14
		2	Acceptance check	Guide for the check of medical class Ⅱ biological safety cabinets YY/T 1540-2017 4.1		2023-02-14
		3	Patrol inspection	Guide for the check of medical class Ⅱ biological safety cabinets YY/T 1540-2017 4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	The annual verification	Guide for the check of medical class Ⅱ biological safety cabinets YY/T 1540-2017 4.3		2023-02-14
		5	Verification records	Guide for the check of medical class Ⅱ biological safety cabinets YY/T 1540-2017 4.4		2023-02-14
		6	Verification conclusion	Guide for the check of medical class Ⅱ biological safety cabinets YY/T 1540-2017 4.5		2023-02-14
191	Medical clean bench	1	All Parameters	Medical clean bench YY/T 1539-2017		2023-02-14
		2	Appearance	Medical clean bench YY/T 1539-2017 5.1		2023-02-14
		3	Material	Medical clean bench YY/T 1539-2017 5.2		2023-02-14
		4	Structure	Medical clean bench YY/T 1539-2017 5.3		2023-02-14
		5	Enclosure	Medical clean bench YY/T 1539-2017 5.3.1		2023-02-14
		6	Window operating port (if available)	Medical clean bench YY/T 1539-2017 5.3.2		2023-02-14
		7	Working surface	Medical clean bench YY/T 1539-2017 5.3.3		2023-02-14
		8	Support feet and casters	Medical clean bench YY/T 1539-2017 5.3.4		2023-02-14
		9	Collecting tank (if available)	Medical clean bench YY/T 1539-2017 5.3.5		2023-02-14
		10	The motor	Medical clean bench YY/T 1539-2017 5.3.7		2023-02-14
		11	Sampling mouth	Medical clean bench YY/T 1539-2017 5.3.8		2023-02-14
		12	Glass window operating port alarm system	Medical clean bench YY/T 1539-2017 5.3.9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Clean ability	Medical clean bench YY/T 1539-2017 5.3.11		2023-02-14
		14	Performance	Medical clean bench YY/T 1539-2017 5.4		2023-02-14
		15	Vibration	Medical clean bench YY/T 1539-2017 5.4.4		2023-02-14
		16	Stability	Medical clean bench YY/T 1539-2017 5.4.9		2023-02-14
		17	The box body resists tipping	Medical clean bench YY/T 1539-2017 5.4.9.1		2023-02-14
		18	Work table is deformable	Medical clean bench YY/T 1539-2017 5.4.9.2		2023-02-14
		19	Temperature rise	Medical clean bench YY/T 1539-2017 5.4.10		2023-02-14
		20	Electrical safety	Medical clean bench YY/T 1539-2017 5.4.12		2023-02-14
192	Surgical luminaires and luminaires for diagnosis.	1	All Parameters	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. YY 9706.241-2020		2023-02-14
		2	General requirements	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.4		2023-02-14
		3	Basic performance	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.4.3		2023-02-14
		4	General requirements for ME equipment testing	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Other conditions	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.5.4		2023-02-14
		6	Test sequence	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.5.8		2023-02-14
		7	Classification of ME devices and ME systems	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.6		2023-02-14
		8	Protection against electric shock	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.6.2		2023-02-14
		9	The operation mode	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.6.6		2023-02-14
		10	ME Device identification, tags, and files	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.7		2023-02-14
		11	External markings for ME devices or parts of ME devices	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.7.2		2023-02-14
		12	Connection to the power grid	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.7.2.101		
		13	Internal markings for ME devices or parts of ME devices	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.7.3		2023-02-14
		14	Light source marking	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.7.3.101		2023-02-14
		15	Operating instruction	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.7.9.2		2023-02-14
		16	An overview of the	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.7.9.2.1		2023-02-14
		17	Warnings and safety instructions	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.7.9.2.2		2023-02-14
		18	Cleaning, disinfection and sterilization	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.7.9.2.12		2023-02-14
		19	ME device protection against click hazards (sources)	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		20	Potential equalizing conductor	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.8.6.7		2023-02-14
		21	Network power supply parts, components and wiring	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.8.11		2023-02-14
		22	Disconnection from the power grid	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.8.11.1		2023-02-14
		23	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.9		2023-02-14
		24	Mechanical hazards associated with moving parts	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.9.2		2023-02-14
		25	Detachable handle	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.9.2.101		2023-02-14
		26	Risk of instability (source)	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.9.4		2023-02-14
		27	Mobility flexibility	Medical electrical equipment- Part 2-41 : Particular requirements		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			and stability	for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.9.4.2.2.101		
		28	Splash hazard (Source)	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.9.5		2023-02-14
		29	Protective measures	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.9.5.1		2023-02-14
		30	The ME equipment	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.9.5.1.101		2023-02-14
		31	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.10		2023-02-14
		32	Ultraviolet radiation	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.10.7		2023-02-14
		33	Protection against hyperthermia and other hazards (sources)	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.11		2023-02-14
		34	ME Device overtemperature	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				201.11.1		
		35	Maximum temperature in normal use	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.11.1.1		2023-02-14
		36	Protection	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.11.1.4		2023-02-14
		37	The power supply/power grid of the ME device is interrupted	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.11.8		2023-02-14
		38	Control and instrument accuracy and hazard output protection	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.12		2023-02-14
		39	Accuracy of controller and instrument	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.12.1		2023-02-14
		40	Overview	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.12.1.101		2023-02-14
		41	Lighting features	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.12.1.102		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		42	Intensity of illumination	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.12.1.102.1		2023-02-14
		43	General requirements	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.12.1.102.1.1		2023-02-14
		44	Spectral characteristics	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.12.1.102.2		2023-02-14
		45	General requirements	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.12.1.102.2.2.1		2023-02-14
		46	The temperature of the exposed surface rises	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.12.1.102.3		2023-02-14
		47	General requirements	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.12.1.102.3.1		2023-02-14
		48	Security features	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.12.1.102.4		2023-02-14
		49	ME Device danger status and fault	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			status	luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.13		
		50	Specific hazardous situations	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.13.1		2023-02-14
		51	Hazard situations associated with fail-safe equipment	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.13.1.101		2023-02-14
		52	Programmable Medical Electrical System (PEMS)	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.14		2023-02-14
		53	ME device structure	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.15		2023-02-14
		54	Mechanical strength	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.15.3		2023-02-14
		55	Overview	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.15.3.1		2023-02-14
		56	The ME system	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.16		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		57	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment- Part 2-41 : Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. IEC 60601-2-41:2013 201.17		2023-02-14
193	Interferential current therapy instrument	1	All Parameters	Interferential current therapy instrument YY/T 0951-2015		2023-02-14
		2	Requirements	Interferential current therapy instrument YY/T 0951-2015 5		2023-02-14
		3	The working conditions	Interferential current therapy instrument YY/T 0951-2015 5.1		2023-02-14
		4	Working frequency	Interferential current therapy instrument YY/T 0951-2015 5.2		2023-02-14
		5	Output current (R.M.S)	Interferential current therapy instrument YY/T 0951-2015 5.3		2023-02-14
		6	Current rate of change under different loads	Interferential current therapy instrument YY/T 0951-2015 5.4		2023-02-14
		7	Modulation frequency	Interferential current therapy instrument YY/T 0951-2015 5.5		2023-02-14
		8	Adjustable amplitude	Interferential current therapy instrument YY/T 0951-2015 5.6		2023-02-14
		9	Differential frequency	Interferential current therapy instrument YY/T 0951-2015 5.7		2023-02-14
		10	Difference frequency change period (if applicable)	Interferential current therapy instrument YY/T 0951-2015 5.8		2023-02-14
		11	Dynamic rhythm (if applicable)	Interferential current therapy instrument YY/T 0951-2015 5.9		2023-02-14
		12	Timing device	Interferential current therapy instrument YY/T 0951-2015 5.10		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Electrode	Interferential current therapy instrument YY/T 0951-2015 5.11		2023-02-14
		14	The performance requirements	Interferential current therapy instrument YY/T 0951-2015 5.11.1	See YY0868	2023-02-14
		15	Current density	Interferential current therapy instrument YY/T 0951-2015 5.11.2		2023-02-14
		16	Suction	Interferential current therapy instrument YY/T 0951-2015 5.12		2023-02-14
		17	Noise	Interferential current therapy instrument YY/T 0951-2015 5.13		2023-02-14
		18	Appearance	Interferential current therapy instrument YY/T 0951-2015 5.14		2023-02-14
		19	Operating instruction	Interferential current therapy instrument YY/T 0951-2015 5.15		2023-02-14
		20	Safety requirements	Interferential current therapy instrument YY/T 0951-2015 5.16	See GB 9706.1-2020、YY9706.210-2021	2023-02-14
		21	Environmental test requirements	Interferential current therapy instrument YY/T 0951-2015 5.17		2023-02-14
		22	Biocompatibility	Interferential current therapy instrument YY/T 0951-2015 5.18	See GB/T 16886.1	2023-02-14
		23	Electromagnetic Compatibility Requirements	Interferential current therapy instrument YY/T 0951-2015 5.19	See YY 9706.102	2023-02-14
		24	Logo, instruction manual	Interferential current therapy instrument YY/T 0951-2015 8		2023-02-14
		25	Mark	Interferential current therapy instrument YY/T 0951-2015 8.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		26	Nameplate	Interferential current therapy instrument YY/T 0951-2015 8.1.1		2023-02-14
		27	The outer packing	Interferential current therapy instrument YY/T 0951-2015 8.1.2		2023-02-14
		28	Product inspection certificate	Interferential current therapy instrument YY/T 0951-2015 8.1.3		2023-02-14
		29	Labels, markings, and symbols that provide information	Interferential current therapy instrument YY/T 0951-2015 8.1.4		2023-02-14
		30	Operating instruction	Interferential current therapy instrument YY/T 0951-2015 8.2		2023-02-14
		31	Packing, transportation and storage	Interferential current therapy instrument YY/T 0951-2015 9		2023-02-14
		32	Packaging	Interferential current therapy instrument YY/T 0951-2015 9.1		2023-02-14
		33	Transport	Interferential current therapy instrument YY/T 0951-2015 9.2		2023-02-14
		34	Storage	Interferential current therapy instrument YY/T 0951-2015 9.3		2023-02-14
194	Electric heating moxibustion equipment	1	All Parameters	Electric heating moxibustion equipment YY/T 1490-2016		2023-02-14
		2	Requirements	Electric heating moxibustion equipment YY/T 1490-2016 5		2023-02-14
		3	Treatment temperature	Electric heating moxibustion equipment YY/T 1490-2016 5.1		2023-02-14
		4	Timing function	Electric heating moxibustion equipment YY/T 1490-2016 5.2		2023-02-14
		5	Working noise	Electric heating moxibustion equipment YY/T 1490-2016 5.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Other features	Electric heating moxibustion equipment YY/T 1490-2016 5.4		2023-02-14
		7	The area size of moxibustion head and moxibustion pad	Electric heating moxibustion equipment YY/T 1490-2016 5.5		2023-02-14
		8	Other requirements for moxibustion pads	Electric heating moxibustion equipment YY/T 1490-2016 5.6		2023-02-14
		9	Biocompatibility	Electric heating moxibustion equipment YY/T 1490-2016 5.7	See GB/T 16886.1	2023-02-14
		10	Operating instruction	Electric heating moxibustion equipment YY/T 1490-2016 5.8		2023-02-14
		11	Appearance	Electric heating moxibustion equipment YY/T 1490-2016 5.9		2023-02-14
		12	Safety requirements	Electric heating moxibustion equipment YY/T 1490-2016 5.10	See GB 9706.1-2020	2023-02-14
		13	Electromagnetic compatibility	Electric heating moxibustion equipment YY/T 1490-2016 5.11	See YY 9706.102	2023-02-14
		14	Environmental test requirements	Electric heating moxibustion equipment YY/T 1490-2016 5.12		2023-02-14
		15	Signs, labels, operating instructions	Electric heating moxibustion equipment YY/T 1490-2016 8		2023-02-14
		16	Mark	Electric heating moxibustion equipment YY/T 1490-2016 8.1		2023-02-14
		17	Nameplate	Electric heating moxibustion equipment YY/T 1490-2016 8.1.1		2023-02-14
		18	The outer packing	Electric heating moxibustion equipment YY/T 1490-2016 8.1.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	Certificate of approval	Electric heating moxibustion equipment YY/T 1490-2016 8.1.3		2023-02-14
		20	Labels, markings, and symbols that provide information	Electric heating moxibustion equipment YY/T 1490-2016 8.1.4		2023-02-14
		21	Operating instruction	Electric heating moxibustion equipment YY/T 1490-2016 8.2		2023-02-14
		22	Packing, transportation and storage	Electric heating moxibustion equipment YY/T 1490-2016 9		2023-02-14
		23	Packaging	Electric heating moxibustion equipment YY/T 1490-2016 9.1		2023-02-14
		24	Transport	Electric heating moxibustion equipment YY/T 1490-2016 9.2		2023-02-14
		25	Storage	Electric heating moxibustion equipment YY/T 1490-2016 9.3		2023-02-14
195	Intradermal needlles	1	All Parameters	Intradermal needlles YY/T 0105-2020		2023-02-14
		2	Structure, classification and specification	Intradermal needlles YY/T 0105-2020 4		2023-02-14
		3	Structure	Intradermal needlles YY/T 0105-2020 4.1		2023-02-14
		4	Classification	Intradermal needlles YY/T 0105-2020 4.2		2023-02-14
		5	Specifications and Materials	Intradermal needlles YY/T 0105-2020 4.3		2023-02-14
		6	Requirements	Intradermal needlles YY/T 0105-2020 5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Size	Intradermal needlles YY/T 0105-2020 5.1		2023-02-14
		8	Tip strength and sharpness	Intradermal needlles YY/T 0105-2020 5.2		2023-02-14
		9	The needle body hardness	Intradermal needlles YY/T 0105-2020 5.3		2023-02-14
		10	Surface roughness	Intradermal needlles YY/T 0105-2020 5.4		2023-02-14
		11	Corrosion resistance	Intradermal needlles YY/T 0105-2020 5.5		2023-02-14
		12	Firmness of needle body and needle handle	Intradermal needlles YY/T 0105-2020 5.6		2023-02-14
		13	Sterile	Intradermal needlles YY/T 0105-2020 5.7	See GB/T 16886.1	2023-02-14
		14	Biocompatibility	Intradermal needlles YY/T 0105-2020 5.8	See GB/T 16886.1	2023-02-14
		15	Appearance	Intradermal needlles YY/T 0105-2020 5.9		2023-02-14
196	Manual negative pressure cupping apparatus	1	All Parameters	Manual negative pressure cupping apparatus YY/T 1624-2019		2023-02-14
		2	Classification and Composition	Manual negative pressure cupping apparatus YY/T 1624-2019 4		2023-02-14
		3	Requirements	Manual negative pressure cupping apparatus YY/T 1624-2019 5		2023-02-14
		4	Basic size of tank	Manual negative pressure cupping apparatus YY/T 1624-2019 5.1		2023-02-14
		5	Appearance	Manual negative pressure cupping apparatus YY/T 1624-2019 5.2		2023-02-14
		6	Negative pressure limit in normal use	Manual negative pressure cupping apparatus YY/T 1624-2019 5.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Suction cupping device negative pressure requirements	Manual negative pressure cupping apparatus YY/T 1624-2019 5.3.1		2023-02-14
		8	Rotary cupping machine negative pressure requirements	Manual negative pressure cupping apparatus YY/T 1624-2019 5.3.2		2023-02-14
		9	The sealing performance	Manual negative pressure cupping apparatus YY/T 1624-2019 5.4		2023-02-14
		10	Air tightness of suction cupping machine tank body in use	Manual negative pressure cupping apparatus YY/T 1624-2019 5.4.1		2023-02-14
		11	Air tightness during use of rotary cupping machine	Manual negative pressure cupping apparatus YY/T 1624-2019 5.4.2		2023-02-14
		12	Air tightness of extraction device	Manual negative pressure cupping apparatus YY/T 1624-2019 5.4.3		2023-02-14
		13	Negative pressure strength	Manual negative pressure cupping apparatus YY/T 1624-2019 5.5		2023-02-14
		14	Suction cupping device tank body negative pressure strength	Manual negative pressure cupping apparatus YY/T 1624-2019 5.5.1		2023-02-14
		15	Negative pressure strength of rotary cupping machine	Manual negative pressure cupping apparatus YY/T 1624-2019 5.5.2		2023-02-14
		16	Falling strength	Manual negative pressure cupping apparatus YY/T 1624-2019 5.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	The suction flatness of the connection hose	Manual negative pressure cupping apparatus YY/T 1624-2019 5.7		2023-02-14
		18	Tank negative pressure elimination function	Manual negative pressure cupping apparatus YY/T 1624-2019 5.8		2023-02-14
		19	Ability to resist cleaning and disinfection	Manual negative pressure cupping apparatus YY/T 1624-2019 5.9		2023-02-14
		20	Biocompatibility	Manual negative pressure cupping apparatus YY/T 1624-2019 5.10	See GB/T 16886.1	2023-02-14
		21	External identification of tank body	Manual negative pressure cupping apparatus YY/T 1624-2019 5.11		2023-02-14
		22	Specification requirements	Manual negative pressure cupping apparatus YY/T 1624-2019 5.12		2023-02-14
197	Co-60 teletherapy unit	1	All Parameters	Co-60 teletherapy unit YY 0096-2019		2023-02-14
		2	Requirements	Interferential current therapy instrument YY 0096-2019 4		2023-02-14
		3	Environmental conditions	Interferential current therapy instrument YY 0096-2019 4.1		2023-02-14
		4	performance	Interferential current therapy instrument YY 0096-2019 4.2		2023-02-14
		5	Error of isocentric position	Interferential current therapy instrument YY 0096-2019 4.2.1		2023-02-14
		6	The trimmed penumbra width	Interferential current therapy instrument YY 0096-2019 4.2.2		2023-02-14
		7	Collimator beam axis	Interferential current therapy instrument YY 0096-2019 4.2.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Deviation of optical field boundary	Interferential current therapy instrument YY 0096-2019 4.2.4		2023-02-14
		9	The deviation between the optical field boundary and the radiation field boundary	Interferential current therapy instrument YY 0096-2019 4.2.5		2023-02-14
		10	The specific release kinetic energy rate of useful gamma rays in the radiation field is not symmetrical	Interferential current therapy instrument YY 0096-2019 4.2.6		2023-02-14
		11	Radiation head	Interferential current therapy instrument YY 0096-2019 4.2.7		2023-02-14
		12	Display of radiation fields	Interferential current therapy instrument YY 0096-2019 4.2.8		2023-02-14
		13	Display of source skin distance	Interferential current therapy instrument YY 0096-2019 4.2.9		2023-02-14
		14	Treatment bed exercise	Interferential current therapy instrument YY 0096-2019 4.2.10		2023-02-14
		15	General requirements	Interferential current therapy instrument YY 0096-2019 4.2.10.1		2023-02-14
		16	Vertical movement of treatment bed	Interferential current therapy instrument YY 0096-2019 4.2.10.2		2023-02-14
		17	Isocentric rotation of treatment bed	Interferential current therapy instrument YY 0096-2019 4.2.10.3		2023-02-14
		18	Stiffness of treatment bed	Interferential current therapy instrument YY 0096-2019 4.2.10.4		2023-02-14
		19	Longitudinal	Interferential current therapy instrument YY 0096-2019		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			stiffness of treatment bed	4.2.10.4.1		
		20	Lateral stiffness of treatment bed	Interferential current therapy instrument YY 0096-2019 4.2.10.4.2		2023-02-14
		21	Absorbed dose rate	Interferential current therapy instrument YY 0096-2019 4.2.11		2023-02-14
		22	Electrical safety	Interferential current therapy instrument YY 0096-2019 4.3	See GB9706.1 YY 9706.102 GB9706.21 1YY0637	2023-02-14
198	Multi-source stereotactic radiotherapy system with gamma beam for head lesion	1	All Parameters	Stereotactic radiotherapy system with gamma beam-Part 1: Multi-source stereotactic radiotherapy system with gamma beam for head lesion YY0831.1-2011		2023-02-14
		2	Requirements	Stereotactic radiotherapy system with gamma beam-Part 1: Multi-source stereotactic radiotherapy system with gamma beam for head lesion YY0831.1-2011 4		2023-02-14
		3	Coordinate system	Stereotactic radiotherapy system with gamma beam-Part 1: Multi-source stereotactic radiotherapy system with gamma beam for head lesion YY0831.1-2011 4.1		2023-02-14
		4	Random file	Stereotactic radiotherapy system with gamma beam-Part 1: Multi-source stereotactic radiotherapy system with gamma beam for head lesion YY0831.1-2011 4.2		2023-02-14
		5	Focal nominal absorbed dose rate	Stereotactic radiotherapy system with gamma beam-Part 1: Multi-source stereotactic radiotherapy system with gamma beam for head lesion YY0831.1-2011 4.3		2023-02-14
		6	Focusing field size	Stereotactic radiotherapy system with gamma beam-Part 1: Multi-source stereotactic radiotherapy system with gamma beam for head lesion YY0831.1-2011 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Focus field dose gradient	Stereotactic radiotherapy system with gamma beam-Part 1: Multi-source stereotactic radiotherapy system with gamma beam for head lesion YY0831.1-2011 4.5		2023-02-14
		8	Locate the reference point deviation	Stereotactic radiotherapy system with gamma beam-Part 1: Multi-source stereotactic radiotherapy system with gamma beam for head lesion YY0831.1-2011 4.6		2023-02-14
		9	Comprehensive error of dose calculation	Stereotactic radiotherapy system with gamma beam-Part 1: Multi-source stereotactic radiotherapy system with gamma beam for head lesion YY0831.1-2011 4.7		2023-02-14
		10	Location error of treatment plan reference point	Stereotactic radiotherapy system with gamma beam-Part 1: Multi-source stereotactic radiotherapy system with gamma beam for head lesion YY0831.1-2011 4.8		2023-02-14
		11	Safety requirements	Stereotactic radiotherapy system with gamma beam-Part 1: Multi-source stereotactic radiotherapy system with gamma beam for head lesion YY0831.1-2011 4.9	See GB9706.1 YY 9706.102 GB9706.21 1YY0637	2023-02-14
199	Multi- Source stereotactic radiotherapy system with gamma beam for body lesion	1	All Parameters	Stereotactic radiotherapy system with gamma beam-Part 2 :Multi- Source stereotactic radiotherapy system with gamma beam for body lesion YY0831.2-2015		2023-02-14
		2	Requirements	Stereotactic radiotherapy system with gamma beam-Part 2 :Multi- Source stereotactic radiotherapy system with gamma beam for body lesion YY0831.2-2015 4		2023-02-14
		3	Coordinate system	Stereotactic radiotherapy system with gamma beam-Part 2 :Multi- Source stereotactic radiotherapy system with gamma beam for body lesion YY0831.2-2015 4.1		2023-02-14
		4	Random file	Stereotactic radiotherapy system with gamma beam-Part 2 :Multi- Source stereotactic radiotherapy system with gamma beam for body lesion YY0831.2-2015 4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Focal nominal absorbed dose rate	Stereotactic radiotherapy system with gamma beam-Part 2 :Multi- Source stereotactic radiotherapy system with gamma beam for body lesion YY0831.2-2015 4.3		2023-02-14
		6	Focusing field size	Stereotactic radiotherapy system with gamma beam-Part 2 :Multi- Source stereotactic radiotherapy system with gamma beam for body lesion YY0831.2-2015 4.4		2023-02-14
		7	Focus field dose gradient	Stereotactic radiotherapy system with gamma beam-Part 2 :Multi- Source stereotactic radiotherapy system with gamma beam for body lesion YY0831.2-2015 4.5		2023-02-14
		8	Locate the reference point deviation	Stereotactic radiotherapy system with gamma beam-Part 2 :Multi- Source stereotactic radiotherapy system with gamma beam for body lesion YY0831.2-2015 4.6		2023-02-14
		9	Comprehensive error of dose calculation	Stereotactic radiotherapy system with gamma beam-Part 2 :Multi- Source stereotactic radiotherapy system with gamma beam for body lesion YY0831.2-2015 4.7		2023-02-14
		10	Treatment plan software 3d image reconstruction position error	Stereotactic radiotherapy system with gamma beam-Part 2 :Multi- Source stereotactic radiotherapy system with gamma beam for body lesion YY0831.2-2015 4.8		2023-02-14
		11	Safety requirements	Stereotactic radiotherapy system with gamma beam-Part 2 :Multi- Source stereotactic radiotherapy system with gamma beam for body lesion YY0831.2-2015 4.9	See GB9706.1 YY 9706.102 GB9706.21 1 YY0637	2023-02-14
200	Blood irradiator	1	All Parameters	Blood irradiator YY/T0848-2011		2023-02-14
		2	Requirements	Blood irradiator YY/T0848-2011 4		2023-02-14
		3	Random file	Blood irradiator YY/T0848-2011 4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Identification, marking	Blood irradiator YY/T0848-2011 4.2		2023-02-14
		5	Irradiation dose	Blood irradiator YY/T0848-2011 4.3		2023-02-14
		6	Reference point absorbed dose	Blood irradiator YY/T0848-2011 4.3.1		2023-02-14
		7	Uniformity of absorbed dose in sample container	Blood irradiator YY/T0848-2011 4.3.2		2023-02-14
		8	Irradiation time	Blood irradiator YY/T0848-2011 4.4		2023-02-14
		9	Normal use and protection under normal conditions	Blood irradiator YY/T0848-2011 4.5		2023-02-14
		10	Stray radiation	Blood irradiator YY/T0848-2011 4.5.1		2023-02-14
		11	Indication of irradiator operating status	Blood irradiator YY/T0848-2011 4.5.2		2023-02-14
		12	Irradiation time/dose	Blood irradiator YY/T0848-2011 4.5.3		2023-02-14
		13	Control dose counting device/timer	Blood irradiator YY/T0848-2011 4.5.4		2023-02-14
		14	Dose/time display	Blood irradiator YY/T0848-2011 4.5.4.1		2023-02-14
		15	Counter direction	Blood irradiator YY/T0848-2011 4.5.4.2		2023-02-14
		16	Storage and protection of information	Blood irradiator YY/T0848-2011 4.5.4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	Irradiation control	Blood irradiator YY/T0848-2011 4.5.5		2023-02-14
		18	Protection against abnormal use	Blood irradiator YY/T0848-2011 4.6		2023-02-14
		19	Protection under single failure condition in normal use	Blood irradiator YY/T0848-2011 4.7		2023-02-14
		20	Protection of network power supply failure	Blood irradiator YY/T0848-2011 4.7.1		2023-02-14
		21	Control dose-counting unit/timer protection during malfunctions	Blood irradiator YY/T0848-2011 4.7.2		2023-02-14
		22	Protection against failure of source drive mechanism	Blood irradiator YY/T0848-2011 4.7.3		2023-02-14
		23	Validity of information on continued radiation exposure	Blood irradiator YY/T0848-2011 4.7.4		2023-02-14
		24	Indication of the state of a single failure	Blood irradiator YY/T0848-2011 4.7.5		2023-02-14
		25	Environmental testing	Blood irradiator YY/T0848-2011 4.8	See GB/T14710	2023-02-14
		26	Electrical safety	Blood irradiator YY/T0848-2011 4.9	See 9706.1 or 4793.1	2023-02-14
201	External	1	All Parameters	Commissioning of radiotherapytreatment planning systems-		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	irradiation therapy technique			testing for typical externai Beamtreatment techniques YY/T0895-2013		
		2	Clinical commissioning test	Commissioning of radiotherapytreatment planning systems-testing for typical externai Beamtreatment techniques YY/T0895-2013 4		2023-02-14
		3	Overview	Commissioning of radiotherapytreatment planning systems-testing for typical externai Beamtreatment techniques YY/T0895-2013 4.1		2023-02-14
		4	Acceptance test	Commissioning of radiotherapytreatment planning systems-testing for typical externai Beamtreatment techniques YY/T0895-2013 4.1.1		2023-02-14
		5	Beam fitting	Commissioning of radiotherapytreatment planning systems-testing for typical externai Beamtreatment techniques YY/T0895-2013 4.1.2		2023-02-14
		6	Phantom for clinical commissioning testing	Commissioning of radiotherapytreatment planning systems-testing for typical externai Beamtreatment techniques YY/T0895-2013 4.2		2023-02-14
		7	Description of clinical commissioning test cases	Commissioning of radiotherapytreatment planning systems-testing for typical externai Beamtreatment techniques YY/T0895-2013 4.3		2023-02-14
		8	Overview	Commissioning of radiotherapytreatment planning systems-testing for typical externai Beamtreatment techniques YY/T0895-2013 4.3.1		2023-02-14
		9	Test cases for dissection and input	Commissioning of radiotherapytreatment planning systems-testing for typical externai Beamtreatment techniques YY/T0895-2013 4.3.2		2023-02-14
		10	Dosimetry test case	Commissioning of radiotherapytreatment planning systems-testing for typical externai Beamtreatment techniques YY/T0895-2013 4.3.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
202	Radiotherapy film	1	All Parameters	Film dose measurement methods used in radiation therapy YY/T1548-2017		2023-02-14
		2	Apparatus and conditions for film dosimetry for radiotherapy	Film dose measurement methods used in radiation therapy YY/T1548-2017 4		2023-02-14
		3	Film	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.1		2023-02-14
		4	Common types of film	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.1.1		2023-02-14
		5	Film choice	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.1.2		2023-02-14
		6	The film cut	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.1.3		2023-02-14
		7	Film digitizer	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.2		2023-02-14
		8	An overview of the	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.2.1		2023-02-14
		9	Light source choice	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.2.2		2023-02-14
		10	Characteristics of light detectors	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.2.3		2023-02-14
		11	Spatial resolution	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.2.4		2023-02-14
		12	Location accuracy	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.2.5		2023-02-14
		13	Acquisition time	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.2.6		2023-02-14
		14	The choice of digitizer	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.2.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Acceptance testing and quality assurance for scanners and densitometers	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.2.8		2023-02-14
		16	Film scanning software	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.3		2023-02-14
		17	Die body	Film dose measurement methods used in radiation therapy YY/T1548-2017 4.4		2023-02-14
		18	Parameter measurement and adjustment	Film dose measurement methods used in radiation therapy YY/T1548-2017 5		2023-02-14
		19	Blank film scanning	Film dose measurement methods used in radiation therapy YY/T1548-2017 5.1		2023-02-14
		20	Medium large (size) film scan	Film dose measurement methods used in radiation therapy YY/T1548-2017 5.2		2023-02-14
		21	Extreme large (size) film scanning	Film dose measurement methods used in radiation therapy YY/T1548-2017 5.3		2023-02-14
		22	Pixel value and standard deviation	Film dose measurement methods used in radiation therapy YY/T1548-2017 5.4		2023-02-14
		23	Film dosimetry process	Film dose measurement methods used in radiation therapy YY/T1548-2017 5.5		2023-02-14
		24	Dose response calibration	Film dose measurement methods used in radiation therapy YY/T1548-2017 6		2023-02-14
		25	Determination of factory dose range	Film dose measurement methods used in radiation therapy YY/T1548-2017 6.1		2023-02-14
		26	Selection of irradiation method and dose	Film dose measurement methods used in radiation therapy YY/T1548-2017 6.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		27	Dose the reference	Film dose measurement methods used in radiation therapy YY/T1548-2017 6.3		2023-02-14
		28	Dose-response calibration of film scans	Film dose measurement methods used in radiation therapy YY/T1548-2017 6.4		2023-02-14
		29	Establish optical density - dose calibration table	Film dose measurement methods used in radiation therapy YY/T1548-2017 6.5		2023-02-14
		30	Establish optical density-dose calibration curves or formulas	Film dose measurement methods used in radiation therapy YY/T1548-2017 6.6		2023-02-14
		31	Precautions during calibration	Film dose measurement methods used in radiation therapy YY/T1548-2017 6.7		2023-02-14
		32	Post-irradiation processing and preservation of film	Film dose measurement methods used in radiation therapy YY/T1548-2017 7		2023-02-14
		33	Post-irradiation treatment and washing	Film dose measurement methods used in radiation therapy YY/T1548-2017 7.1		2023-02-14
		34	Best time to read film information	Film dose measurement methods used in radiation therapy YY/T1548-2017 7.2		2023-02-14
		35	Transportation and storage	Film dose measurement methods used in radiation therapy YY/T1548-2017 7.3		2023-02-14
		36	Ultraviolet light	Film dose measurement methods used in radiation therapy YY/T1548-2017 7.4		2023-02-14
203	Radiotherapy	1	All Parameters	Gating interface used in radiation therapy YY/T1711-2020		2023-02-14
		2	Requirements and	Gating interface used in radiation therapy YY/T1711-2020 4		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			test methods			
		3	Electrical interface	Gating interface used in radiation therapy YY/T1711-2020 4.1		2023-02-14
		4	Conditions under which the beam termination function works properly	Gating interface used in radiation therapy YY/T1711-2020 4.2		2023-02-14
		5	The delay time of the beam holding switching action	Gating interface used in radiation therapy YY/T1711-2020 4.3		2023-02-14
		6	Gating time	Gating interface used in radiation therapy YY/T1711-2020 4.4		2023-02-14
		7	Error handling and recovery	Gating interface used in radiation therapy YY/T1711-2020 4.5		2023-02-14
		8	TDD error logs	Gating interface used in radiation therapy YY/T1711-2020 4.5.1		2023-02-14
		9	PPMS failsafe protection	Gating interface used in radiation therapy YY/T1711-2020 4.5.2		2023-02-14
		10	Basic operations and basic performance	Gating interface used in radiation therapy YY/T1711-2020 4.6		2023-02-14
204	Stethoscope	1	All Parameters	Stethoscope YY/T 1035-2021		2023-02-14
		2	Requirements	Stethoscope YY/T 1035-2021 4		2023-02-14
		3	Appearance and structure requirements	Stethoscope YY/T 1035-2021 4.1		2023-02-14
		4	Acoustic characteristics of	Stethoscope YY/T 1035-2021 4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			stethoscope			
		5	Listening to the human ear	Stethoscope YY/T 1035-2021 4.2.1		2023-02-14
		6	Frequency response curve of acoustic attenuation stethoscope	Stethoscope YY/T 1035-2021 4.2.2		2023-02-14
		7	Electroacoustic characteristics of acoustic gain stethoscope	Stethoscope YY/T 1035-2021 4.2.3		2023-02-14
		8	Output sound pressure level	Stethoscope YY/T 1035-2021 4.2.3.1		2023-02-14
		9	Equivalent input noise level	Stethoscope YY/T 1035-2021 4.2.3.2		2023-02-14
		10	Total harmonic distortion	Stethoscope YY/T 1035-2021 4.2.3.3		2023-02-14
		11	Stethoscope earrings required	Stethoscope YY/T 1035-2021 4.3		2023-02-14
		12	Sound connection catheter requirements	Stethoscope YY/T 1035-2021 4.4		2023-02-14
		13	Safety requirements	Stethoscope YY/T 1035-2021 4.5	See GB9706.1	2023-02-14
		14	Electromagnetic compatibility	Stethoscope YY/T 1035-2021 4.6	See YY9706.102	2023-02-14
		15	Biocompatibility	Stethoscope YY/T 1035-2021 4.7	See GB/T 16886	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Environmental adaptability	Stethoscope YY/T 1035-2021 4.8	See GB/T14710	2023-02-14
205	water treatment equipments for haemodialysis applications and related therapies	1	All Parameters	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010		2023-02-14
		2	Requirements	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5		2023-02-14
		3	The working conditions	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.1		2023-02-14
		4	Treatment water quality requirements	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.2		2023-02-14
		5	Microbiological index	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.2.1	See GB/T 5750.2	2023-02-14
		6	Chemical pollutant index	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.2.2	See GB/T 5750.2	2023-02-14
		7	Requirements for water treatment equipment	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3		2023-02-14
		8	Overview	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.1		2023-02-14
		9	Water treatment equipment in general	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Processing process requirements	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.3		2023-02-14
		11	Purification system	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.4		2023-02-14
		12	Tank filter	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.4.1		2023-02-14
		13	Filter element type filter	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.4.2		2023-02-14
		14	Softener	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.4.3		2023-02-14
		15	Carbon adsorption tank	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.4.4		2023-02-14
		16	Temperature control device (if available)	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.4.5		2023-02-14
		17	Reverse osmosis unit	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.4.6		2023-02-14
		18	Deionizing device (if available)	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.4.7		2023-02-14
		19	Organic matter removal device (anion exchange	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.4.8		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			resin) (if available)			
		20	Chemical injection unit (if available)	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.4.9		2023-02-14
		21	Storage and delivery system	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.5		2023-02-14
		22	Pure water tank (if any)	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.5.1		2023-02-14
		23	Delivery line	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.5.2		2023-02-14
		24	Ultraviolet disinfection device (if available)	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.5.3		2023-02-14
		25	Endotoxin filter (if available)	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.5.4		2023-02-14
		26	Disinfection system	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.6		2023-02-14
		27	Chemical disinfection device (if any)	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.6.1		2023-02-14
		28	Ozone disinfection unit (if available)	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.6.2		2023-02-14
		29	Thermal	Technical requirements of water treatment equipments for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			disinfection device (if available)	haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.3.6.3		
		30	Electrical requirements	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.4	SeeGB 9706.1 or GB 4793.1	2023-02-14
		31	Material requirements	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.5		2023-02-14
		32	Installation requirements	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.6		2023-02-14
		33	Environmental test requirements	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 5.7		2023-02-14
		34	Mark	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 8.1		2023-02-14
		35	External sign	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 8.1.1		2023-02-14
		36	Packing mark (if any)	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 8.1.2		2023-02-14
		37	Inspection certificate	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 8.1.3		2023-02-14
		38	Operating instruction	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 8.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		39	Packing, transportation and storage	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 9		2023-02-14
		40	Packing (if any)	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 9.1		2023-02-14
		41	Transport	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 9.2		2023-02-14
		42	Storage	Technical requirements of water treatment equipments for haemodialysis applications and related therapies-Part 1: For multi-beds haemodialysis YY 0793.1-2010 9.3		2023-02-14
206	Gamma beam therapy equipment	1	All Parameters	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013		2023-02-14
		2	General requirements	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 4		2023-02-14
		3	General requirements for ME equipment testing	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 5		2023-02-14
		4	Classification of ME devices and ME systems	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 6		2023-02-14
		5	ME device identification, tags, and files	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 7		2023-02-14
		6	ME equipment protection against	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			electric shock hazard	therapy equipment IEC 60601-2-11:2013 8		
		7	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 9		2023-02-14
		8	Protection against unwanted or excessive radiation hazards	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 10		2023-02-14
		9	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 11		2023-02-14
		10	Control and instrument accuracy and hazard output protection	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 12		2023-02-14
		11	ME Device hazard status and fault status	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 13		2023-02-14
		12	Programmable electrical medical system	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 14		2023-02-14
		13	ME device structure	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 15		2023-02-14
		14	The ME system	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 16		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment-Part 2-11:Particular requirements for the basic safety and essential performance of gamma beam therapy equipment IEC 60601-2-11:2013 17	See YY 9706.102	2023-02-14
207	Electron accelerators in the range 1 MeV to 50 MeV	1	All Parameters	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014		2023-02-14
		2	General requirements	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 4		2023-02-14
		3	General requirements for ME equipment testing	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 5		2023-02-14
		4	Classification of ME devices and ME systems	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 6		2023-02-14
		5	ME device identification, tags, and files	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 7		2023-02-14
		6	ME equipment shock hazard protection	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 8		2023-02-14
		7	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 9		2023-02-14
		8	Protection against unwanted or excessive radiation	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 10		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			hazards			
		9	Protection against unwanted or excessive radiation hazards	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 11		2023-02-14
		10	Control and instrument accuracy and hazard output protection	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 12		2023-02-14
		11	ME Device danger and fault conditions	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 13		2023-02-14
		12	Programmable electrical medical system	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 14		2023-02-14
		13	ME device structure	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 15		2023-02-14
		14	The ME system	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 16		2023-02-14
		15	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 17	See YY 9706.102	2023-02-14
		16	Electronic imaging devices (e.g. EPID)	Medical electrical equipment Part 2-1:Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV IEC 60601-2-1:2014 101		2023-02-14
208	Magnetic	1	All Parameters	Medical electrical equipment Part 2-33:Particular requirements		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	resonance equipment for medical diagnosis			for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015		
		2	General requirements	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 4		2023-02-14
		3	General requirements for testing medical devices	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 5		2023-02-14
		4	Classification of medical electrical equipment and systems	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 6		2023-02-14
		5	Identification, marking and documentation of medical electrical equipment	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 7		2023-02-14
		6	Protection against electric shock hazards	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 8	See GB 9706.1-2020	2023-02-14
		7	Protection against mechanical hazards	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 9	See GB 9706.1-2020	2023-02-14
		8	Protection against unnecessary or excessive radiation	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015	See GB 9706.1-2020	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			hazards	10		
		9	Protection against ultra mild and other safety hazards	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 11	See GB 9706.1-2020	2023-02-14
		10	Control accuracy, instrumentation and hazard output prevention	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 12		2023-02-14
		11	Abnormal state of operation or failure	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 13	See GB 9706.1-2020	2023-02-14
		12	Programmable Electrical Medical System (PEMS)	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 14	See GB 9706.1-2020	2023-02-14
		13	ME device structure	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 15	See GB 9706.1-2020	2023-02-14
		14	Medical electrical system	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 16	See GB 9706.1-2020	2023-02-14
		15	Electromagnetic compatibility of medical electrical equipment and systems	Medical electrical equipment Part 2-33:Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601-2-33:2015 17	See YY 9706.102	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
209	Automatically-controlled brachytherapy afterloading equipment	1	All Parameters	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013		2023-02-14
		2	General requirements	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 4		2023-02-14
		3	General requirements for ME equipment testing	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 5		2023-02-14
		4	Classification of ME devices and ME systems	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 6		2023-02-14
		5	ME device identification, tags, and files	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 7		2023-02-14
		6	ME equipment protection against electric shock hazard	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 8		2023-02-14
		7	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 9		2023-02-14
		8	Protection against unwanted or	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			excessive radiation hazards (sources)	controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 10		
		9	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 11		2023-02-14
		10	Control and instrument accuracy and hazard output protection	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 12		2023-02-14
		11	ME Device danger status and fault status	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 13		2023-02-14
		12	Programmable electrical medical system	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 14		2023-02-14
		13	ME device structure	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 15		2023-02-14
		14	The ME system	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 16		2023-02-14
		15	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment Part 2-17:Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2013 17	See YY 9706.102	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
210	Medical electrical device	1	All Parameters	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD		2023-02-14
		2	Conditions for application to ME EQUIPMENT or ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.1		2023-02-14
		3	General requirement for RISK MANAGEMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.2.2		2023-02-14
		4	HAZARDS identified in the IEC 60601-series	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.2.3.1		2023-02-14
		5	HAZARDS not identified in the IEC 60601 series	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.2.3.2		2023-02-14
		6	ESSENTIAL PERFORMANCE	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.3		2023-02-14
		7	EXPECTED SERVICE LIFE	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.4		2023-02-14
		8	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.5		2023-02-14
		9	ME EQUIPMENT or ME SYSTEM parts that contact the	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			PATIENT			
		10	SINGLE FAULT CONDITION for ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.7		2023-02-14
		11	Components of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.8		2023-02-14
		12	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.9		2023-02-14
		13	Source of power for ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.10.1		2023-02-14
		14	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.10.2		2023-02-14
		15	Power input	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 4.11		2023-02-14
		16	Protection against electric shock	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 6.2		2023-02-14
		17	Protection against harmful ingress of	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			water or particulate matter	6.3		
		18	Method(s) of sterilization	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 6.4		2023-02-14
		19	Suitability for use in an OXYGEN RICH ENVIRONMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 6.5		2023-02-14
		20	Mode of operation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 6.6		2023-02-14
		21	Legibility of markings	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.1.2		2023-02-14
		22	Durability of markings	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.1.3		2023-02-14
		23	Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.1		2023-02-14
		24	Identification	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.2		2023-02-14
		25	Consult ACCOMPANYING DOCUMENTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		26	ACCESSORIES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.4		2023-02-14
		27	ME EQUIPMENT intended to receive power from other equipment	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.5		2023-02-14
		28	Connection to the SUPPLY MAINS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.6		2023-02-14
		29	Electrical input power from the SUPPLY MAINS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.7		2023-02-14
		30	Output connectors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.8		2023-02-14
		31	IP classification	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.9		2023-02-14
		32	APPLIED PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.10		2023-02-14
		33	Mode of operation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.11		2023-02-14
		34	Fuses	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.12		2023-02-14
		35	Physiological effects (safety signs	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			and warning statements)	7.2.13		
		36	HIGH VOLTAGE TERMINAL DEVICES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.14		2023-02-14
		37	Cooling conditions	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.15		2023-02-14
		38	Mechanical stability	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.16		2023-02-14
		39	Protective packaging	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.17		2023-02-14
		40	External pressure source	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.18		2023-02-14
		41	FUNCTIONAL EARTH TERMINALS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.19		2023-02-14
		42	Removable protective means	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.20		2023-02-14
		43	Mass of MOBILE ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.2.21		2023-02-14
		44	Heating elements or lampholders	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.3.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		45	HIGH VOLTAGE parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.3.2		2023-02-14
		46	Batteries	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.3.3		2023-02-14
		47	Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.3.4		2023-02-14
		48	PROTECTIVE EARTH TERMINALS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.3.5		2023-02-14
		49	FUNCTIONAL EARTH TERMINALS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.3.6		2023-02-14
		50	Supply terminals	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.3.7		2023-02-14
		51	Temperature of supply terminals	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.3.8		2023-02-14
		52	Power switches	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.4.1		2023-02-14
		53	Control devices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.4.2		2023-02-14
		54	Units of measurement	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				7.4.3		
		55	Safety signs	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.5		2023-02-14
		56	Explanation of symbols	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.6.1		2023-02-14
		57	Symbols from Annex D	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.6.2		2023-02-14
		58	Symbols for controls and performance	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.6.3		2023-02-14
		59	PROTECTIVE EARTH CONDUCTOR	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.7.1		2023-02-14
		60	PROTECTIVE EARTH CONNECTIONS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.7.2		2023-02-14
		61	Green and yellow insulation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.7.3		2023-02-14
		62	Neutral conductor	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.7.4		2023-02-14
		63	POWER SUPPLY CORD conductors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.7.5		2023-02-14
		64	Colours of indicator	Medical electrical equipment –Part 1: General requirements for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			lights	basic safety and essential performance IEC 60601-1:2012,MOD 7.8.1		
		65	Colours of controls	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.8.2		2023-02-14
		66	General	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.1		2023-02-14
		67	General	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.1		2023-02-14
		68	Warning and safety notices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.2		2023-02-14
		69	ME EQUIPMENT specified for connection to a separate power supply	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.3		2023-02-14
		70	Electrical power source	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.4		2023-02-14
		71	ME EQUIPMENT description	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.5		2023-02-14
		72	Installation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.6		2023-02-14
		73	Isolation from the SUPPLY MAINS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				7.9.2.7		
		74	Start-up PROCEDURE	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.8		2023-02-14
		75	Operating instructions	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.9		2023-02-14
		76	Messages	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.10		2023-02-14
		77	Shutdown PROCEDURE	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.11		2023-02-14
		78	Cleaning, disinfection and sterilization	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.12		2023-02-14
		79	Maintenance	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.13		2023-02-14
		80	ACCESSORIES, supplementary equipment, used material	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.14		2023-02-14
		81	Environmental protection	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.15		2023-02-14
		82	Reference to the technical description	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.16		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		83	ME EQUIPMENT emitting radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.17		2023-02-14
		84	ME EQUIPMENT and ACCESSORIES supplied sterile	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.18		2023-02-14
		85	Unique version identifier	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.2.19		2023-02-14
		86	General	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.3.1		2023-02-14
		87	Replacement of fuses, POWER SUPPLY CORDS and other parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.3.2		2023-02-14
		88	Circuit diagrams, component part lists, etc.	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.3.3		2023-02-14
		89	Mains isolation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 7.9.3.4		2023-02-14
		90	Connection to a separate power source	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.2.1		2023-02-14
		91	Connection to an external d.c. power source	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.2.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		92	Classification of APPLIED PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.3		2023-02-14
		93	PATIENT CONNECTIONS intended to deliver current	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.4.1		2023-02-14
		94	ACCESSIBLE PARTS including and APPLIED PARTS a)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.4.2 a		2023-02-14
		95	ACCESSIBLE PARTS including and APPLIED PARTS b)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.4.2 b		2023-02-14
		96	ACCESSIBLE PARTS including and APPLIED PARTS c)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.4.2 c		2023-02-14
		97	ACCESSIBLE PARTS including and APPLIED PARTS d)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.4.2 d		2023-02-14
		98	ACCESSIBLE PARTS including and APPLIED PARTS e)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.4.2 e		2023-02-14
		99	ME EQUIPMENT intended to be connected to a	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			power source by a plug			
		100	Internal capacitive circuits	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.4.4		2023-02-14
		101	MEANS OF PATIENT PROTECTION (MOPP)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.5.1.2		2023-02-14
		102	MEANS OF OPERATOR PROTECTION (MOOP)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.5.1.3		2023-02-14
		103	F-TYPE APPLIED PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.5.2.1		2023-02-14
		104	TYPE B APPLIED PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.5.2.2		2023-02-14
		105	PATIENT leads or PATIENT cables	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.5.2.3		2023-02-14
		106	DEFIBRILLATION -PROOF APPLIED PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.5.5		2023-02-14
		107	PROTECTIVE EARTH TERMINAL	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.6.2		2023-02-14
		108	Protective earthing of moving parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				8.6.3		
		109	Impedance and current-carrying capability	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.6.4		2023-02-14
		110	Surface coatings	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.6.5		2023-02-14
		111	Plugs and sockets	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.6.6		2023-02-14
		112	POTENTIAL EQUALIZATION CONDUCTOR	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.6.7		2023-02-14
		113	FUNCTIONAL EARTH TERMINAL	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.6.8		2023-02-14
		114	CLASS II ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.6.9		2023-02-14
		115	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.7		2023-02-14
		116	Distance through solid insulation or use of thin sheet material	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.8.2		2023-02-14
		117	Dielectric strength	Medical electrical equipment –Part 1: General requirements for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				basic safety and essential performance IEC 60601-1:2012,MOD 8.8.3		
		118	Mechanical strength and resistance to heat	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.8.4.1		2023-02-14
		119	Resistance to environmental stress	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.8.4.2		2023-02-14
		120	General	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.1.1		2023-02-14
		121	CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.1.2		2023-02-14
		122	CREEPAGE DISTANCES across glass, mica, ceramic and similar materials	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.1.3		2023-02-14
		123	ME EQUIPMENT RATED for high altitudes	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.1.5		2023-02-14
		124	Material groups classification	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.1.7		2023-02-14
		125	Pollution degree classification	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				8.9.1.8		
		126	Overvoltage category classification	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.1.9		2023-02-14
		127	AIR CLEARANCE for MAINS PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.1.10		2023-02-14
		128	SUPPLY MAINS overvoltage	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.1.11		2023-02-14
		129	SECONDARY CIRCUITS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.1.12		2023-02-14
		130	PEAK WORKING VOLTAGES above 1 400 V peak or d.c.	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.1.13		2023-02-14
		131	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.1.14		2023-02-14
		132	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION -PROOF APPLIED PARTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.1.15		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		133	Application	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.2		2023-02-14
		134	Insulating compound forming solid insulation between conductive parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.3.2		2023-02-14
		135	Insulating compound forming a cemented joint with other insulating parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.9.3.3		2023-02-14
		136	Fixing of components	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.10.1		2023-02-14
		137	Fixing of wiring	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.10.2		2023-02-14
		138	Connections between different parts of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.10.3		2023-02-14
		139	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.10.4		2023-02-14
		140	Mechanical protection of wiring	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				8.10.5		
		141	Guiding rollers for insulated conductors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.10.6		2023-02-14
		142	Insulation of internal wiring	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.10.7		2023-02-14
		143	Isolation from the SUPPLY MAINS a)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.1 a		2023-02-14
		144	Isolation from the SUPPLY MAINS b)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.1 b		2023-02-14
		145	Isolation from the SUPPLY MAINS c)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.1 c		2023-02-14
		146	Isolation from the SUPPLY MAINS d)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.1 d		2023-02-14
		147	Isolation from the SUPPLY MAINS e)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.1 e		2023-02-14
		148	Isolation from the SUPPLY MAINS f)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.1 f		2023-02-14
		149	Isolation from the SUPPLY MAINS g)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.1 g		2023-02-14
		150	Isolation from the	Medical electrical equipment –Part 1: General requirements for		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			SUPPLY MAINS h)	basic safety and essential performance IEC 60601-1:2012,MOD 8.11.1 h		
		151	Isolation from the SUPPLY MAINS i)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.1 i		2023-02-14
		152	MULTIPLE SOCKET-OUTLETS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.2		2023-02-14
		153	Application	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.3.1		2023-02-14
		154	Types	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.3.2		2023-02-14
		155	Cross-sectional area of POWER SUPPLY CORD conductors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.3.3		2023-02-14
		156	APPLIANCE COUPLERS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.3.4		2023-02-14
		157	Cord anchorage	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.3.5		2023-02-14
		158	Cord guards	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.3.6		2023-02-14
		159	General requirements for MAINS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			TERMINAL DEVICES			
		160	Arrangement of MAINS TERMINAL DEVICES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.4.2		2023-02-14
		161	Fixing of mains terminals	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.4.3		2023-02-14
		162	Connections to mains terminals	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.4.4		2023-02-14
		163	Accessibility of the connection	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.4.5		2023-02-14
		164	Mains fuses and OVER-CURRENT RELEASES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.5		2023-02-14
		165	Internal wiring of the MAINS PART	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 8.11.6		2023-02-14
		166	General	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.2.1		2023-02-14
		167	TRAPPING ZONE	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.2.2		2023-02-14
		168	Other MECHANICAL HAZARDS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.2.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			associated with moving parts			
		169	Emergency stopping devices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.2.4		2023-02-14
		170	Release of PATIENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.2.5		2023-02-14
		171	MECHANICAL HAZARD associated with surfaces, corners and edges	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.3		2023-02-14
		172	Instability – overbalance	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.4.2		2023-02-14
		173	Instability from unwanted lateral movement (including sliding)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.4.3		2023-02-14
		174	Grips and other handling devices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.4.4		2023-02-14
		175	Protective means	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.5.1		2023-02-14
		176	Cathode ray tubes	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.5.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		177	Audible acoustic energy	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.6.2.1		2023-02-14
		178	Infrasound and ultrasound energy	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.6.2.2		2023-02-14
		179	Hand-transmitted vibration	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.6.3		2023-02-14
		180	Pneumatic and hydraulic parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.7.2		2023-02-14
		181	Maximum pressure	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.7.3		2023-02-14
		182	Pressure rating of ME EQUIPMENT parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.7.4		2023-02-14
		183	Pressure vessels	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.7.5		2023-02-14
		184	Pressure-control device	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.7.6		2023-02-14
		185	Pressure-relief device	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.7.7		2023-02-14
		186	RATED maximum supply pressure	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.7.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		187	General	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.8.1		2023-02-14
		188	TENSILE SAFETY FACTOR	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.8.2		2023-02-14
		189	Strength of PATIENT or OPERATOR support or suspension systems	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.8.3		2023-02-14
		190	Systems with MECHANICAL PROTECTIVE DEVICES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.8.4		2023-02-14
		191	Systems without MECHANICAL PROTECTIVE DEVICES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 9.8.5		2023-02-14
		192	ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 10.1.1		2023-02-14
		193	ME EQUIPMENT Intended to produce diagnostic or therapeutic X-radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 10.1.2		2023-02-14
		194	Alpha, beta, gamma,	Medical electrical equipment –Part 1: General requirements for		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			neutron and other particle radiation	basic safety and essential performance IEC 60601-1:2012,MOD 10.2		
		195	Microwave radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 10.3		2023-02-14
		196	Lasers	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 10.4		2023-02-14
		197	Other visible electromagnetic radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 10.5		2023-02-14
		198	Infrared radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 10.6		2023-02-14
		199	Ultraviolet radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 10.7		2023-02-14
		200	Maximum temperature during NORMAL USE	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.1.1		2023-02-14
		201	APPLIED PARTS intended to supply heat to a PATIENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.1.2.1		2023-02-14
		202	APPLIED PARTS not intended to supply heat to a PATIENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.1.2.2		2023-02-14
		203	GUARDS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.1.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		204	Fire prevention	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.2		2023-02-14
		205	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.3		2023-02-14
		206	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.4		2023-02-14
		207	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.5		2023-02-14
		208	Overflow in ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.6.2		2023-02-14
		209	Spillage on ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.6.3		2023-02-14
		210	Leakage	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.6.4		2023-02-14
		211	Ingress of water or particulate matter into ME EQUIPMENT and	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.6.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			ME SYSTEMS			
		212	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.6.6		2023-02-14
		213	Sterilization of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.6.7		2023-02-14
		214	Compatibility with substances used with the ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.6.8		2023-02-14
		215	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.7		2023-02-14
		216	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 11.8		2023-02-14
		217	Accuracy of controls and instruments	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 12.1		2023-02-14
		218	USABILITY of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 12.2		2023-02-14
		219	ALARM SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 12.3		2023-02-14
		220	Intentional	Medical electrical equipment –Part 1: General requirements for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			exceeding of safety limits	basic safety and essential performance IEC 60601-1:2012,MOD 12.4.1		
		221	Indication relevant to safety	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 12.4.2		2023-02-14
		222	Accidental selection of excessive output values	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 12.4.3		2023-02-14
		223	Incorrect output	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 12.4.4		2023-02-14
		224	Limits	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 12.4.5.1		2023-02-14
		225	Diagnostic X-ray equipment	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 12.4.5.2		2023-02-14
		226	Radiotherapy equipment	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 12.4.5.3		2023-02-14
		227	Other ME EQUIPMENT producing diagnostic or therapeutic radiation	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 12.4.5.4		2023-02-14
		228	Diagnostic or therapeutic acoustic pressure	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 12.4.6		2023-02-14
		229	Emissions, deformation of	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			ENCLOSURE or exceeding maximum temperature	13.1.2		
		230	Exceeding LEAKAGE CURRENT or voltage limits	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.1.3		2023-02-14
		231	Specific MECHANICAL HAZARDS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.1.4		2023-02-14
		232	Electrical SINGLE FAULT CONDITION	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.2		2023-02-14
		233	Overheating of transformers in ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.3		2023-02-14
		234	Failure of THERMOSTATS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.4		2023-02-14
		235	Failure of temperature limiting devices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.5		2023-02-14
		236	Leakage of liquid	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.6		2023-02-14
		237	Impairment of cooling that could result in a HAZARDOUS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			SITUATION			
		238	Locking of moving parts	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.8		2023-02-14
		239	Interruption and short circuiting of motor capacitors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.9		2023-02-14
		240	Additional test criteria for motor operated ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.10		2023-02-14
		241	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.11		2023-02-14
		242	Failure of parts that might result in a MECHANICAL HAZARD	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.12		2023-02-14
		243	ME EQUIPMENT with heating elements	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.13.2		2023-02-14
		244	ME EQUIPMENT with motors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 13.2.13.3		2023-02-14
		245	ME EQUIPMENT RATED for non-	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			CONTINUOUS OPERATION	13.2.13.4		
		246	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 14		2023-02-14
		247	Arrangements of controls and indicators of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.1		2023-02-14
		248	Serviceability	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.2		2023-02-14
		249	Push test	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.3.2		2023-02-14
		250	Impact test	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.3.3		2023-02-14
		251	HAND-HELD ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.3.4.1		2023-02-14
		252	PORTABLE ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.3.4.2		2023-02-14
		253	Rough handling test	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.3.5		2023-02-14
		254	Mould stress relief test	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				15.3.6		
		255	Environmental influences	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.3.7		2023-02-14
		256	Construction of connectors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.1		2023-02-14
		257	Temperature and overload control devices	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.2		2023-02-14
		258	Housing	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.3.1		2023-02-14
		259	Connection	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.3.2		2023-02-14
		260	Protection against overcharging	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.3.3		2023-02-14
		261	Lithium batteries	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.3.4		2023-02-14
		262	Excessive current and voltage protection	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.3.5		2023-02-14
		263	Indicators	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.4		2023-02-14
		264	Pre-set controls	Medical electrical equipment –Part 1: General requirements for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				basic safety and essential performance IEC 60601-1:2012,MOD 15.4.5		
		265	Fixing, prevention of maladjustment	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.6.1		2023-02-14
		266	Limitation of movement	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.6.2		2023-02-14
		267	Mechanical strength	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.7.1		2023-02-14
		268	Accidental operation of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.7.2		2023-02-14
		269	Entry of liquids	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.7.3		2023-02-14
		270	Internal wiring of ME EQUIPMENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.8		2023-02-14
		271	Oil containers	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.4.9		2023-02-14
		272	Short-circuit test	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.5.1.2		2023-02-14
		273	Overload test	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.5.1.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		274	Dielectric strength	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.5.2		2023-02-14
		275	Construction of transformers used to provide separation as required by 8.5	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 15.5.3		2023-02-14
		276	General requirements for the ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 16.1		2023-02-14
		277	ACCOMPANYING DOCUMENTS of an ME SYSTEM	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 16.2		2023-02-14
		278	Power supply	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 16.3		2023-02-14
		279	ENCLOSURES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 16.4		2023-02-14
		280	SEPARATION DEVICES	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 16.5		2023-02-14
		281	TOUCH CURRENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 16.6.1		2023-02-14
		282	EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 16.6.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		283	PATIENT LEAKAGE CURRENT	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 16.6.3		2023-02-14
		284	Protection against MECHANICAL HAZARDS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 16.7		2023-02-14
		285	Interruption of the power supply to parts of an ME SYSTEM	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 16.8		2023-02-14
		286	Connection terminals and connectors	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 16.9.1		2023-02-14
		287	MAINS PARTS, components and layout	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 16.9.2		2023-02-14
		288	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012,MOD 17		2023-02-14
211	Surgical implants	1	All Parameters	Implants for surgery—Magnetic resonance compatibility—Part 1:Safety marking YY/T 0987.1-2016		2023-02-14
		2	Methods of Marking	Implants for surgery—Magnetic resonance compatibility—Part 1:Safety marking YY/T 0987.1-2016		2023-02-14
		3	Required Information	Implants for surgery—Magnetic resonance compatibility—Part 1:Safety marking YY/T 0987.1-2016 6		2023-02-14
		4	Information Include in MR Marking	Implants for surgery—Magnetic resonance compatibility—Part 1:Safety marking YY/T 0987.1-2016 7		2023-02-14
		5	Summary of Test Method	Implants for surgery—Magnetic resonance compatibility—Part 2:Magnetically induced displacement force test method YY/T		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				0987.2-2016		
		6	Report	Implants for surgery—Magnetic resonance compatibility—Part 2:Magnetically induced displacement force test method YY/T 0987.2-2016 10		2023-02-14
		7	Summary of Test Method	Implants for surgery—Magnetic resonance compatibility—Part 3:Evaluation of MR image artifacts from passive implants YY/T 0987.3-2016		2023-02-14
		8	Report	Implants for surgery—Magnetic resonance compatibility—Part 3:Evaluation of MR image artifacts from passive implants YY/T 0987.3-2016 9		2023-02-14
		9	Summary of Test Method	Implants for surgery—Magnetic resonance compatibility—Part 4:Radio frequency induced heating on or near passive implants test method YY/T 0987.4-2016		2023-02-14
		10	Report	Implants for surgery—Magnetic resonance compatibility—Part 4:Radio frequency induced heating on or near passive implants test method YY/T 0987.4-2016 10		2023-02-14
		11	Summary of Test Method	Implants for surgery—Magnetic resonance compatibility—Part 5:Magnetically induced torque test method YY/T 0987.5-2016		2023-02-14
		12	Report	Implants for surgery—Magnetic resonance compatibility—Part 5:Magnetically induced torque test method YY/T 0987.5-2016 10		2023-02-14
212	Protective devices against diagnostic medical X-radiation	1	All Parameters	Protective devices against diagnostic medical X-radiation—Device and tool YY/T 0128-2004		2023-02-14
		2	Protective shielding	Protective devices against diagnostic medical X-radiation—Device and tool YY/T 0128-2004 4.1		2023-02-14
		3	Protective room	Protective devices against diagnostic medical X-radiation—Device and tool YY/T 0128-2004 4.2		2023-02-14
		4	Protective Chair	Protective devices against diagnostic medical X-radiation—Device and tool YY/T 0128-2004 4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Protective door	Protective devices against diagnostic medical X-radiation—Device and tool YY/T 0128-2004 4.4		2023-02-14
		6	Protective glasses	Protective devices against diagnostic medical X-radiation—Device and tool YY/T 0128-2004 4.5		2023-02-14
		7	Protective mask	Protective devices against diagnostic medical X-radiation—Device and tool YY/T 0128-2004 4.6		2023-02-14
		8	Protective aprons	Protective devices against diagnostic medical X-radiation—Device and tool YY/T 0128-2004 4.7		2023-02-14
		9	Appearance	Protective devices against diagnostic medical X-radiation—Device and tool YY/T 0128-2004 4.8		2023-02-14
		10	Marking and labels	Protective devices against diagnostic medical X-radiation—Device and tool YY/T 0128-2004 7		2023-02-14
		11	Package, transportation and storage	Protective devices against diagnostic medical X-radiation—Device and tool YY/T 0128-2004 8		2023-02-14
213	Protective devices against diagnostic medical X-radiation	1	All Parameters	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994		2023-02-14
		2	Procedure	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 4		2023-02-14
		3	Measurement of quantities	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 5		2023-02-14
		4	Radiation quantities	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 5.1		2023-02-14
		5	Geometrical quantities	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 5.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Measuring arrangement in the broad beam	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 5.3		2023-02-14
		7	Measuring arrangement in the narrow beam	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 5.4		2023-02-14
		8	Position of the radiation detector	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 5.5		2023-02-14
		9	Test Instrumentation	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 5.6		2023-02-14
		10	Test objects	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 5.7		2023-02-14
		11	Radiation quantities	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 5.8		2023-02-14
		12	determination of attenuation properties	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 6		2023-02-14
		13	Attenuation ratio	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 6.1		2023-02-14
		14	Build up factor	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 6.2		2023-02-14
		15	Attenuation Equivalent	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				0292.1-1997 IEC 61331-1：1994 6.3		
		16	Lead equivalent	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 6.4		2023-02-14
		17	Homogeneity	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 6.5		2023-02-14
		18	Statement of compliance	Protective devices against diagnostic medical X-radiation—Part 1: Determination of attenuation properties of materials YY/T 0292.1-1997 IEC 61331-1：1994 7		2023-02-14
214	Protective devices against diagnostic medical X-radiation	1	All Parameters	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994		2023-02-14
		2	Dimensions	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 4		2023-02-14
		3	Thickness of protective glass plates	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 4.1		2023-02-14
		4	Plane dimensions of protective glass plates	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 4.2		2023-02-14
		5	Designation of nominal sizes	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 4.3		2023-02-14
		6	Geometrical accuracy of protective glass	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			plates			
		7	Squareness	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 5.1		2023-02-14
		8	Flatness	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 5.2		2023-02-14
		9	Parallelism	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 5.3		2023-02-14
		10	Narrow sides	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 5.4		2023-02-14
		11	Edges	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 5.5		2023-02-14
		12	Optical quality of meterial	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 6		2023-02-14
		13	Definition of zones for determining homogenety	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 6.1		2023-02-14
		14	Bubbles	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 6.2		2023-02-14
		15	Streaks and other inhomogeneity	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 6.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Transmittance	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 7		2023-02-14
		17	Attenuation properties	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 8		2023-02-14
		18	Minimum value of attenuation equivalent	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 8.1		2023-02-14
		19	Determination	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 8.2		2023-02-14
		20	Information	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 8.3		2023-02-14
		21	Verification	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 8.4		2023-02-14
		22	Marking	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 9		2023-02-14
		23	Accompanying documents	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 10		2023-02-14
		24	Statement of compliance	Protective devices against diagnostic medical X-radiation—Part 2:Protective glass plates YY 0292.2-1997 IEC 1331-2：1994 11		2023-02-14
215	Medical therapeutic X-	1	All Parameters	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	ray equipment	2	Working conditions	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.1		2023-02-14
		3	Tube current adjustment range and indication variation	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.2		2023-02-14
		4	Tube voltage adjustment range and indication variation	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.3		2023-02-14
		5	Output dose rate and half-value layer	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.4		2023-02-14
		6	Timer adjustment range and variation	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.5		2023-02-14
		7	high-voltage cable plug and socket	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.6		2023-02-14
		8	Sealing performance	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.7		2023-02-14
		9	Filter	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.8		2023-02-14
		10	Beam limiting device	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.9		2023-02-14
		11	Patient support	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.10		2023-02-14
		12	Supporting device of X-ray tube assembly	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.11		2023-02-14
		13	Noise	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.12		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Appearance	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.13		2023-02-14
		15	Environmental Testing	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.14		2023-02-14
		16	Safety	General specifications for medical therapeutic X-ray equipment YY/T 0317-2007 4.15		2023-02-14
216	XZ1-4/250 Therapy X-ray tube	1	All Parameters	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009		2023-02-14
		2	Requirement	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 4		2023-02-14
		3	Environmental condition	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 4.1		2023-02-14
		4	Overall dimension and electrode connection	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 4.2		2023-02-14
		5	Appearance and structure	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 4.3		2023-02-14
		6	Photoelectric properties	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 4.4		2023-02-14
		7	Environmental test	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 4.5		2023-02-14
		8	Bond strength of pipe bedding	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 4.6		2023-02-14
		9	Sealing of cooling circuit	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 4.7		2023-02-14
		10	Working life	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 4.8		2023-02-14
		11	Marker, certificate and product specification	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Marker	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 7.1		2023-02-14
		13	Certificate and product specification	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 7.2		2023-02-14
		14	Packaging, transportation, storage	XZ1-4/250 Therapy X-ray tube YY/T 0747-2009 8		2023-02-14
217	Medical X-ray equipment	1	All Parameters	Environmental requirements and test methods for medical X-ray equipment YY/T0291-2016		2023-02-14
		2	Special case	Environmental requirements and test methods for medical X-ray equipment YY/T0291-2016 5.1		2023-02-14
		3	temperature&humid test	Environmental requirements and test methods for medical X-ray equipment YY/T0291-2016 5.2.1		2023-02-14
		4	Vibration test	Environmental requirements and test methods for medical X-ray equipment YY/T0291-2016 5.2.2		2023-02-14
		5	Crash test	Environmental requirements and test methods for medical X-ray equipment YY/T0291-2016 5.2.3		2023-02-14
		6	The adaptability of the power supply test	Environmental requirements and test methods for medical X-ray equipment YY/T0291-2016 5.2.4		2023-02-14
218	imaging system of positron emission and X-ray computed tomography	1	All Parameters	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011		2023-02-14
		2	Spatial resolution	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.1.1		2023-02-14
		3	recovery coefficient	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.1.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	tomographic sensitivity	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.1.3		2023-02-14
		5	count rate characteristic	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.1.4		2023-02-14
		6	scatter measurement	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.1.5		2023-02-14
		7	attenuation correction	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.1.6		2023-02-14
		8	imaging noise	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.2.1		2023-02-14
		9	CT value's uniformity	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.2.2		2023-02-14
		10	CT value's accuracy	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.2.3		2023-02-14
		11	High-contrast resolution	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.2.4		2023-02-14
		12	Low-contrast resolution	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.2.5		2023-02-14
		13	Artifact	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.2.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Slice thickness	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.2.7		2023-02-14
		15	CT gantry	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.2.8		2023-02-14
		16	X-ray generator	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.2.9		2023-02-14
		17	Plug and socket of high voltage cable	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.2.10		2023-02-14
		18	Indication meter	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.2.11		2023-02-14
		19	PET/CT image registration accuracy	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.3.1		2023-02-14
		20	PET/CT patient table	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.3.2		2023-02-14
		21	Running noise of PET/CT system	Characteristics and test methods for imaging system of positron emission and X-ray computed tomography YY/T 0829-2011 4.3.3		2023-02-14
219	imaging dose of X-ray image-guided devices eusd in radiotherapy equipment	1	All Parameters	imaging dose of X-ray image-guided devices eusd in radiotherapy equipment YY/T0888-2013		2023-02-14
		2	Generic requirements	imaging dose of X-ray image-guided devices eusd in radiotherapy equipment YY/T0888-2013 4		2023-02-14
		3	Description of KV X-ray CT GD	imaging dose of X-ray image-guided devices eusd in radiotherapy equipment YY/T0888-2013 5		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Imaging Dose			
		4	Description of MSV X-ray CT GD Imaging Dose	imaging dose of X-ray image-guided devices eusd in radiotherapy equipment YY/T0888-2013 6		2023-02-14
220	Performance and test methods for single photon emission and x-ray computed tomography systems	1	All Parameters	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016		2023-02-14
		2	System plane sensitivity	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.2		2023-02-14
		3	Spatial resolution	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.3		2023-02-14
		4	Nonuniformity	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.4		2023-02-14
		5	Intrinsic Energy Resolution	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.5		2023-02-14
		6	Natural multiwindow space coordination	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.6		2023-02-14
		7	Inherent Space nonlinearity	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.7		2023-02-14
		8	System Count Rate Characteristic	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.8		2023-02-14
		9	Probe Shielding leakage (system)	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.9		2023-02-14
		10	Center of gravity shift of rotation	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.10		2023-02-14
		11	Probe Tilt	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.11		2023-02-14
		12	Non-parallelism of collimator hole	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.12		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	System spatial sensitivity of SPECT	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.13		2023-02-14
		14	Scattering fraction	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.14		2023-02-14
		15	System spatial resolution of SPECT	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.15		2023-02-14
		16	A test method for SPECT that works in a conforming measurement pattern	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.16		2023-02-14
		17	Scan stability	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.17		2023-02-14
		18	Spatial resolution of whole body imaging system	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.1.18		2023-02-14
		19	Image noise	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.1		2023-02-14
		20	UNIFORMITY OF CT.	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.2		2023-02-14
		21	ACCURACY OF CT.	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.3		2023-02-14
		22	Spatial Resolution (High Contrast Resolution)	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.4		2023-02-14
		23	Low contrast resolution	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		24	Artifact	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.6		2023-02-14
		25	Slice thickness	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.7		2023-02-14
		26	CT scanner	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.8		2023-02-14
		27	Accuracy of x-ray tube voltage	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.9.1		2023-02-14
		28	Accuracy of x-ray tube current	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.9.2		2023-02-14
		29	Time accuracy of scanning	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.9.3		2023-02-14
		30	High voltage cable plug and socket	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.10		2023-02-14
		31	Indicating Instrument	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.2.11		2023-02-14
		32	Accuracy of SPECT / CT image registration	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.3.1		2023-02-14
		33	SPECT / CT table	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.3.2		2023-02-14
		34	Operational Noise of SPECT / CT system	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 4.3.3		2023-02-14
		35	Intrinsic spatial resolution	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.1		2023-02-14
		36	Intrinsic spatial linearity	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.2		2023-02-14
		37	Intrinsic energy resolution	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		38	Inherent universal source heterogeneity	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.4		2023-02-14
		39	Multi-window spatial coordination	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.5		2023-02-14
		40	Intrinsic counting rate characteristics in air	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.6		2023-02-14
		41	Intrinsic spatial resolution at 75ks-1	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.7		2023-02-14
		42	Intrinsic flooding heterogeneity at 7ks-1	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.8		2023-02-14
		43	Spatial resolution of scattering-free system	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.9		2023-02-14
		44	Spatial resolution of scattering system	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.10		2023-02-14
		45	System plane sensitivity and penetrability	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.11		2023-02-14
		46	Probe shielding	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.12		2023-02-14
		47	Counting rate characteristics of scattering system	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.13		2023-02-14
		48	System calibration (offset correction)	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.14		2023-02-14
		49	Spatial resolution of SPECT intrinsic reconstruction	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.15		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		50	Reconstruction spatial resolution of SPECT band scattering	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.16		2023-02-14
		51	System volume sensitivity	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.17		2023-02-14
		52	Sensitivity difference between probes	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.18		2023-02-14
		53	Spatial resolution of whole body system without scattering	Performance and test methods for single photon emission and x-ray computed tomography systems YY/T1408-2016 A.19		2023-02-14
221	Stereotactic and plan system for radiotherapy with X-rays	1	All Parameters	Stereotactic and plan system for radiotherapy with X-rays-Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011		2023-02-14
		2	Coordinate system	Stereotactic and plan system for radiotherapy with X-rays-Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011 4.1		2023-02-14
		3	Accompanying documents	Stereotactic and plan system for radiotherapy with X-rays-Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011 4.2		2023-02-14
		4	Radiation field size deviation	Stereotactic and plan system for radiotherapy with X-rays-Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011 4.3		2023-02-14
		5	Penumbra of radiation field	Stereotactic and plan system for radiotherapy with X-rays-Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011 4.4		2023-02-14
		6	Leakage radiation through collimator	Stereotactic and plan system for radiotherapy with X-rays-Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011 4.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Deviation of radiation field center and isocenter	Stereotactic and plan system for radiotherapy with X-rays- Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011 4.6		2023-02-14
		8	Repeated positioning deviation	Stereotactic and plan system for radiotherapy with X-rays- Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011 4.7		2023-02-14
		9	Treatment planning software performance	Stereotactic and plan system for radiotherapy with X-rays- Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011 4.8		2023-02-14
		10	Dose calculation error of treatment planning software	Stereotactic and plan system for radiotherapy with X-rays- Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011 4.8.1		2023-02-14
		11	Calculation error of target position in treatment planning software	Stereotactic and plan system for radiotherapy with X-rays- Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011 4.8.2		2023-02-14
		12	Area coincidence rate	Stereotactic and plan system for radiotherapy with X-rays- Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011 4.8.3		2023-02-14
		13	Treatment plan software security requirements	Stereotactic and plan system for radiotherapy with X-rays- Part1:Stereota,ctic and plan ,system for radiother,,apy with X-rays f,or hea,dlesion YY0832.1-2011 4.8.3		2023-02-14
222	Stereotactic and plan system for radiotherapy with X-rays	1	All Parameters	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015		2023-02-14
		2	Coordinate system	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.1		2023-02-14
		3	Accompanying documents	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				with X-radiation for bodylesion YY0832.2-2015 4.2		
		4	Radiation field size deviation	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.3		2023-02-14
		5	Penumbra of radiation field	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.4		2023-02-14
		6	Leakage radiation through collimator	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.5		2023-02-14
		7	Deviation of radiation field center and isocenter	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.6		2023-02-14
		8	Repeated positioning deviation	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.7		2023-02-14
		9	Treatment planning software performance	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.8		2023-02-14
		10	Dose calculation error of treatment planning software	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.8.1		2023-02-14
		11	Calculation error of target position in treatment planning software	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.8.2		2023-02-14
		12	Equal dose area coincidence rate	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.8.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Safety requirements	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.9		2023-02-14
		14	Treatment plan software security requirements	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.9.1		2023-02-14
		15	System hardware security requirements	Stereotactic and planning system for radiotherapy with X-radiation- Part2:Stereotactic and planning system for radiotherapy with X-radiation for bodylesion YY0832.2-2015 4.9.2		2023-02-14
223	Image-guided radiotherapy equipment of X-ray-based	1	All Parameters	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019		2023-02-14
		2	Accompanying documents	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019 4.1		2023-02-14
		3	Dimension of x-igrt equipment Fujino	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019 4.2		2023-02-14
		4	Report point guidance range of x-igrt equipment	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019 4.3		2023-02-14
		5	Image quality of x-igrt equipment	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019 4.4		2023-02-14
		6	Imaging dose	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019 4.5		2023-02-14
		7	Accuracy of x-igrt positioning correction calculation	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019 4.6		2023-02-14
		8	Repeatability of x-igrt junction correction calculation	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019 4.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Influence of reference image layer thickness on x-igrt junction correction calculation	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019 4.8		2023-02-14
		10	Influence of DRR algorithm of reference image on x-igrt junction correction calculation	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019 4.9		2023-02-14
		11	Influence of radiation quality on x-igrt junction correction calculation	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019 4.10		2023-02-14
		12	Influence of x-igrt reconstruction algorithm on x-igrt junction correction calculation	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019 4.11		2023-02-14
		13	The influence of image registration algorithm on x-igrt positioning correction calculation	Image-guided radiotherapy equipment of X-ray-based-Performance characteristics and test methods YY1650-2019 4.12		2023-02-14
224	Therapeutic X-ray equipment	1	All Parameters	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	operating in the range 10kV to 1MV			equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015		
		2	General requirements	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 4		2023-02-14
		3	General requirements for ME equipment testing	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 5		2023-02-14
		4	Classification of ME devices and ME systems	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 6		2023-02-14
		5	ME device identification, tags, and files	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 7		2023-02-14
		6	Protection against electrical injury from medical electrical equipment	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 8		2023-02-14
		7	Protection against mechanical injury from ME equipment and ME systems	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 9		2023-02-14
		8	Protection against unwanted or excessive radiation hazards	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 10		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Protection against hyperthermia and other hazards	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 11		2023-02-14
		10	Accuracy of working data and protection against dangerous output	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 12		2023-02-14
		11	Hazardous conditions and failure conditions of medical electrical equipment	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 13		2023-02-14
		12	Programmable electrical medical system	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 14		2023-02-14
		13	Interpretation of medical electrical equipment	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 15		2023-02-14
		14	Medical electrical system	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 16		2023-02-14
		15	Electromagnetic compatibility of medical electrical equipment and medical electrical	Medical electrical equipment Part 2-8:Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10kV to 1MV IEC 60601-2-8:2015 17	See YY 9706.102	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			system			
225	Mammographie X-ray equipment and mammographie stereotactic devices	1	All Parameters	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD		2023-02-14
		2	Scope, object and related standards	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.1		2023-02-14
		3	Normative references	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.2		2023-02-14
		4	Terms and definitions	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.3		2023-02-14
		5	General requirements	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.4		2023-02-14
		6	General requirements for testing of ME EQUIPMENT	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.5		2023-02-14
		7	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	ME EQUIPMENT identification,marking and documents	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.7		2023-02-14
		9	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.8		2023-02-14
		10	Protection against MECHNICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.9		2023-02-14
		11	Protection against unwanted and excessive rediation HAZARDS	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.10		2023-02-14
		12	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.11		2023-02-14
		13	Accuracy of controls and instruments and protection against hazardous outputs	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.12		2023-02-14
		14	Hazardous situations and fault conditionss for ME EQUIPMENT	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.13		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.14		2023-02-14
		16	Construction of ME EQUIPMENT	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.15		2023-02-14
		17	ME SYSTEMS	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.16		2023-02-14
		18	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 201.17		2023-02-14
		19	Electromagnetic compatibility - Requirement and tests	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 202		2023-02-14
		20	Immunitu tetsing of ESSENTIAL PERFORMANCE	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 202.1		2023-02-14
		21	Radiation protection in diagnostic X-ray equipment	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 203		2023-02-14
		22	General	Medical electrical equipment-Part 2-45:Particular requirements		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			requirements	for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 203.4		
		23	ME EQUIPMENT identification, marking and documents	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 203.5		2023-02-14
		24	RADIATION MANAGEMENT	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 203.6		2023-02-14
		25	RADIATION QUALITY	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 203.7		2023-02-14
		26	Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 203.8		2023-02-14
		27	FOCAL SPOT TO SKIN DISTANCE	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 203.9		2023-02-14
		28	ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 203.10		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		29	Protection against residual radiation	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices IEC 60601-2-45:2015，MOD 203.11		2023-02-14
		30	Protection against STRAY RADIATION	Medical electrical equipment-Requirements for the safety of radiotherapy IEC 60601-2-45:2015，MOD 203.13		2023-02-14
226	X-ray equipment for radiography and radioscopy	1	All Parameters	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD		2023-02-14
		2	Scope, object and related standards	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.1		2023-02-14
		3	Normative references	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.2		2023-02-14
		4	Terms and definitions	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.3		2023-02-14
		5	General requirements	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.4		2023-02-14
		6	General requirements for testing of ME EQUIPMENT	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.5		2023-02-14
		7	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	ME EQUIPMENT identification,marking and documents	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.7		2023-02-14
		9	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.8		2023-02-14
		10	Protection against MECHNICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.9		2023-02-14
		11	Protection against unwanted and excessive rediation HAZARDS	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.10		2023-02-14
		12	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.11		2023-02-14
		13	Accuracy of controls and instruments and protection against hazardous outputs	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.12		2023-02-14
		14	Hazardous situations and fault conditionss for ME EQUIPMENT	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.13		2023-02-14
		15	PROGRAMMABL	Medical electrical equipment-Part 2-54:Particular requirement for		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			E ELECTRICAL MEDICAL SYSTEMS (PEMS)	the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.14		
		16	Construction of ME EQUIPMENT	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.15		2023-02-14
		17	ME SYSTEMS	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.16		2023-02-14
		18	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 201.17		2023-02-14
		19	Electromagnetic compatibility - Requirement and tests	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 202		2023-02-14
		20	Radiation protection in diagnostic X-ray equipment	Medical electrical equipment-Part 2-54:Particular requirement for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2018,MOD 203		2023-02-14
227	Dental extra-oral X-ray equipment	1	All Parameters	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD		2023-02-14
		2	Scope, object and related standards	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.1		2023-02-14
		3	Normative references	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Terms and definitions	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.3		2023-02-14
		5	General requirements	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.4		2023-02-14
		6	General requirements for testing of ME EQUIPMENT	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.5		2023-02-14
		7	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.6		2023-02-14
		8	ME EQUIPMENT identification,marking and documents	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.7		2023-02-14
		9	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.8		2023-02-14
		10	Protection against MECHNICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.9		2023-02-14
		11	Protection against unwanted and excessive rediation HAZARDS	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.10		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.11		2023-02-14
		13	Accuracy of controls and instruments and protection against hazardous outputs	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.12		2023-02-14
		14	Hazardous situations and fault conditionss for ME EQUIPMENT	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.13		2023-02-14
		15	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.14		2023-02-14
		16	Construction of ME EQUIPMENT	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.15		2023-02-14
		17	ME SYSTEMS	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.16		2023-02-14
		18	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 201.17		2023-02-14
		19	Electromagnetic compatibility - Requirement and	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 202		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			tests			
		20	Radiation protection in diagnostic X-ray equipment	Medical electrical equipment-Part 2-63: Particular requirements for basic safety and essential performance of dental extra-oral X-ray equipment IEC 60601-2-63:2017,MOD 203		2023-02-14
228	Dental intra-oral X-ray equipment	1	All Parameters	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD		2023-02-14
		2	Scope, object and related standards	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.1		2023-02-14
		3	Normative references	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.2		2023-02-14
		4	Terms and definitions	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.3		2023-02-14
		5	General requirements	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.4		2023-02-14
		6	General requirements for testing of ME EQUIPMENT	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.5		2023-02-14
		7	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.6		2023-02-14
		8	ME EQUIPMENT identification,marking and documents	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.8		2023-02-14
		10	Protection against MECHNICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.9		2023-02-14
		11	Protection against unwanted and excessive rediation HAZARDS	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.10		2023-02-14
		12	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.11		2023-02-14
		13	Accuracy of controls and instruments and protection against hazardous outputs	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.12		2023-02-14
		14	Hazardous situations and fault conditionss for ME EQUIPMENT	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.13		2023-02-14
		15	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.14		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Construction of ME EQUIPMENT	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.15		2023-02-14
		17	ME SYSTEMS	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.16		2023-02-14
		18	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 201.17		2023-02-14
		19	Electromagnetic compatibility - Requirement and tests	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 202		2023-02-14
		20	Radiation protection in diagnostic X-ray equipment	Medical electrical equipment-Part 2-65: Particular requirements for basic safety and essential performance of dental intra-oral X-ray equipment IEC 60601-2-65:2017,MOD 203		2023-02-14
229	Diagnostic X-ray equipment	1	All Parameters	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD		2023-02-14
		2	Scope, object and related standards	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 1		2023-02-14
		3	Normative references	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Terms and definitions	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 3		2023-02-14
		5	General requirements	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 4		2023-02-14
		6	ME EQUIPMENT identification,marking and documents	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 5		2023-02-14
		7	RADIATION MANAGEMENT	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 6		2023-02-14
		8	RADIATION QUALITY	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 7		2023-02-14
		9	Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 8		2023-02-14
		10	FOCAL SPOT TO SKIN DISTANCE	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 9		2023-02-14
		11	ATTENUATION of	Medical electrical equipment-Part 1-3: General requirements for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR	basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 10		
		12	Protection against residual radiation	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 11		2023-02-14
		13	Protection against LEAKAGE RADIATION	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 12		2023-02-14
		14	Protection against STRAY RADIATION	Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2013,MOD 13		2023-02-14
230	X-ray tube assemblies	1	All Parameters	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD		2023-02-14
		2	Scope, object and related standards	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.1		2023-02-14
		3	Normative references	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.2		2023-02-14
		4	Terms and definitions	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.3		
		5	General requirements	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.4		2023-02-14
		6	General requirements for testing of ME EQUIPMENT	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.5		2023-02-14
		7	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.6		2023-02-14
		8	ME EQUIPMENT identification,marking and documents	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.7		2023-02-14
		9	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.8		2023-02-14
		10	Protection against MECHNICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.9		2023-02-14
		11	Protection against unwanted and excessive rediation	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			HAZARDS	201.10		
		12	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.11		2023-02-14
		13	Accuracy of controls and instruments and protection against hazardous outputs	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.12		2023-02-14
		14	Hazardous situations and fault conditionss for ME EQUIPMENT	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.13		2023-02-14
		15	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.14		2023-02-14
		16	Construction of ME EQUIPMENT	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.15		2023-02-14
		17	ME SYSTEMS	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.16		2023-02-14
		18	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 201.17		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	Radiation protection in diagnostic X-ray equipment	Medical electrical equipment-Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2017,MOD 203		2023-02-14
231	X-ray equipment for interventional procedures	1	All Parameters	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD		2023-02-14
		2	Scope, object and related standards	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.1		2023-02-14
		3	Normative references	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.2		2023-02-14
		4	Terms and definitions	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.3		2023-02-14
		5	General requirements	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.4		2023-02-14
		6	General requirements for testing of ME EQUIPMENT	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.5		2023-02-14
		7	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.6		2023-02-14
		8	ME EQUIPMENT identification,marking and documents	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.7		2023-02-14

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		№	Item/ Parameter			
		9	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.8		2023-02-14
		10	Protection against MECHNICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.9		2023-02-14
		11	Protection against unwanted and excessive rediation HAZARDS	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.10		2023-02-14
		12	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.11		2023-02-14
		13	Accuracy of controls and instruments and protection against hazardous outputs	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.12		2023-02-14
		14	Hazardous situations and fault conditionss for ME EQUIPMENT	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.13		2023-02-14
		15	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.14		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Construction of ME EQUIPMENT	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.15		2023-02-14
		17	ME SYSTEMS	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.16		2023-02-14
		18	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 201.17		2023-02-14
		19	Electromagnetic compatibility - Requirement and tests	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 202		2023-02-14
		20	Radiation protection in diagnostic X-ray equipment	Medical electrical equipment-Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2017,MOD 203		2023-02-14
232	X-ray equipment for computed tomography	1	All Parameters	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD		2023-02-14
		2	Scope, object and related standards	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.1		2023-02-14
		3	Normative references	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.2		2023-02-14
		4	Terms and definitions	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	General requirements	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.4		2023-02-14
		6	General requirements for testing of ME EQUIPMENT	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.5		2023-02-14
		7	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.6		2023-02-14
		8	ME EQUIPMENT identification,marking and documents	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.7		2023-02-14
		9	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.8		2023-02-14
		10	Protection against MECHNICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.9		2023-02-14
		11	Protection against unwanted and excessive rediation HAZARDS	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.10		2023-02-14
		12	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.11		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Accuracy of controls and instruments and protection against hazardous outputs	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.12		2023-02-14
		14	Hazardous situations and fault conditionss for ME EQUIPMENT	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.13		2023-02-14
		15	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.14		2023-02-14
		16	Construction of ME EQUIPMENT	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.15		2023-02-14
		17	ME SYSTEMS	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.16		2023-02-14
		18	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.17		2023-02-14
		19	Requirements for CT COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS TREAMENT	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 201.101		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			PLANNING(RTP)			
		20	Electromagnetic compatibility - Requirement and tests	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 202		2023-02-14
		21	Radiation protection in diagnostic X-ray equipment	Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2016,MOD 203		2023-02-14
		22	Modulation transfer function evalution of CT scanning device	Image quality evaluation method for computed tomography system –part1: Modulation transfer function evalution YY/T 1766.1-2021 4		2023-02-14
		23	Low contrast resosution evalution of CT scanning device	mage quality evaluation method for computed tomography system –part2:Low contrast resosution evalution YY/T 1766.2-2021 4		2023-02-14
		24	Objective comparative evaluation of low contrast resolution using reduced dose image reconstruction techniques	mage quality evaluation method for computed tomography system –part2:Low contrast resosution evalution YY/T 1766.2-2021 5		2023-02-14
233	Angiographic injector	1	All Parameters	Particular specifications for angiographic injector YY/T 0891-2013		2023-02-14
		2	flow rate	Particular specifications for angiographic injector YY/T 0891-2013 5.2		2023-02-14
		3	Injection dose	Particular specifications for angiographic injector YY/T 0891-		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				2013 5.3		
		4	fill rate	Particular specifications for angiographic injector YY/T 0891-2013 5.4		2023-02-14
		5	maximum injection pressure	Particular specifications for angiographic injector YY/T 0891-2013 5.5		2023-02-14
		6	pressure limit	Particular specifications for angiographic injector YY/T 0891-2013 5.6		2023-02-14
		7	injection delay	Particular specifications for angiographic injector YY/T 0891-2013 5.7		2023-02-14
		8	X-ray delay	Particular specifications for angiographic injector YY/T 0891-2013 5.8		2023-02-14
		9	rise time	Particular specifications for angiographic injector YY/T 0891-2013 5.9		2023-02-14
		10	injector head rotation angle	Particular specifications for angiographic injector YY/T 0891-2013 5.1		2023-02-14
		11	Function	Particular specifications for angiographic injector YY/T 0891-2013 5.11		2023-02-14
		12	Appearance	Particular specifications for angiographic injector YY/T 0891-2013 5.12		2023-02-14
		13	Environmental Test	Particular specifications for angiographic injector YY/T 0891-2013 5.13		2023-02-14
		14	Safety	Particular specifications for angiographic injector YY/T 0891-2013 5.14		2023-02-14
234	Medical image display systems	1	All Parameters	Medical electrical equipment Medical image display systems Part 1: Evaluation methods YY/T 0910.1-2021 IEC 62563-1:2016		2023-02-14
		2	Visul evaluation methods General	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.3.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Overall image quality evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.3.2		2023-02-14
		4	Greyscale resolution evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.3.3		2023-02-14
		5	Luminance response evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.3.4		2023-02-14
		6	Luminance uniformity evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.3.5		2023-02-14
		7	Chromaticity evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.3.6		2023-02-14
		8	Pixel faults evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.3.7		2023-02-14
		9	Veiling glare evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.3.8		2023-02-14
		10	Geometrical image evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.3.9		2023-02-14
		11	Angular viewing evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.3.10		2023-02-14
		12	Clinical evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.3.11		
		13	Quantitative evlluation methods	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.4		2023-02-14
		14	Basic Luminance evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.4.1		2023-02-14
		15	Basic Luminance evaluation without ambient light	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.4.2		2023-02-14
		16	Luminance response evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:20163 7.4.3		2023-02-14
		17	Luminance evaluation of multiple displays	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.4.4		2023-02-14
		18	Chromaticity evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.4.5		2023-02-14
		19	Chromaticity evaluation of multiple displays	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.4.6		2023-02-14
		20	Luminance uniformity evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.4.7		2023-02-14
		21	Viewing angle evaluation	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0910.1-2021 IEC 62563-1:2016 7.4.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	Gray scale chromaticity evaluation	Medcial electrical equipment— medcial image display systems—Part 1 :Evaluation methods YY/T 0910.1-2021 IEC 62563-1:2016 7.4.9		2023-02-14
235	Radiotherapy simulators	1	All Parameters	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999		2023-02-14
		2	Classification	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 5		2023-02-14
		3	Identification, marking and documents	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 6		2023-02-14
		4	Environmental conditions	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 10		2023-02-14
		5	Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 19		2023-02-14
		6	Dielectric strength	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 20		2023-02-14
		7	Mectianical strength	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 21		2023-02-14
		8	Moving parts	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 22		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Pneumatic and hydraulic power	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 27		2023-02-14
		10	Suspended masses	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 28		2023-02-14
		11	X-RADIATION generated by SIMULATORS	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 29		2023-02-14
		12	PROTECTION AGAINST HAZARDS OF IGNITIONOF FLAMMABLE ANAESTHETIC MIXTURES	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 6		2023-02-14
		13	PROTECTION AGAINST EXCESSIVETEMPERATURES AND OTHER SAFETY HAZARDS	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 7		2023-02-14
		14	ACCURACY OF OPERATING DATA AND PROTECTIONAGAINST HAZARDOUS OUTPUT	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 8		2023-02-14
		15	ABNORMAL	Medical electrical equipment –Part 2-29:Particular requirements		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			OPERATION AND FAULT CONDITIONS;ENVIRONMENTAL TESTS	for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 9		
		16	CONSTRUCTIONAL REQUIREMENTS	Medical electrical equipment –Part 2-29:Particular requirements for the safety ofradiotherapy simulators GB9706.16-2015 IEC60601-2-29:1999 10		2023-02-14
236	Radiotherapy simulator	1	All Parameters	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993		2023-02-14
		2	Digital indication of DELINEATED RADIATION FIELDS	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.1.1		2023-02-14
		3	Light field indicator of DELINEATED RADIATION FIELDS	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.1.2		2023-02-14
		4	Reproducibility	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.1.3		2023-02-14
		5	Geometric shape of delinestor	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.1.4		2023-02-14
		6	Illuminance of DELINEATED light FIELDS	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.1.5		2023-02-14
		7	Indication of DELINEATED RADIATION BEAM AXIS on entrance surface	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.2.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Indication of DELINEATED RADIATION BEAM AXIS on exit surface	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.2.2		2023-02-14
		9	Variation of DELINEATED RADIATION BEAM AXIS with SAD changing	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.2.3		2023-02-14
		10	Isocenter	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.3		2023-02-14
		11	Indication of the distance along the DELINEATED RADIATION BEAM AXIS	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.4		2023-02-14
		12	Zero position of rotational scales	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.5		2023-02-14
		13	Congruence of opposed DELINEATED RADIATION FIELDS	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.6		2023-02-14
		14	Movements of the PATIENT SUPPORT	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.7		2023-02-14
		15	Rigidity of the PATIENT SUPPORT	Radiotherapy simulator capability and test methods GB/T 17856-1999 eqv IEC 1168:1993 5.7.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
237	Medical X-ray TV system	1	All Parameters	General technical requirments for Medical X-ray TV system SJ/T 11095-1996		2023-02-14
		2	working time	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.1		2023-02-14
		3	appearance	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.2		2023-02-14
		4	Electrical and optical performance	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.3		2023-02-14
		5	insulating resistance	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.4.1		2023-02-14
		6	Dielectric strength	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.4.2		2023-02-14
		7	leakage current	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.4.3		2023-02-14
		8	reliability	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.5		2023-02-14
		9	high temperature load test	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.6.1		2023-02-14
		10	High temperature storage test	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.6.2		2023-02-14
		11	Low temperature load test	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.6.3		2023-02-14
		12	Low Temperature Storage Test	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.6.4		2023-02-14
		13	Damp heat test	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.6.5		2023-02-14
		14	Vibration Test	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.6.6		2023-02-14
		15	Collsion Test	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.6.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Falling test	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 4.6.8		2023-02-14
		17	Factory test	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 5.1		2023-02-14
		18	Type test	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 5.2		2023-02-14
		19	Marking	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 6.1		2023-02-14
		20	Packaging	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 6.2		2023-02-14
		21	Transportation	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 6.3		2023-02-14
		22	Storage	General technical requirments for Medical X-ray TV system SJ/T 11095-1996 6.4		2023-02-14
238	Middle speed calcium tungstate intensifying screen	1	All Parameters	Middle speed calcium tungstate intensifying screen YY/T 0095-2013		2023-02-14
		2	Basic dimensions	Middle speed calcium tungstate intensifying screen YY/T 0095-2013 4.2		2023-02-14
		3	intensifying factor	Middle speed calcium tungstate intensifying screen YY/T 0095-2013 4.3		2023-02-14
		4	Limiting resolution	Middle speed calcium tungstate intensifying screen YY/T 0095-2013 4.4		2023-02-14
		5	Lag effect time	Middle speed calcium tungstate intensifying screen YY/T 0095-2013 4.5		2023-02-14
		6	luminance spectrum	Middle speed calcium tungstate intensifying screen YY/T 0095-2013 4.6		2023-02-14
		7	Uniformity of luminance	Middle speed calcium tungstate intensifying screen YY/T 0095-2013 4.7		2023-02-14
		8	Surface quality	Middle speed calcium tungstate intensifying screen YY/T 0095-2013 4.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Markings, labels, instruction for use	Middle speed calcium tungstate intensifying screen YY/T 0095-2013 7		2023-02-14
		10	Packaging, transportation, storage	Middle speed calcium tungstate intensifying screen YY/T 0095-2013 8		2023-02-14
239	CT injector	1	All Parameters	Particular specifications for CT injector YY/T 0935-2014		2023-02-14
		2	flow rate	Particular specifications for CT injector YY/T 0935-2014 5.2		2023-02-14
		3	Injection dose	Particular specifications for CT injector YY/T 0935-2014 5.3		2023-02-14
		4	fill rate	Particular specifications for CT injector YY/T 0935-2014 5.4		2023-02-14
		5	maximum injection pressure	Particular specifications for CT injector YY/T 0935-2014 5.5		2023-02-14
		6	pressure limit	Particular specifications for CT injector YY/T 0935-2014 5.6		2023-02-14
		7	injection delay time	Particular specifications for CT injector YY/T 0935-2014 5.7		2023-02-14
		8	scan delay time	Particular specifications for CT injector YY/T 0935-2014 5.8		2023-02-14
		9	injector head rotation angle	Particular specifications for CT injector YY/T 0935-2014 5.9		2023-02-14
		10	function	Particular specifications for CT injector YY/T 0935-2014 5.10		2023-02-14
		11	Appearance	Particular specifications for CT injector YY/T 0935-2014 5.11		2023-02-14
		12	Environmental tests	Particular specifications for CT injector YY/T 0935-2014 5.12		2023-02-14
		13	Safety	Particular specifications for CT injector YY/T 0935-2014 5.13		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
240	Radiotherapy simulators	1	All Parameters	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008		2023-02-14
		2	General requirements	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 4		2023-02-14
		3	General requirements for ME equipment testing	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 5		2023-02-14
		4	Classification of ME devices and ME systems	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 6		2023-02-14
		5	ME device identification, tags, and files	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 7		2023-02-14
		6	ME equipment protection against electric shock hazard (sources)	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 8		2023-02-14
		7	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 9		2023-02-14
		8	ME device structure	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 10		2023-02-14
		9	Protection against unwanted or excessive radiation	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 11		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			hazards			
		10	Control and instrument accuracy and hazard output protection	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 12		2023-02-14
		11	ME Device critical conditions and fault conditions	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 13		2023-02-14
		12	Programmable electrical medical system	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 14		2023-02-14
		13	Equipment structure of ME	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 15		2023-02-14
		14	The ME system	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 16		2023-02-14
		15	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment Part 2-29:Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008 17	See YY 9706.102	2023-02-14
241	Digital X-ray imaging devices	1	All Parameters	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0590.1-2018 IEC 62220-1:2015		2023-02-14
		2	Determination of the detective quantum efficiency	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0590.1-2018 IEC 62220-1:2015 6		2023-02-14
242	High-voltage generators of	1	All Parameters	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	diagnostic X-ray generators			generators GB9706.3-2000 IEC60601-2-7:1998		
		2	General requirements	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 3		2023-02-14
		3	Classification	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 5		2023-02-14
		4	Identification, marking and documents	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 6		2023-02-14
		5	Environmental conditions	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 10		2023-02-14
		6	Limitation of voltage and/or energy	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 15		2023-02-14
		7	ENCLOSURES and PROTECTIVE COVERS	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 16		2023-02-14
		8	Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 19		2023-02-14
		9	Dielectric strength	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 20		2023-02-14
		10	X-RADIATION	Medical electrical equipment—Part 2 Particular requirements		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 29		
		11	Electromagnetic compatibility	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 36		2023-02-14
		12	Excessive temperatures	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 42		2023-02-14
		13	Accuracy of operating data	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 50		2023-02-14
		14	Protection against hazardous output	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 51		2023-02-14
		15	ABNORMAL OPERATION AND FAULT CONDITIONS;ENVIRONMENTAL TESTS	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 9		2023-02-14
		16	CONSTRUCTIONAL REQUIREMENTS	Medical electrical equipment—Part 2 Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators GB9706.3-2000 IEC60601-2-7:1998 10		2023-02-14
243	Therapeutic X-ray generators	1	All Parameters	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987		2023-02-14
		2	General requirements	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Classification	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 5		2023-02-14
		4	Identification, marking and documents	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 6		2023-02-14
		5	Power input	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 7		2023-02-14
		6	Environmental conditions	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 2		2023-02-14
		7	Requirements related toclassification	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 4		2023-02-14
		8	Limitation of voltage and/or current	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 5		2023-02-14
		9	Enclosures and PROTECTIVE COVERS	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 16		2023-02-14
		10	Insulation and PROTECTIVEIMP EDANCES	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 17		2023-02-14
		11	Protective earthing, functionalearthing and potential equalization	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 18		2023-02-14
		12	Continuous LEAKAGECURRE	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			NTS and PATIENTAUXILIARY CURRENTS	IEC601-2-8:1987 19		
		13	Dielectric strength	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 20		2023-02-14
		14	Protection against mechanical hazards	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 4		2023-02-14
		15	Protection against hazardsfrom unwanted or excessive radiation	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 5		2023-02-14
		16	Electromagnetic compatibility	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 36		2023-02-14
		17	Protection against hazardsof ignition of flammable anaestheticmixtures	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 6		2023-02-14
		18	Protection againstexcessive temperatures andother safety hazards	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 7		2023-02-14
		19	Accuracy of operating data	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 50		2023-02-14
		20	Protection against hazardous output	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				IEC601-2-8:1987 51		
		21	Abnormal operation and faultconditions, envoronmental tests	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 9		2023-02-14
		22	Constructional requirements	Medical electrical equipment Part :Particular requirements for the safety of therapeutic X-ray generators GB9706.10-1997 IEC601-2-8:1987 10		2023-02-14
244	X-ray source assemblies and X-ray tube assemblies for medical diagnosis	1	All Parameters	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993		2023-02-14
		2	Classification	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 5		2023-02-14
		3	Identification, marking and documents	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 6		2023-02-14
		4	Power input	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 7		2023-02-14
		5	ENVIRONMENTAL CONDITIONS	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 8		2023-02-14
		6	ENCLOSURES and PROTECTIVE	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			COVERS	for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 16		
		7	Protective earthing, functional eartliing and potential equalization	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 18		2023-02-14
		8	Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 19		2023-02-14
		9	Expelled parts	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 25		2023-02-14
		10	PROTECTION AGAINST HAZARDS FROMUNWANTED OR EXCESSIVE RADIATION	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 5		2023-02-14
		11	PROTECTION AGAINST HAZARDS OF IGNITION OFFLAMMABLE ANAESTHETIC MIXTURES	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 6		2023-02-14
		12	Excessive	Medical electrical equipment Part 2:Particular requirements for		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			temperatures	the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 42		
		13	Pressure vessels and parts subject to PRESSURE	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 45		2023-02-14
		14	ACCURACY OF OPERATING DATA ANDPROTECTION AGAINST HAZARDOUS OUTPUT	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 8		2023-02-14
		15	ABNORMAL OPERATION AND FAULT CONDITIONS,ENVIRONMENTAL TESTS	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 9		2023-02-14
		16	CONSTRUCTIONAL REQUIREMENTS	Medical electrical equipment Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis GB9706.11-1997 IEC60601-2-28:1993 10		2023-02-14
245	X-ray tube assemblies for medical diagnosis	1	All Parameters	Medical electrical equipment -- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2010		2023-02-14
		2	General requirements	Medical electrical equipment -- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2010 201.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	General requirements for testing ME EQUIPMENT	Medical electrical equipment -- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2010 201.5		2023-02-14
		4	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment -- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2010 201.6		2023-02-14
		5	ME EQUIPMENT identification, marking and documents	Medical electrical equipment -- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2010 201.7		2023-02-14
		6	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment -- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2010 201.8		2023-02-14
		7	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment -- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2010 201.9		2023-02-14
		8	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment -- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2010 201.11		2023-02-14
		9	RADIATION protection in diagnostic X-RAY EQUIPMENT	Medical electrical equipment -- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2010 203		2023-02-14
246	Radiation protection in	1	All Parameters	Medical electrical equipment Part 1:General requirements for safety 3.Collateral standard:General requirements for radiation		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	diagnostic X-ray equipment			protection in diagnostic X-ray equipment GB9706.12-1997 IEC601-1-3:1994		
		2	Identification, marking and documents	Medical electrical equipment Part 1:General requirements for safety 3.Collateral standard:General requirements for radiation protection in diagnostic X-ray equipment GB9706.12-1997 IEC601-1-3:1994 6		2023-02-14
		3	RADIATION QUALITY	Medical electrical equipment Part 1:General requirements for safety 3.Collateral standard:General requirements for radiation protection in diagnostic X-ray equipment GB9706.12-1997 IEC601-1-3:1994 29.201		2023-02-14
		4	Limitation and indication of the extent of the X-RAY BEAM	Medical electrical equipment Part 1:General requirements for safety 3.Collateral standard:General requirements for radiation protection in diagnostic X-ray equipment GB9706.12-1997 IEC601-1-3:1994 29.202		2023-02-14
		5	Relationship between X-RAY FIELD and IMAGE RECEPTION AREA	Medical electrical equipment Part 1:General requirements for safety 3.Collateral standard:General requirements for radiation protection in diagnostic X-ray equipment GB9706.12-1997 IEC601-1-3:1994 29.203		2023-02-14
		6	LEAKAGE RADIATION	Medical electrical equipment Part 1:General requirements for safety 3.Collateral standard:General requirements for radiation protection in diagnostic X-ray equipment GB9706.12-1997 IEC601-1-3:1994 29.204		2023-02-14
		7	FOCAL SPOT TO SKIN DISTANCE	Medical electrical equipment Part 1:General requirements for safety 3.Collateral standard:General requirements for radiation protection in diagnostic X-ray equipment GB9706.12-1997 IEC601-1-3:1994 29.205		2023-02-14
		8	ATTENUATION of the X-RAY BEAM	Medical electrical equipment Part 1:General requirements for safety 3.Collateral standard:General requirements for radiation protection in diagnostic X-ray equipment GB9706.12-1997		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				IEC601-1-3:1994 29.206		
		9	PRIMARY PROTECTIVE SHIELDING	Medical electrical equipment Part 1:General requirements for safety 3.Collateral standard:General requirements for radiation protection in diagnostic X-ray equipment GB9706.12-1997 IEC601-1-3:1994 29.207		2023-02-14
		10	Protection against STRAY RADIATION	Medical electrical equipment Part 1:General requirements for safety 3.Collateral standard:General requirements for radiation protection in diagnostic X-ray equipment GB9706.12-1997 IEC601-1-3:1994 29.208		2023-02-14
247	X-ray equipment for radiography and radioscopy	1	All Parameters	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009		2023-02-14
		2	General requirements	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 201.4		2023-02-14
		3	ME EQUIPMENT identification, marking and documents	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 201.7		2023-02-14
		4	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 201.8		2023-02-14
		5	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 201.9		2023-02-14
		6	Protection against	Medical electrical equipment - Part 2-54: Particular requirements		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			excessive temperatures and other HAZARDS	for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 201.11		
		7	Electromagnetic compatibility – Requirements and tests	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 202		2023-02-14
		8	General requirements	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 203.4		2023-02-14
		9	ME EQUIPMENT identification, marking and documents	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 203.5		2023-02-14
		10	RADIATION management	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 203.6		2023-02-14
		11	RADIATION QUALITY	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 203.7		2023-02-14
		12	Limitation of the extent of the X-RAY BEAM and relationship between X-RAYFIELD and IMAGE RECEPTION AREA	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 203.8		2023-02-14
		13	FOCAL SPOT TO SKIN DISTANCE	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				for radiography and radioscopy IEC 60601-2-54:2009 203.9		
		14	ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGERECEPTOR	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 203.10		2023-02-14
		15	Protection against RESIDUAL RADIATION	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 203.11		2023-02-14
		16	Protection against LEAKAGE RADIATION	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 203.12		2023-02-14
		17	Protection against STRAY RADIATION	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009 203.13		2023-02-14
248	Associated equipment of X-ray equipment	1	All Parameters	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994		2023-02-14
		2	Identification, marking and documents	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 6		2023-02-14
		3	ENVIRONMENTAL CONDITIONS	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 2		2023-02-14
		4	PROTECTION AGAINSTELECTRIC SHOCK	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			HAZARDS			
		5	Mectianical strength	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 21		2023-02-14
		6	Moving parts	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 22		2023-02-14
		7	Stability in NORMAL USE	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 24		2023-02-14
		8	Suspended masses	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 28		2023-02-14
		9	PROTECTION AGAINST HAZARDS FROMUNWANTED OR EXCESSIVE RADIATION	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 5		2023-02-14
		10	PROTECTION AGAINST HAZARDS OF IGNITION OFFLAMMABLE ANAESTHETIC MIXTURES	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 6		2023-02-14
		11	PROTECTION AGAINST EXCESSIVETEMPERATURES AND	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 7		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			OTHER SAFETY HAZARDS			
		12	ACCURACY OF OPERATING DATA ANDPROTECTION AGAINST HAZARDOUS OUTPUT	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 8		2023-02-14
		13	ABNORMAL OPERATION AND FAULT CONDITIONS;ENVIRONMENTAL TESTS	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 9		2023-02-14
		14	CONSTRUCTIONAL REQUIREMENTS	Medical electrical equipment—Part 2:Particular requirements for the safety of associated equipment of X-ray equipment GB9706.14-1997 IEC601-1-32:1994 10		2023-02-14
249	X-ray equipment for interventional procedures	1	All Parameters	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000		2023-02-14
		2	Identification, marking and documents	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000 6		2023-02-14
		3	Environmental conditions	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000 10		2023-02-14
		4	PROTECTION AGAINST ELECTRIC	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000 3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			SHOCK HAZARDS			
		5	Mechanical strength	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000 21		2023-02-14
		6	Moving parts	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000 22		2023-02-14
		7	PROTECTION AGAINST HAZARDS FROMUNWANTED OR EXCESSIVE RADIATION	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000 5		2023-02-14
		8	PROTECTION AGAINST HAZARDS OF IGNITION OFFLAMMABLE ANAESTHETIC MIXTURES	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000 6		2023-02-14
		9	Excessive temperatures	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000 42		2023-02-14
		10	Overflow, spillage, leakage, humidity, ingress of liquids,cleaning, sterilization and disinfection	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000 44		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	ACCURACY OF OPERATING DATA AND PROTECTIONAGAINST HAZARDOUS OUTPUT	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000 8		2023-02-14
		12	ABNORMAL OPERATION AND FAULT CONDITIONS;ENVIRONMENTAL TESTS	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000 9		2023-02-14
		13	CONSTRUCTIONAL REQUIREMENTS	Medical electrical equipment- Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures GB9706.23-2005 IEC60601-2-43:2000 10		2023-02-14
250	Mammographic X-ray equipment and mammographic stereotactic devices	1	All Parameters	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001		2023-02-14
		2	General requirements	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 3		2023-02-14
		3	Classification	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 5		2023-02-14
		4	Identification, marking and	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			documents	mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 6		
		5	Environmental conditions	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 10		2023-02-14
		6	Limitation of voltage and/or energy	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 15		2023-02-14
		7	ENCLOSURES and PROTECTIVE COVERS	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 16		2023-02-14
		8	Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 19		2023-02-14
		9	Dielectric strength	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 20		2023-02-14
		10	Mechanical strength	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 21		2023-02-14
		11	Moving parts	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 22		
		12	Stability in NORMAL USE	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 24		2023-02-14
		13	X-RADIATION	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 29		2023-02-14
		14	Electromagnetic compatibility	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 36		2023-02-14
		15	PROTECTION AGAINST HAZARDS OF IGNITION OFFLAMMABLE ANAESTHETIC MIXTURES	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 6		2023-02-14
		16	PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 7		2023-02-14
		17	Accuracy of operating data	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 9		
		18	Protection against hazardous output	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 3		2023-02-14
		19	ABNORMAL OPERATION AND FAULT CONDITIONS;ENVIRONMENTAL TESTS	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 9		2023-02-14
		20	Components and general assembly	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 6		2023-02-14
		21	MAINS PARTS, components and layout	Medical electrical equipment- Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices GB9706.24-2005 IEC60601-2-45:2001 1		2023-02-14
251	Diagnostic X-ray equipment	1	All Parameters	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 9		2023-02-14
		2	Statement of compliance	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 5		2023-02-14
		3	Composition of reference materials	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard:		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6		
		4	General	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 7		2023-02-14
		5	Marking requirements in subclauses	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 8		2023-02-14
		6	References in subclauses	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 9		2023-02-14
		7	Dosimetric calibration	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 5.2.2		2023-02-14
		8	General requirements for the reference of subassemblies and ACCESSORIES	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 5.2.3		2023-02-14
		9	Instructions for use	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 5.2.4		2023-02-14
		10	Normal initiation and termination of the IRRADIATION	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				3:2008 + A1:2013 6.2.1		
		11	Safety measures against failure of normal termination of the IRRADIATION	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.2.2		2023-02-14
		12	Adjustment of RADIATION dose and RADIATION QUALITY	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.3.1		2023-02-14
		13	Reproducibility of the RADIATION output	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.3.2		2023-02-14
		14	Indication of the X-RAY SOURCE ASSEMBLY selected	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.4.1		2023-02-14
		15	Indication of LOADING STATE	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.4.2		2023-02-14
		16	Indication of LOADING FACTORS and MODES OF OPERATION	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.4.3		2023-02-14
		17	Indication of automatic modes	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				3:2008 + A1:2013 6.4.4		
		18	Dosimetric indications	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.4.5		2023-02-14
		19	AUTOMATIC CONTROL SYSTEM	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.5		2023-02-14
		20	SCATTERED RADIATION reduction	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.6		2023-02-14
		21	General	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.7.1		2023-02-14
		22	System performance	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.7.2		2023-02-14
		23	Nominal focal spot value	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.7.3		2023-02-14
		24	RADIATION DETECTOR or X-RAY IMAGE RECEPTOR	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 6.7.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		25	HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 7.1		2023-02-14
		26	Waveform of the X-RAY TUBE VOLTAGE	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 7.2		2023-02-14
		27	Indication of FILTER properties	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 7.3		2023-02-14
		28	Test for FILTRATION by irremovable materials	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 7.4		2023-02-14
		29	Test for ADDED FILTERS and materials	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 7.5		2023-02-14
		30	Test for HALF - VALUE LAYER	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 7.6		2023-02-14
		31	General	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 8.1		2023-02-14
		32	Enclosure of X-	Medical electrical equipment – Part 1-3: General requirements for		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			RAY TUBES	basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 8.2		
		33	Limiting DIAPHRAGM in X-RAY TUBE ASSEMBLIES	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 8.3		2023-02-14
		34	Confinement of EXTRA-FOCAL RADIATION	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 8.4		2023-02-14
		35	General	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 8.5.1		2023-02-14
		36	FOCAL SPOT TO IMAGE RECEPTOR DISTANCE	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 8.5.2		2023-02-14
		37	FOCAL SPOT TO IMAGE RECEPTOR DISTANCE RECEPTION AREA	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 8.5.3		2023-02-14
		38	Positioning of the PATIENT and restriction of the irradiated area	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 8.5.4		2023-02-14
		39	General	Medical electrical equipment – Part 1-3: General requirements for		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 9.1		
		40	Information in the ACCOMPANYING DOCUMENTS	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 9.2		2023-02-14
		41	General	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 10.1		2023-02-14
		42	Information in the ACCOMPANYING DOCUMENTS	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 10.2		2023-02-14
		43	Protection against RESIDUAL RADIATION	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 11		2023-02-14
		44	General	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 12.1		2023-02-14
		45	Mounting of X-RAY SOURCE ASSEMBLIES and X-RAY IMAGING ARRANGEMENTS	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 12.2		2023-02-14
		46	Statement of reference	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard:		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			LOADING conditions	Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 12.3		
		47	LEAKAGE RADIATION in the LOADING STATE	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 12.4		2023-02-14
		48	LEAKAGE RADIATION when not in the LOADING STATE	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 12.5		2023-02-14
		49	General	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 13.1		2023-02-14
		50	Control of X-RAY EQUIPMENT from a PROTECTED AREA	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 13.2		2023-02-14
		51	Protection by distance	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 13.3		2023-02-14
		52	Designated SIGNIFICANT ZONES OF OCCUPANCY	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 13.4		2023-02-14
		53	Handgrips and control devices	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008 + A1:2013 13.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
252	Dental extra-oral X-ray equipment	1	All Parameters	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012		2023-02-14
		2	Scope, object and related standards	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.1		2023-02-14
		3	Normative references	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.2		2023-02-14
		4	Terms and definitions	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.3		2023-02-14
		5	General requirements	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.4		2023-02-14
		6	General requirements for testing of ME EQUIPMENT	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.5		2023-02-14
		7	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.6		2023-02-14
		8	ME EQUIPMENT identification, marking and documents	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.7		2023-02-14
		9	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.9		2023-02-14
		11	Protection against unwanted and excessive radiation HAZARDS	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.10		2023-02-14
		12	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.11		2023-02-14
		13	Accuracy of controls and instruments and protection against hazardousoutputs	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.12		2023-02-14
		14	HAZARDOUS SITUATIONS and fault conditions	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.13		2023-02-14
		15	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.14		2023-02-14
		16	Construction of ME EQUIPMENT	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.15		2023-02-14
		17	ME SYSTEMS	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				X-ray equipment IEC:60601-2-63:2012 201.16		
		18	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 201.17		2023-02-14
		19	Immunity testing of ESSENTIAL PERFORMANCE	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 202.101	See YY0505-2012	2023-02-14
		20	General requirements	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 203.4		2023-02-14
		21	ME EQUIPMENT identification, marking and documents	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 203.5		2023-02-14
		22	Radiation management	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 203.6		2023-02-14
		23	RADIATION QUALITY	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 203.7		2023-02-14
		24	Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 203.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		25	FOCAL SPOT TO SKIN DISTANCE	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 203.9		2023-02-14
		26	Attenuation of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 203.10		2023-02-14
		27	Protection against residual radiation	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 203.11		2023-02-14
		28	Protection against STRAY RADIATION	Medical electrical equipment –Part 2-63: Particular requirements for the basic safety and essential performanceof dental extra-oral X-ray equipment IEC:60601-2-63:2012 203.13		2023-02-14
253	Dental intra-oral X-ray equipment	1	All Parameters	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012		2023-02-14
		2	Scope, object and related standards	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.1		2023-02-14
		3	Normative references	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.2		2023-02-14
		4	Terms and definitions	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.3		2023-02-14
		5	General requirements	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	General requirements for testing of ME EQUIPMENT	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.5		2023-02-14
		7	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.6		2023-02-14
		8	ME EQUIPMENT identification, marking and documents	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.7		2023-02-14
		9	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.8		2023-02-14
		10	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.9		2023-02-14
		11	Protection against unwanted and excessive radiation HAZARDS	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.10		2023-02-14
		12	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.11		2023-02-14
		13	Accuracy of controls and	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			instruments and protection against hazardousoutputs	X-ray equipment IEC 60601-2-65:2012 201.12		
		14	HAZARDOUS SITUATIONS and fault conditions	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.13		2023-02-14
		15	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.14		2023-02-14
		16	Construction of ME EQUIPMENT	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.15		2023-02-14
		17	ME SYSTEMS	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.16		2023-02-14
		18	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 201.17		2023-02-14
		19	Immunity testing of ESSENTIAL PERFORMANCE	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 202.101	See GB/T16886.5-2003 GB/T16886.10-2005	2023-02-14
		20	General requirements	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 203.4		2023-02-14
		21	ME EQUIPMENT identification,	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			marking and documents	X-ray equipment IEC 60601-2-65:2012 203.5		
		22	RADIATION management	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 203.6		2023-02-14
		23	RADIATION QUALITY	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 203.7		2023-02-14
		24	Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 203.8		2023-02-14
		25	FOCAL SPOT TO SKIN DISTANCE	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 203.9		2023-02-14
		26	ATTENUATION OF THE X-RAY BEAM between the PATIENT and the X-RAY IMAGERECEPTOR	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 203.10		2023-02-14
		27	Protection against RESIDUAL RADIATION	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 203.11		2023-02-14
		28	Protection against	Medical electrical equipment –Part 2-65: Particular requirements		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			LEAKAGE RADIATION	for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 203.12		
		29	Protection against STRAY RADIATION	Medical electrical equipment –Part 2-65: Particular requirements for the basic safety and essential performanceof dental intra-oral X-ray equipment IEC 60601-2-65:2012 203.13		2023-02-14
254	X-ray equipment for interventional procedures	1	All Parameters	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010		2023-02-14
		2	General requirements	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.4		2023-02-14
		3	ESSENTIAL PERFORMANCE	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.4.3		2023-02-14
		4	SUPPLY MAINS FOR ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.4.10.2		2023-02-14
		5	Recovery management	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.4.101		2023-02-14
		6	RADIATION dose documentation	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.4.102		2023-02-14
		7	General requirements for testing of ME EQUIPMENT	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.5		2023-02-14
		8	Classification of ME EQUIPMENT	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			and ME SYSTEMS	60601-2-43:2010 201.6		
		9	Marking on the outside of ME QUIPMENT or ME EQUIPMENT parts	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.7.2		2023-02-14
		10	Colours of indicator lights	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.7.8.1		2023-02-14
		11	ACCOMPANYING DOCUMENTS	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.7.9		2023-02-14
		12	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.8		2023-02-14
		13	HAZARDS associated with moving parts	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.9.2		2023-02-14
		14	HAZARDS associated with support systems	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.9.8		2023-02-14
		15	Protection against unwanted and excessive radiation HAZARDS	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.10		2023-02-14
		16	Excessive temperatures in ME EQUIPMENT	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.11.1		2023-02-14
		17	Overflow, spillage,	Medical electrical equipment-part 2-43 Particular requirement for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			leakage, ingress of water or particulate matter, cleaning,disinfection, sterilization and compatibility with substances used with the MEEQUIPMENT	the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.11.6		
		18	Protection against excessive temperatures of X-RAY TUBE ASSEMBLIES	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.11.101		2023-02-14
		19	Protection against excessive temperatures of BEAM LIMITING DEVICES	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.11.102		2023-02-14
		20	Protection against hazardous output	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.12.4		2023-02-14
		21	HAZARDOUS SITUATIONS and fault conditions	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.13		2023-02-14
		22	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.14		2023-02-14
		23	Construction of ME	Medical electrical equipment-part 2-43 Particular requirement for		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			EQUIPMENT	the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.15		
		24	ME SYSTEMS	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.16		2023-02-14
		25	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 201.17		2023-02-14
		26	Electromagnetic compatibility – Requirements and tests	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 202		2023-02-14
		27	General requirements	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.4		2023-02-14
		28	Instructions for use	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.5.2.4		2023-02-14
		29	Initiation and termination of the IRRADIATION	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.6.2		2023-02-14
		30	RADIATION dose and RADIATION QUALITY	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.6.3		2023-02-14
		31	Indication of operational states	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.6.4		2023-02-14
		32	AUTOMATIC CONTROL	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			SYSTEM	60601-2-43:2010 203.6.5		
		33	SCATTERED RADIATION reduction	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.6.6		2023-02-14
		34	Imaging performance	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.6.7		2023-02-14
		35	Range of AIR KERMA RATES in RADIOSCOPY	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.6.101		2023-02-14
		36	Accessibility of switching between RADIOSCOPY and RADIOGRAPHY	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.6.102		2023-02-14
		37	IRRADIATION disabling switch	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.6.103		2023-02-14
		38	Last-image-hold (LIH)	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.6.104		2023-02-14
		39	Limitation of RADIATION output	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.6.105		2023-02-14
		40	RADIATION QUALITY	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.7		2023-02-14
		41	Limitation of the extent of the X-RAY BEAM and	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			relationship between X-RAY FIELDand IMAGE RECEPTION AREA			
		42	Boundary and dimensions of the X-RAY FIELD	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.8.101		2023-02-14
		43	Methods of beam limitation in X-RAY EQUIPMENT	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.8.102		2023-02-14
		44	Interception of the X-RAY BEAM in RADIOSCOPY	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.8.103		2023-02-14
		45	FOCAL SPOT TO SKIN DISTANCE	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.9		2023-02-14
		46	ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGERECEPTOR	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.10		2023-02-14
		47	Protection against RESIDUAL RADIATION	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.11		2023-02-14
		48	Protection against LEAKAGE RADIATION	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.12		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		49	Control of X-RAY EQUIPMENT from a PROTECTED AREA	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.13.2		2023-02-14
		50	Protection by distance	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.13.3		2023-02-14
		51	Designated SIGNIFICANT ZONES OF OCCUPANCY	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.13.4		2023-02-14
		52	Handgrips and control devices	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.13.5		2023-02-14
		53	Test for STRAY RADIATION	Medical electrical equipment-part 2-43 Particular requirement for the safety of X-ray equipment for interventional procedures IEC 60601-2-43:2010 203.13.6		2023-02-14
255	X-ray equipment for computed tomography	1	All Parameters	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012		2023-02-14
		2	General requirements	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.4		2023-02-14
		3	General requirements for testing of ME EQUIPMENT	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.5		2023-02-14
		4	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	ME EQUIPMENT identification, marking and documents	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.7		2023-02-14
		6	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.8		2023-02-14
		7	Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.9		2023-02-14
		8	Protection against unwanted and excessive RADIATION HAZARDS	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.10		2023-02-14
		9	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.11		2023-02-14
		10	Accuracy of controls and instruments and protection against hazardousoutputs	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.12		2023-02-14
		11	Hazardous situations and fault conditions	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.13		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.14		2023-02-14
		13	Construction of ME EQUIPMENT	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.15		2023-02-14
		14	ME SYSTEMS	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.16		2023-02-14
		15	ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.17		2023-02-14
		16	Requirements for CT SCANNERS providing images for RADIOTHERAPY TREATMENT PLANNING (RTP)	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 201.101		2023-02-14
		17	Immunity testing of ESSENTIAL PERFORMANCE	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 202.101	See YY0505-2012	2023-02-14
		18	General requirements	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.4		2023-02-14
		19	ME EQUIPMENT	Medical electrical equipment –Part 2-44: Particular requirements		2023-02-14

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		№	Item/ Parameter			
			identification, marking and documents	for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.5		
		20	RADIATION management	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.6		2023-02-14
		21	RADIATION QUALITY	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.7		2023-02-14
		22	Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELDand IMAGE RECEPTION AREA	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.8		2023-02-14
		23	FOCAL SPOT TO SKIN DISTANCE	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.9		2023-02-14
		24	ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.10		2023-02-14
		25	Protection against RESIDUAL RADIATION	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.11		2023-02-14
		26	Protection against	Medical electrical equipment –Part 2-44: Particular requirements		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			LEAKAGE RADIATION	for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.12		
		27	Protection against STRAY RADIATION	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.13		2023-02-14
		28	Emergency TERMINATION of X-RADIATION	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.101		2023-02-14
		29	Visual indication	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.102		2023-02-14
		30	Indication of operational READY STATE	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.103		2023-02-14
		31	Connection of external INTERLOCKS	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.104		2023-02-14
		32	Charging mode INTERLOCK	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.105		2023-02-14
		33	Control of RADIATION output	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.106		2023-02-14
		34	Safety measures against excessive X-RADIATION	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.107		2023-02-14
		35	Dosimetry PHANTOM	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.108		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		36	Dose statements	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.109		2023-02-14
		37	DOSE PROFILE statement	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.110		2023-02-14
		38	SENSITIVITY PROFILE statement	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.111		2023-02-14
		39	Display and recording of CTDIvol and DLP	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.112		2023-02-14
		40	GEOMETRIC EFFICIENCY IN THE Z DIRECTION	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.113		2023-02-14
		41	Post-exposure display of changed CT CONDITIONS OF OPERATION	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.114		2023-02-14
		42	Indication and position of the TOMOGRAPHIC SECTION	Medical electrical equipment –Part 2-44: Particular requirements for the basic safety and essential performanceof X-ray equipment for computed tomography IEC 60601-2-44:2012 203.115		2023-02-14
256	Mammographic X-ray equipment and mammographic stereotactic devices	1	All Parameters	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011		2023-02-14
		2	General requirements	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.4		
		3	ESSENTIAL PERFORMANCE	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.4.3		2023-02-14
		4	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.4.10.2		2023-02-14
		5	Data recording	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.4.101		2023-02-14
		6	General requirements for testing of ME EQUIPMENT	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.5		2023-02-14
		7	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.6		2023-02-14
		8	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.7.2		2023-02-14
		9	Indicator lights and controls	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				60601-2-45:2011 201.7.8		
		10	ACCOMPANYING DOCUMENTS	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.7.9		2023-02-14
		11	Limitation of voltage, current or energy	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.8.4		2023-02-14
		12	Separation of parts	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.8.5		2023-02-14
		13	Protective earthing, functional earthing and potential equalization ofME EQUIPMENT	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.8.6		2023-02-14
		14	LEAKAGE CURRENTS and PATIENT auxiliary currents	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.8.7		2023-02-14
		15	Insulation	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.8.8		2023-02-14
		16	MECHANICAL HAZARDS of ME EQUIPMENT	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.9.1		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	HAZARDS associated with moving parts	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.9.2		2023-02-14
		18	Protection against unwanted and excessive radiation HAZARDS	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.10		2023-02-14
		19	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.11		2023-02-14
		20	Accuracy of controls and instruments and protection against hazardousoutputs	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.12		2023-02-14
		21	Hazardous situations and fault conditions	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.13		2023-02-14
		22	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.14		2023-02-14
		23	ME EQUIPMENT components and general assembly	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.15.4		2023-02-14
		24	ME SYSTEMS	Medical electrical equipment –Part 2-45: Particular requirements		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.16		
		25	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 201.17		2023-02-14
		26	Electromagnetic compatibility – Requirements and tests	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 202		2023-02-14
		27	General requirements	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.4		2023-02-14
		28	ME EQUIPMENT identification, marking and documents	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.5		2023-02-14
		29	Initiation and termination of the IRRADIATION	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.6.2		2023-02-14
		30	RADIATION dose and RADIATION QUALITY	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.6.3		2023-02-14
		31	Indication of operational states	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				60601-2-45:2011 203.6.4		
		32	AUTOMATIC CONTROL SYSTEM	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.6.5		2023-02-14
		33	Imaging performance	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.6.7		2023-02-14
		34	HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.7.1		2023-02-14
		35	Indication of FILTER properties	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.7.3		2023-02-14
		36	Test for HALF-VALUE LAYER	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.7.6		2023-02-14
		37	Limitation and indication of the extent of the X-RAY BEAM and relationshipbetween X-RAY FIELD and IMAGE RECEPTION	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.8		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			AREA			
		38	FOCAL SPOT TO SKIN DISTANCE	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.9		2023-02-14
		39	ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGERECEPTOR	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.10		2023-02-14
		40	Protection against RESIDUAL RADIATION	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.11		2023-02-14
		41	Protection against STRAY RADIATION	Medical electrical equipment –Part 2-45: Particular requirements for the basic safety and essential performanceof mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2011 203.13		2023-02-14
257	Medical diagnostic X-ray equipment	1	All Parameters	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021		2023-02-14
		2	Classification and compose	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 4		2023-02-14
		3	Classification	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 4.1		2023-02-14
		4	Compose	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 4.2		2023-02-14
		5	Requirements	General specifications on medical diagnostic X-ray equipment		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				YY/T 0106-2021 6		
		6	Working conditions	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 5.1		2023-02-14
		7	Electric power	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 5.2		2023-02-14
		8	Loading factors and control	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 5.3		2023-02-14
		9	Imaging performance	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 5.4		2023-02-14
		10	Radiation safety	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 5.5		2023-02-14
		11	Pediatric check	General specifications for medcial diagnostic X-ray equipment YY/T 0106-2021 5.6		2023-02-14
		12	Mechanical device performance	General specifications for medcial diagnostic X-ray equipment YY/T 0106-2021 5.7		2023-02-14
		13	Network and software	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 5.8		2023-02-14
		14	X-ray tomography	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 5.9		2023-02-14
		15	Accompanying document	General specifications for medcial diagnostic X-ray equipment YY/T 0106-2021 5.10		2023-02-14
		16	display system	General specifications for medcial diagnostic X-ray equipment YY/T 0106-2021 5.11		2023-02-14
		17	X-ray high-voltage cable plug and socket	General specifications on medical diagnostic X-ray equipment YY/T 0106-2008 5.8		2023-02-14
		18	Appearance	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 5.12		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	Environmental tests	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 5.15		2023-02-14
		20	Safety	General specifications on medical diagnostic X-ray equipment YY/T 0106-2021 5.14		2023-02-14
258	Medical X-ray Angiography Equipment	1	All Parameters	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009		2023-02-14
		2	Classification and Composition	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 4		2023-02-14
		3	Classification	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 4.1		2023-02-14
		4	Composition	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 4.2		2023-02-14
		5	Requirements	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 5		2023-02-14
		6	Operating Conditions	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 5.1		2023-02-14
		7	Electric Power	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 5.2		2023-02-14
		8	Loading Factors and Control	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 5.3		2023-02-14
		9	Imaging Performance	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 5.4		2023-02-14
		10	Performance of Mechanical Device	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 5.5		2023-02-14
		11	Software Function	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 5.6		2023-02-14
		12	Liquid Cooling System	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 5.7		2023-02-14
		13	Plug and Socket of High Voltage Cable	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 5.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Appearance	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 5.9		2023-02-14
		15	Environmental Test	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 5.1		2023-02-14
		16	Safety	Particular Specifications for Medical X-ray Angiography Equipment YY/T 0740-2009 5.11		2023-02-14
259	Digital medical X-ray radiography system	1	All Parameters	General specifications for digital medical X-ray radiography system YY/T 0741-2018		2023-02-14
		2	Working conditions	General specifications for digital medical X-ray radiography system YY/T 0741-2018 5.1		2023-02-14
		3	Electric power	General specifications for digital medical X-ray radiography system YY/T 0741-2018 5.2		2023-02-14
		4	Loading factors and control	General specifications for digital medical X-ray radiography system YY/T 0741-2018 5.3		2023-02-14
		5	Image quality	General specifications for digital medical X-ray radiography system YY/T 0741-2018 5.4		2023-02-14
		6	Performance of mechanical devices	General specifications for digital medical X-ray radiography system YY/T 0741-2018 5.5		2023-02-14
		7	Network and software	General specifications for digital medical X-ray radiography system YY/T 0741-2018 5.6		2023-02-14
		8	X-ray high-voltage cable plug and socket	General specifications for digital medical X-ray radiography system YY/T 0741-2018 5.7		2023-02-14
		9	Appearance	General specifications for digital medical X-ray radiography system YY/T 0741-2018 5.8		2023-02-14
		10	Environmental tests	General specifications for digital medical X-ray radiography system YY/T 0741-2018 5.9		2023-02-14
		11	Safety	General specifications for digital medical X-ray radiography system YY/T 0741-2018 5.10		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
260	Gastrointestinal diagnostic X-ray equipment	1	All Parameters	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021		2023-02-14
		2	Classification and compose	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 4		2023-02-14
		3	Classification	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 4.1		2023-02-14
		4	compose	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 4.2		2023-02-14
		5	Requirements	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5		2023-02-14
		6	Working conditions	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.1		2023-02-14
		7	Electric power	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.2		2023-02-14
		8	Loading factors and control	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.3		2023-02-14
		9	X-ray indirect radiography and radio scopy imaging performance	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.4		2023-02-14
		10	Radiation safety	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.5		2023-02-14
		11	Gastrointestinal diagnostic bed	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.6		2023-02-14
		12	Noise	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.11		2023-02-14
		13	Remote control	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.7		2023-02-14
		14	Foot switch	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Displayer	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.10		2023-02-14
		16	Appearance	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.14		2023-02-14
		17	Environmental tests	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.15		2023-02-14
		18	Safety	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.16		2023-02-14
		19	Accompanying document	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.8		2023-02-14
		20	Network and Software	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.12		2023-02-14
		21	High voltage cable plug and socket	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021 5.13		2023-02-14
261	X-ray gastrointestinal diagnostic table	1	All Parameters	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009		2023-02-14
		2	Working conditions	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.1		2023-02-14
		3	Performance for table tilting	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.2		2023-02-14
		4	Performance for table moving	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.3		2023-02-14
		5	performance for Spot film device	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.4		2023-02-14
		6	Compression device	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.5		2023-02-14
		7	Height of foot rests	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.6		2023-02-14
		8	Fluoroscopy coverage	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Other Requirements	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.8		2023-02-14
		10	Braking force	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.9		2023-02-14
		11	Start force	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.10		2023-02-14
		12	Weight	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.11		2023-02-14
		13	Noise	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.12		2023-02-14
		14	Appearance	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.13		2023-02-14
		15	Environmental tests	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.14		2023-02-14
		16	Safety	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009 5.15		2023-02-14
262	Mobile C-arm X-ray equipment	1	All Parameters	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018		2023-02-14
		2	Electric power	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.2		2023-02-14
		3	X-ray tube voltage	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-218 5.3.1		2023-02-14
		4	X-ray tube current	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.3.2		2023-02-14
		5	Loading time	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.3.3		2023-02-14
		6	Current time product	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.3.4		2023-02-14
		7	Against overload	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.3.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Imaging performance	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.4		2023-02-14
		9	radiation safety	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.5		2023-02-14
		10	Performance of mechanical devices	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.6		2023-02-14
		11	Software	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.7		2023-02-14
		12	X-ray high-voltage cable plug and socket	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.8		2023-02-14
		13	Noise	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.9		2023-02-14
		14	Appearance	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.10		2023-02-14
		15	Environmental tests	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.11		2023-02-14
		16	Safety	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018 5.12		2023-02-14
263	Remote control radioscopy X-ray equipment	1	All Parameters	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009		2023-02-14
		2	Working conditions	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.1		2023-02-14
		3	Maximum output power	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.2		2023-02-14
		4	X-ray tube voltage	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.3		2023-02-14
		5	X-ray tube current	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	X-ray high-voltage cable plug and socket	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.5		2023-02-14
		7	X-ray image intensifier TV system	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.6		2023-02-14
		8	Automatic control performance	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.7		2023-02-14
		9	Performance of mechanical movement	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.8		2023-02-14
		10	Means of communication	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.9		2023-02-14
		11	Patients monitor	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.10		2023-02-14
		12	Braking force	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.11		2023-02-14
		13	Indicator for Length	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.12		2023-02-14
		14	Indicator for Angle	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.13		2023-02-14
		15	Weight	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.14		2023-02-14
		16	Noise	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.15		2023-02-14
		17	Appearance	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.16		2023-02-14
		18	Environmental tests	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.17		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	Safety	Particular specifications for remote control radioscopy X-ray equipment YY/T 0745-2009 5.18		2023-02-14
264	medcial X-ray equipment install on the vehicle	1	All Parameters	Particular specifications for medcial X-ray equipment install on the vehicle YY/T 0746-2021		2023-02-14
		2	Electric power	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.2		2023-02-14
		3	Basic requirement	Particular specifications for medcial X-ray equipment install on the vehicle YY/T 0746-2021 5.2		2023-02-14
		4	X-ray tube voltage	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.3.1		2023-02-14
		5	X-ray tube current	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.3.2		2023-02-14
		6	Loading time	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.3.3		2023-02-14
		7	Current time product	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.3.4		2023-02-14
		8	Against overload	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.3.5		2023-02-14
		9	Imaging performance	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.4		2023-02-14
		10	Range for Mechanical movement	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.5.1		2023-02-14
		11	Indicator for Length	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.5.2		2023-02-14
		12	Indicator for Angle	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.5.3		2023-02-14
		13	Braking force	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.5.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Start force	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.5.5		2023-02-14
		15	Weight	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.5.6		2023-02-14
		16	Noise	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.5.7		2023-02-14
		17	Software	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.6		2023-02-14
		18	X-ray high-voltage cable plug and socket	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.7		2023-02-14
		19	Space requirements for carrying vehicles	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.3		2023-02-14
		20	Input Power	Particular specifications for medcial X-ray equipment install on the vehicle YY/T 0746-2021 5.4		2023-02-14
		21	Installation Stability	Particular specifications for medcial X-ray equipment install on the vehicle YY/T 0746-2009 5.5		2023-02-14
		22	Protective earthing requirement	Particular specifications for medcial X-ray equipment install on the vehicle YY/T 0746-2021 5.6		2023-02-14
		23	Appearance	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.12		2023-02-14
		24	Environmental tests	Particular specifications for medcial X-ray equipment install on the vehicle YY/T 0746-2021 5.7		2023-02-14
		25	Safety	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2009 5.14		2023-02-14
265	Mammographic X-ray equipment	1	All Parameters	Particular specifications for mammographic X-ray equipment YY/T0706-2017		2023-02-14
		2	Electric power	Particular specifications for mammographic X-ray equipment YY/T0706-2017 5.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	loading factors control and display	Particular specifications for mammographic X-ray equipment YY/T0706-2017 5.3		2023-02-14
		4	imaging performance	Particular specifications for mammographic X-ray equipment YY/T0706-2017 5.4		2023-02-14
		5	Performance of mechanical device	Particular specifications for mammographic X-ray equipment YY/T0706-2017 5.5		2023-02-14
		6	software	Particular specifications for mammographic X-ray equipment YY/T0706-2017 5.6		2023-02-14
		7	high voltage cable plug and socket	Particular specifications for mammographic X-ray equipment YY/T0706-2017 5.7		2023-02-14
		8	appearance	Particular specifications for mammographic X-ray equipment YY/T0706-2017 5.8		2023-02-14
		9	environmental tests	Particular specifications for mammographic X-ray equipment YY/T0706-2017 5.9		2023-02-14
		10	safety	Particular specifications for mammographic X-ray equipment YY/T0706-2017 5.10		2023-02-14
266	Mobile radiography X-ray equipment	1	All Parameters	Particular specifications for mobile radiography X-ray equipment YY/T0707-2008		2023-02-14
		2	Electric power	Particular specifications for mobile radiography X-ray equipment YY/T0707-2008 5.2		2023-02-14
		3	loading factors and control	Particular specifications for mobile radiography X-ray equipment YY/T0707-2008 5.3		2023-02-14
		4	imaging performance	Particular specifications for mobile radiography X-ray equipment YY/T0707-2008 5.4		2023-02-14
		5	Performance of mechanical device	Particular specifications for mobile radiography X-ray equipment YY/T0707-2008 5.5		2023-02-14
		6	noise	Particular specifications for mobile radiography X-ray equipment YY/T0707-2008 5.6		2023-02-14
		7	internally power capacity	Particular specifications for mobile radiography X-ray equipment YY/T0707-2008 5.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	moving mode size	Particular specifications for mobile radiography X-ray equipment YY/T0707-2008 5.8		2023-02-14
		9	high voltage cable plug and socket	Particular specifications for mobile radiography X-ray equipment YY/T0707-2008 5.9		2023-02-14
		10	appearance	Particular specifications for mobile radiography X-ray equipment YY/T0707-2008 5.10		2023-02-14
		11	environmental tests	Particular specifications for mobile radiography X-ray equipment YY/T0707-2008 5.11		2023-02-14
		12	safety requirement	Particular specifications for mobile radiography X-ray equipment YY/T0707-2008 5.12		2023-02-14
267	Mini medical diagnostic X-ray equipment	1	All Parameters	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009		2023-02-14
		2	Maximum output power	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.2		2023-02-14
		3	Adjustments of X-ray tube voltage	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.3.1		2023-02-14
		4	Variation of the value of the tube voltage	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.3.2		2023-02-14
		5	Adjustments of X-ray tube current	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.4.1		2023-02-14
		6	Variation of the value of the Tube current	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.4.2		2023-02-14
		7	Loading time and timing device	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.5		2023-02-14
		8	Effective irradiation fields size	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.6		2023-02-14
		9	screen brightness	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.7.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Spatial resolution	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.7.2		2023-02-14
		11	Gray scale	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.7.3		2023-02-14
		12	Beam limiting device	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.8		2023-02-14
		13	Focus-receptor distance and Focus-skin distance	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.9		2023-02-14
		14	Additional shield	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.10		2023-02-14
		15	Leakage radiation under loading conditions	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.11		2023-02-14
		16	Appearance	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.12		2023-02-14
		17	Environmental tests	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.13		2023-02-14
		18	safety	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009 5.14		2023-02-14
268	X-ray unit for Oral cavity	1	All Parameters	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020		2023-02-14
		2	Classification and compose	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 4		2023-02-14
		3	Classification	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 4.1		2023-02-14
		4	compose	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 4.2		2023-02-14
		5	Requirements	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Working conditions	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 5.1		2023-02-14
		7	Electric power	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 5.2		2023-02-14
		8	Loading factors and control	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 5.3		2023-02-14
		9	Imaging performance	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 5.4		2023-02-14
		10	Performance of mechanical devices	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 5.5		2023-02-14
		11	Software	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 5.6		2023-02-14
		12	Appearance	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 5.7		2023-02-14
		13	Environmental tests	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 5.8		2023-02-14
		14	safety	Particular specifications for X-ray unit for Oral cavity YY/T 0010-2020 5.9		2023-02-14
269	Dual energy X-ray bone densitometer	1	All Parameters	Particular specifications for dual-energy X-ray absorptiometry YY/T 0724-2021		2023-02-14
		2	Classification and compose	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 4		2023-02-14
		3	Classification	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 4.1		2023-02-14
		4	compose	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 4.2		2023-02-14
		5	Requirements	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 5		2023-02-14
		6	Working conditions	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Electric power	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 5.2		2023-02-14
		8	Loading factors and control	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 5.3		2023-02-14
		9	X-ray irradiation	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 5.4		2023-02-14
		10	Supporting device	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 5.7		2023-02-14
		11	Report output and software function	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 5.8		2023-02-14
		12	Noise	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 5.9		2023-02-14
		13	Bone mineral density	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 5.6		2023-02-14
		14	Appearance	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 5.10		2023-02-14
		15	Environmental tests	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 5.11		2023-02-14
		16	safety	Particular specifications for dual energy X-ray bone densitometer YY/T 0724-2021 5.12		2023-02-14
		17	Detector	Particular specifications for dual-energy X-ray absorptiometry YY/T 0724-2021 5.5		2023-02-14
270	X-ray tube assemblies	1	All Parameters	Determination of the permanent filtration of X-ray tube assemblies YY/T 0062-2004 IEC 60522:1999		2023-02-14
		2	Measurement of inherent filtration	Determination of the permanent filtration of X-ray tube assemblies YY/T 0062-2004 IEC 60522:1999 4		2023-02-14
		3	Gereral	Determination of the permanent filtration of X-ray tube assemblies YY/T 0062-2004 IEC 60522:1999 4.1		2023-02-14
		4	Test samples	Determination of the permanent filtration of X-ray tube assemblies YY/T 0062-2004 IEC 60522:1999 4.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Generation of the X-RAY BEAM for measurement	Determination of the permanent filtration of X-ray tube assemblies YY/T 0062-2004 IEC 60522:1999 4.3		2023-02-14
		6	Radiation detector	Determination of the permanent filtration of X-ray tube assemblies YY/T 0062-2004 IEC 60522:1999 4.4		2023-02-14
		7	Composition of reference materials	Determination of the permanent filtration of X-ray tube assemblies YY/T 0062-2004 IEC 60522:1999 4.5		2023-02-14
		8	Method of measurement	Determination of the permanent filtration of X-ray tube assemblies YY/T 0062-2004 IEC 60522:1999 4.6		2023-02-14
		9	Indications and statements of PERMANENT FILTRATION	Determination of the permanent filtration of X-ray tube assemblies YY/T 0062-2004 IEC 60522:1999 5		2023-02-14
271	Medical electrical equipment—X-ray tube assemblies	1	All Parameters	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005		2023-02-14
		2	Determinations for the evaluation of the FOCAL SPOT characteristics	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 4		2023-02-14
		3	Statement of the FOCAL SPOT characteristics	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 4.1		2023-02-14
		4	Longitudinal axis of the X-RAY TUBE ASSEMBLY	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 4.2		2023-02-14
		5	REFERENCE AXIS of the X-RAY TUBE ASSEMBLY	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 4.3		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Direction of evaluation for the FOCAL SPOT length	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 4.4		2023-02-14
		7	Direction of evaluation for the FOCAL SPOT w h	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 4.5		2023-02-14
		8	FOCAL SPOT camera set-up	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 5		2023-02-14
		9	Overview	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 5.1		2023-02-14
		10	Test Equipment	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 5.2		2023-02-14
		11	Test arrangement	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 5.3		2023-02-14
		12	Total uncertainty of the camera set-up	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 5.4		2023-02-14
		13	Production of RADIOGRAMS	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 6		2023-02-14
		14	Overview	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 6.1		2023-02-14
		15	Operating conditions	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				60336:2005 6.2		
		16	Production of FOCAL SPOT SLIT RADIOGRAMS or FOCAL SPOT PINHOLE	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 6.3		2023-02-14
		17	Statement of compliance	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 6.4		2023-02-14
		18	Determination of the LINE SPREAD FUNCTION	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 7		2023-02-14
		19	Overview	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 7.1		2023-02-14
		20	Measuring equipment and measuring arrangement	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 7.2		2023-02-14
		21	Measurement of the density distribution	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 7.3		2023-02-14
		22	Determination of the LINE SPREAD FUNCTION	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 7.4		2023-02-14
		23	Statement of compliance	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 7.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		24	Determination of FOCAL SPOT dimensions	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 8		2023-02-14
		25	Overview	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 8.1		2023-02-14
		26	Measurement and determination	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 8.2		2023-02-14
		27	Specified NOMINAL FOCAL SPOT VALUES	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 8.3		2023-02-14
		28	Statement of compliance	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 8.4		2023-02-14
		29	Marking of compliance	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 8.5		2023-02-14
		30	Determination of the MODULATION TRANSFER FUNCTION	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 9		2023-02-14
		31	Overview	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 9.1		2023-02-14
		32	Specified MODULATION TRANSFER FUNCTION	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 9.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		33	Calculation of the MODULATION TRANSFER FUNCTION	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 9.3		2023-02-14
		34	Evaluation of compliance of the MTF	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 9.4		2023-02-14
		35	Statement of compliance	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 9.5		2023-02-14
		36	FOCAL SPOT STAR RADIOGRAMS	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 10		2023-02-14
		37	Overview	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 10.1		2023-02-14
		38	Test Equipment	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 10.2		2023-02-14
		39	STAR PATTERN RESOLUTION LIMIT	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 11		2023-02-14
		40	Overview	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 11.1		2023-02-14
		41	Specified STAR PATTERN RESOLUTION LIMIT	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 11.2		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		42	Measurement	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 11.3		2023-02-14
		43	Determination of the STAR PATTERN RESOLUTION LIMIT	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 11.4		2023-02-14
		44	Evaluation and statement of compliance	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 11.5		2023-02-14
		45	BLOOMING VALUE	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 12		2023-02-14
		46	Overview	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 12.1		2023-02-14
		47	Determination of the BLOOMING VALUE	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 12.2		2023-02-14
		48	Evaluation and statement of compliance	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 12.3		2023-02-14
		49	Alternate measurement methods	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots YY/T0063-2007 IEC 60336:2005 13		2023-02-14
272	X-ray tube assemblies for medical diagnosis	1	All Parameters	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010		2023-02-14
		2	Electrical characteristics of an	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			X-ray tube			
		3	X-ray tube voltage	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 4.1		2023-02-14
		4	Nominal X-ray tube voltage	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 4.2		2023-02-14
		5	X-ray tube current	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 4.3		2023-02-14
		6	Cathode emission characteristic	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 4.4		2023-02-14
		7	tube cover emission characteristic	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 4.5		2023-02-14
		8	Loading of an X-ray tube	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 5		2023-02-14
		9	Loading time	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 5.1		2023-02-14
		10	Cycle	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 5.2		2023-02-14
		11	Input power	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 6		2023-02-14
		12	Radiography ratings	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 7		2023-02-14
		13	Single load fixed	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 7.1		2023-02-14
		14	Seral load fixed	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis YY/T 0064-2016 IEC60613:2010 7.2		2023-02-14
273	Medical diagnostic X-ray tube assemblies	1	All Parameters	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018		2023-02-14
		2	Classification	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Requirements	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 4		2023-02-14
		4	Working conditions	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 4.1		2023-02-14
		5	X-ray tube focus	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 4.2		2023-02-14
		6	accompanying documents	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 4.3		2023-02-14
		7	Sealing performance	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 4.4		2023-02-14
		8	safety devices of X-ray tube assemblies for heat capacity	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 4.5		2023-02-14
		9	X-ray tube assemblies for filtration	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 4.6		2023-02-14
		10	Leakage radiation for X-ray tube assemblies for	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 4.7		2023-02-14
		11	High voltage cable outlet	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 4.8		2023-02-14
		12	Environmental tests	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 4.9		2023-02-14
		13	safety	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 4.10		2023-02-14
		14	Appearance	General specifications of medical diagnostic X-ray tube assemblies YY/T 0609-2018 4.11		2023-02-14
274	Medical X-ray radiographic table	1	All Parameters	Particular specifications for medical X-ray radiographic table YY/T 0737-2009		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	Classification and compose	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 4		2023-02-14
		3	Classification	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 4.1		2023-02-14
		4	compose	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 4.2		2023-02-14
		5	Requirements	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5		2023-02-14
		6	Working conditions	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.1		2023-02-14
		7	Height of table	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.2		2023-02-14
		8	Range of the table movement	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.3		2023-02-14
		9	X-ray tube head supporting device	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.4		2023-02-14
		10	table top	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.5		2023-02-14
		11	Grid	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.6		2023-02-14
		12	table load	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.7		2023-02-14
		13	Indicator for Length	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.8		2023-02-14
		14	Indicator for Angle	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.9		2023-02-14
		15	Start force	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.10		2023-02-14
		16	Braking force	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.11		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	power-driven motions	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.12		2023-02-14
		18	Appearance	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.13		2023-02-14
		19	Environmental tests	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.14		2023-02-14
		20	Safety	Particular specifications for medical X-ray radiographic table YY/T 0737-2009 5.15		2023-02-14
275	Cardiovascular table	1	All Parameters	Particular specifications for cardiovascular table YY/T 0738-2009		2023-02-14
		2	Classification and compose	Particular specifications for cardiovascular table YY/T 0738-2009 4		2023-02-14
		3	Classification	Particular specifications for cardiovascular table YY/T 0738-2009 4.1		2023-02-14
		4	compose	Particular specifications for cardiovascular table YY/T 0738-2009 4.2		2023-02-14
		5	Requirements	Particular specifications for cardiovascular table YY/T 0738-2009 5		2023-02-14
		6	Working conditions	Particular specifications for cardiovascular table YY/T 0738-2009 5.1		2023-02-14
		7	Brake	Particular specifications for cardiovascular table YY/T 0738-2009 5.2		2023-02-14
		8	table top material	Particular specifications for cardiovascular table YY/T 0738-2009 5.3		2023-02-14
		9	Range of Mechanical movement	Particular specifications for cardiovascular table YY/T 0738-2009 5.4		2023-02-14
		10	Start force	Particular specifications for cardiovascular table YY/T 0738-2009 5.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Noise	Particular specifications for cardiovascular table YY/T 0738-2009 5.6		2023-02-14
		12	Weight	Particular specifications for cardiovascular table YY/T 0738-2009 5.7		2023-02-14
		13	Foot Switch	Particular specifications for cardiovascular table YY/T 0738-2009 5.8		2023-02-14
		14	Structure and layout	Particular specifications for cardiovascular table YY/T 0738-2009 5.9		2023-02-14
		15	Other	Particular specifications for cardiovascular table YY/T 0738-2009 5.10		2023-02-14
		16	Appearance	Particular specifications for cardiovascular table YY/T 0738-2009 5.11		2023-02-14
		17	Environmental tests	Particular specifications for cardiovascular table YY/T 0738-2009 5.12		2023-02-14
		18	Safety	Particular specifications for cardiovascular table YY/T 0738-2009 5.13		2023-02-14
276	Wall stand of medical X-ray equipment	1	All Parameters	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009		2023-02-14
		2	Working conditions	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009 4.1		2023-02-14
		3	Range of Mechanical movement	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009 4.2		2023-02-14
		4	Braking force	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009 4.3		2023-02-14
		5	Starting Force	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009 4.4		2023-02-14
		6	Noise	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009 4.5		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Cassette holder	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009 4.6		2023-02-14
		8	Front panel of Cassette holder	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009 4.7		2023-02-14
		9	Grids	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009 4.8		2023-02-14
		10	Appearance	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009 4.9		2023-02-14
		11	Environmental tests	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009 4.10		2023-02-14
		12	safety	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009 4.11		2023-02-14
277	Digital X-ray imaging devices	1	All Parameters	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0590.1-2018 IEC 62220-1:2015		2023-02-14
		2	Determination of the detective quantum efficiency	Medical electrical equipment -- Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency YY/T 0590.1-2018 IEC 62220-1:2015 6		2023-02-14
278	X-ray Radiographic cassette	1	All Parameters	X-ray Radiographic cassette YY/T 0011-2007		2023-02-14
		2	Cassette's Basic dimensions、Limited Deviation、Weight	X-ray Radiographic cassette YY/T 0011-2007 3.1		2023-02-14
		3	Cassette materials	X-ray Radiographic cassette YY/T 0011-2007 3.2		2023-02-14
		4	Cassette Hinges and Locking of joint	X-ray Radiographic cassette YY/T 0011-2007 3.3		2023-02-14
		5	Cassette shall not leak light	X-ray Radiographic cassette YY/T 0011-2007 3.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Cassette shall be well attached with intensifying sceens and the X-ray film	X-ray Radiographic cassette YY/T 0011-2007 3.5		2023-02-14
		7	Aluminum equivalent of cassette cover、aluminum equivalent of cassette box body	X-ray Radiographic cassette YY/T 0011-2007 3.6		2023-02-14
		8	Cassette lead foil and cushion	X-ray Radiographic cassette YY/T 0011-2007 3.7		2023-02-14
		9	Cassette hinge、rivet、locking of joint	X-ray Radiographic cassette YY/T 0011-2007 3.8		2023-02-14
		10	Cassette receptive fieldss and four edges	X-ray Radiographic cassette YY/T 0011-2007 3.9		2023-02-14
		11	Cassette corners	X-ray Radiographic cassette YY/T 0011-2007 3.1		2023-02-14
		12	Cassette plating	X-ray Radiographic cassette YY/T 0011-2007 3.11		2023-02-14
		13	Markings, package, transportation and storage	X-ray Radiographic cassette YY/T 0011-2007 6		2023-02-14
		14	Markings	X-ray Radiographic cassette YY/T 0011-2007 6.1		2023-02-14
		15	Package	X-ray Radiographic cassette YY/T 0011-2007 6.2		2023-02-14
		16	Transportation	X-ray Radiographic cassette YY/T 0011-2007 6.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	Storage	X-ray Radiographic cassette YY/T 0011-2007 6.4		2023-02-14
279	Medical diagnostic X-ray adjustable beam limiting	1	All Parameters	General Specification for medical diagnostic X-ray adjustable beam limiting YY/T 0129-2007		2023-02-14
		2	Working conditions	General Specification for medical diagnostic X-ray adjustable beam limiting YY/T 0129-2007 3.1		2023-02-14
		3	Maximum X-ray radiation fields	General Specification for medical diagnostic X-ray adjustable beam limiting YY/T 0129-2007 3.2		2023-02-14
		4	Minimum X-ray radiation fields	General Specification for medical diagnostic X-ray adjustable beam limiting YY/T 0129-2007 3.3		2023-02-14
		5	Light fields indicator	General Specification for medical diagnostic X-ray adjustable beam limiting YY/T 0129-2007 3.4		2023-02-14
		6	Leakage radiation in the loading state	General Specification for medical diagnostic X-ray adjustable beam limiting YY/T 0129-2007 3.5		2023-02-14
		7	Equivalent filtration	General Specification for medical diagnostic X-ray adjustable beam limiting YY/T 0129-2007 3.6		2023-02-14
		8	Additional filtration	General Specification for medical diagnostic X-ray adjustable beam limiting YY/T 0129-2007 3.7		2023-02-14
		9	Accompanying documents	General Specification for medical diagnostic X-ray adjustable beam limiting YY/T 0129-2007 3.8		2023-02-14
		10	Environmental Tests	General Specification for medical diagnostic X-ray adjustable beam limiting YY/T 0129-2007 3.9		2023-02-14
		11	Safety	General Specification for medical diagnostic X-ray adjustable beam limiting YY/T 0129-2007 3.1		2023-02-14
		12	Appearance	General Specification for medical diagnostic X-ray adjustable beam limiting YY/T 0129-2007 3.11		2023-02-14
280	Medical diagnostic X-ray equipment - High voltage	1	All Parameters	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008		2023-02-14
		2	Basic dimensions and form of plugs	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.1.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	cable plugs and socket		and sockets			
		3	Markings	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.1.2		2023-02-14
		4	Connection	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.1.3		2023-02-14
		5	Physical performance of plugs and sockets	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.2		2023-02-14
		6	Contact area	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.3		2023-02-14
		7	DC dielectric strength	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.4		2023-02-14
		8	AC dielectric strength	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.5		2023-02-14
		9	Sealing performance	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.6		2023-02-14
		10	Durability of pin of plug	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.7		2023-02-14
		11	Durability of patch	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.8		2023-02-14
		12	Mechanical strength	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.9		2023-02-14
		13	Reliability	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.10		2023-02-14
		14	Performance of against mechanical stress	Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and socket GB/T 10151-2008 4.11		2023-02-14
281	Diagnostic X-ray imaging	1	All Parameters	Diagnostic X-ray imaging equipment—Characteristic of general purpose and mammographic anti-scatter grids YY/T 0480-2021		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	equipment—General purpose and mammographic anti-scatter grids			IEC 60627:2013		
		2	Measurement and determination of physical characteristics	Diagnostic X-ray imaging equipment—Characteristic of general purpose and mammographic anti-scatter grids YY/T 0480-2021 IEC 60627:2013 5		2023-02-14
		3	Method and arrangement for measurement	Diagnostic X-ray imaging equipment—Characteristic of general purpose and mammographic anti-scatter grids YY/T 0480-2021 IEC 60627:2013 5.1		2023-02-14
		4	Physical Characteristics	Diagnostic X-ray imaging equipment—Characteristic of general purpose and mammographic anti-scatter grids YY/T 0480-2021 IEC 60627:2013 5.2		2023-02-14
		5	Requirements for anti-scatter grids	Diagnostic X-ray imaging equipment—Characteristic of general purpose and mammographic anti-scatter grids YY/T 0480-2021 IEC 60627:2013 7		2023-02-14
		6	Manufacturing tolerance	Diagnostic X-ray imaging equipment—Characteristic of general purpose and mammographic anti-scatter grids YY/T 0480-2021 IEC 60627:2013 6.1		2023-02-14
		7	Determine the limit of application	Diagnostic X-ray imaging equipment—Characteristic of general purpose and mammographic anti-scatter grids YY/T 0480-2021IEC 60627:2013 6.2		2023-02-14
		8	Accuracy of characteristics	Diagnostic X-ray imaging equipment—Characteristic of general purpose and mammographic anti-scatter grids YY/T 0480-2021IEC 60627:2013 6.3		2023-02-14
		9	Marking and accompanying documents	Diagnostic X-ray imaging equipment—Characteristic of general purpose and mammographic anti-scatter grids YY/T 0480-2021IEC 60627:2013 6.4		2023-02-14
		10	Statement of compliance	Diagnostic X-ray imaging equipment—Characteristic of general purpose and mammographic anti-scatter grids YY/T 0480-2004 IEC 60627:2001 6.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
282	Medical diagnostic X-ray device for tomography	1	All Parameters	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009		2023-02-14
		2	Classification	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 4		2023-02-14
		3	Requirements	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5		2023-02-14
		4	Working conditions	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5.1		2023-02-14
		5	Height of tomographic plane	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5.2		2023-02-14
		6	Exposure angle	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5.3		2023-02-14
		7	Movement and track of tomography	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5.4		2023-02-14
		8	Thickness of tomographic plane	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5.5		2023-02-14
		9	Planeness of tomographic plane	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5.6		2023-02-14
		10	Spatial resolution of tomographic plane	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5.7		2023-02-14
		11	Noise	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5.8		2023-02-14
		12	Braking force	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5.9		2023-02-14
		13	Appearance	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5.1		2023-02-14
		14	Environmental Tests	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5.11		2023-02-14
		15	Safety	Specifications for Medical diagnostic X-ray device for tomography YY/T 0202-2009 5.12		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
283	Medical X-ray image intensifier and TV system	1	All Parameters	capability items and test methods for Medical X-ray image intensifier and TV system SJ/T 11094-1996		2023-02-14
		2	Resolution	capability items and test methods for Medical X-ray image intensifier and TV system SJ/T 11094-1996 3.1		2023-02-14
		3	contrast sensitivity	capability items and test methods for Medical X-ray image intensifier and TV system SJ/T 11094-1996 3.2		2023-02-14
		4	Image detectable brightness level	capability items and test methods for Medical X-ray image intensifier and TV system SJ/T 11094-1996 3.3		2023-02-14
		5	Minimum exposure dose rate	capability items and test methods for Medical X-ray image intensifier and TV system SJ/T 11094-1996 3.4		2023-02-14
		6	Image brightness stability	capability items and test methods for Medical X-ray image intensifier and TV system SJ/T 11094-1996 3.5		2023-02-14
		7	lasting accuracy	capability items and test methods for Medical X-ray image intensifier and TV system SJ/T 11094-1996 3.5.1		2023-02-14
		8	Time response	capability items and test methods for Medical X-ray image intensifier and TV system SJ/T 11094-1996 3.5.2		2023-02-14
284	Medical X-ray TV system	1	All Parameters	Test method for Medical X-ray TV system SJ/T 11096-1996		2023-02-14
		2	Testing conditions	Test method for Medical X-ray TV system SJ/T 11096-1996 4		2023-02-14
		3	Circular geometric distortion	Test method for Medical X-ray TV system SJ/T 11096-1996 5.1		2023-02-14
		4	Image geometric distortion	Test method for Medical X-ray TV system SJ/T 11096-1996 5.2		2023-02-14
		5	Horizontal scanning nonlinear distortion	Test method for Medical X-ray TV system SJ/T 11096-1996 5.3.2.1		2023-02-14
		6	Vertical scanning nonlinear distortion	Test method for Medical X-ray TV system SJ/T 11096-1996 5.3.2.2		2023-02-14
		7	Resolution	Test method for Medical X-ray TV system SJ/T 11096-1996 5.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Brightness level identification	Test method for Medical X-ray TV system SJ/T 11096-1996 5.5		2023-02-14
		9	signal-to-noise ratio	Test method for Medical X-ray TV system SJ/T 11096-1996 5.6		2023-02-14
285	X-ray image intensifier TV system for medical diagnosis	1	All Parameters	General technical requirements for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013		2023-02-14
		2	useful entrance fields size	General technical requirements for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013 4.1		2023-02-14
		3	Image distortion	General technical requirements for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013 4.2		2023-02-14
		4	Contrast range	General technical requirements for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013 4.3		2023-02-14
		5	Image detectable gray level	General technical requirements for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013 4.4		2023-02-14
		6	line pair resolution	General technical requirements for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013 4.5		2023-02-14
		7	low contrast resolution	General technical requirements for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013 4.6		2023-02-14
		8	image brightness stability signal	General technical requirements for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013 4.7		2023-02-14
		9	Video voltage output	General technical requirements for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013 4.8		2023-02-14
		10	Environmental Tests	General technical requirements for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013 4.9		2023-02-14
		11	Safety	General technical requirements for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013 4.10	see GB9706.1-2007	2023-02-14
286	Medical X-ray image intensifier	1	All Parameters	Medical X-ray image intensifier YY/T 0093-2013		2023-02-14
		2	Main technical	Medical X-ray image intensifier YY/T 0093-2013 5.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			performance			
		3	the area and requirements of blemish	Medical X-ray image intensifier YY/T 0093-2013 5.3		2023-02-14
		4	X-ray radiation leakage	Medical X-ray image intensifier YY/T 0093-2013 5.4		2023-02-14
		5	Appearance	Medical X-ray image intensifier YY/T 0093-2013 5.5		2023-02-14
		6	Safety	Medical X-ray image intensifier YY/T 0093-2013 5.6		2023-02-14
		7	Environmental requirements	Medical X-ray image intensifier YY/T 0093-2013 5.7		2023-02-14
		8	Instruction for use and package markings	Medical X-ray image intensifier YY/T 0093-2013 8		2023-02-14
		9	Packaging, transportation and storage	Medical X-ray image intensifier YY/T 0093-2013 9		2023-02-14
287	Medical radiographic fluorescent screen	1	All Parameters	Medical radiographic fluorescent screen YY/T 0094-2013		2023-02-14
		2	Basic dimensions	Medical radiographic fluorescent screen YY/T 0094-2013 4.2		2023-02-14
		3	Luminance	Medical radiographic fluorescent screen YY/T 0094-2013 4.3		2023-02-14
		4	limiting resolution	Medical radiographic fluorescent screen YY/T 0094-2013 4.4		2023-02-14
		5	Lag effect time	Medical radiographic fluorescent screen YY/T 0094-2013 4.5		2023-02-14
		6	luminance spectrum	Medical radiographic fluorescent screen YY/T 0094-2013 4.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Uniformity of luminance	Medical radiographic fluorescent screen YY/T 0094-2013 4.7		2023-02-14
		8	Surface quality	Medical radiographic fluorescent screen YY/T 0094-2013 4.8		2023-02-14
		9	Markings, labels, instruction for use	Medical radiographic fluorescent screen YY/T 0094-2013 7		2023-02-14
		10	Packaging, transportation, storage	Medical radiographic fluorescent screen YY/T 0094-2013 8		2023-02-14
288	X-ray equipment for computed tomography	1	All Parameters	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002		2023-02-14
		2	General requirements	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 3		2023-02-14
		3	Classification	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 5		2023-02-14
		4	Identification, marking and documents	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 6		2023-02-14
		5	Environmental conditions	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 10		2023-02-14
		6	Limitation of voltage and/or energy	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 15		2023-02-14
		7	ENCLOSURES and PROTECTIVE COVERS	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 16		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 19		2023-02-14
		9	Dielectric strength	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 20		2023-02-14
		10	Moving parts	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 22		2023-02-14
		11	Pneumatic and hydraulic power	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 27		2023-02-14
		12	PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 5		2023-02-14
		13	Electromagnetic compatibility	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 36		2023-02-14
		14	PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			MIXTURES			
		15	PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 7		2023-02-14
		16	ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 8		2023-02-14
		17	ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 9		2023-02-14
		18	Components and general assembly	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 56		2023-02-14
		19	Batteries	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 56.7		2023-02-14
		20	MAINS PARTS, components and layout	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography GB9706.18-2006 IEC60601-2-44:2002 57		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
289	X-ray equipment for computed tomography	1	All Parameters	General specifications for X-ray equipment for computed tomography YY/T 0310-2015		2023-02-14
		2	Image noise	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.2.1		2023-02-14
		3	Uniformity of CT values	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.2.2		2023-02-14
		4	Accuracy of CT values	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.2.3		2023-02-14
		5	Spatial resolution	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.2.4		2023-02-14
		6	Low contrast resolution	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.2.5		2023-02-14
		7	Running noise	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.2.6		2023-02-14
		8	Artifacts	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.2.7		2023-02-14
		9	Slice thickness	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.2.8		2023-02-14
		10	Gantry	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.3		2023-02-14
		11	Patient support	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.4		2023-02-14
		12	X-ray tube voltage	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.5.1		2023-02-14
		13	X-ray tube current	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.5.2		2023-02-14
		14	Loading time	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.5.3		2023-02-14
		15	X-ray high-voltage cable plug and	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.5.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			socket			
		16	Software	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.6		2023-02-14
		17	Positioning a patient support surface	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.7.1		2023-02-14
		18	patient support surface	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.7.2		2023-02-14
		19	diagnostic table sag	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.7.3		2023-02-14
		20	Integrated positioning lamp for patient positioning	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.7.4		2023-02-14
		21	The typical scan mode of RTP images	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.7.5		2023-02-14
		22	HU conversion	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.7.6		2023-02-14
		23	The geometry precision of image data	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.7.7		2023-02-14
		24	Appearance	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.8		2023-02-14
		25	Environmental tests	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.9		2023-02-14
		26	Safety	General specifications for X-ray equipment for computed tomography YY/T 0310-2015 5.1		2023-02-14
290	Computed radiography device	1	All Parameters	Particular specifications for computed radiography device YY/T 0794-2010		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	Effective imaging region	Particular specifications for computed radiography device YY/T 0794-2010 5.2		2023-02-14
		3	Bit depth	Particular specifications for computed radiography device YY/T 0794-2010 5.3		2023-02-14
		4	Imaging time	Particular specifications for computed radiography device YY/T 0794-2010 5.4		2023-02-14
		5	Number of processing IP board per hour	Particular specifications for computed radiography device YY/T 0794-2010 5.5		2023-02-14
		6	Liminal contrast	Particular specifications for computed radiography device YY/T 0794-2010 5.6		2023-02-14
		7	Spatial resolution	Particular specifications for computed radiography device YY/T 0794-2010 5.7		2023-02-14
		8	Uniformity of image	Particular specifications for computed radiography device YY/T 0794-2010 5.8		2023-02-14
		9	Image attenuation	Particular specifications for computed radiography device YY/T 0794-2010 5.9		2023-02-14
		10	Completeness of erasure	Particular specifications for computed radiography device YY/T 0794-2010 5.10		2023-02-14
		11	Geometric distortion	Particular specifications for computed radiography device YY/T 0794-2010 5.11		2023-02-14
		12	Safty of management data	Particular specifications for computed radiography device YY/T 0794-2010 5.12		2023-02-14
		13	Information management	Particular specifications for computed radiography device YY/T 0794-2010 5.13		2023-02-14
		14	Film printing	Particular specifications for computed radiography device YY/T 0794-2010 5.14		2023-02-14
		15	Medical digital image and communication	Particular specifications for computed radiography device YY/T 0794-2010 5.15		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			standards			
		16	Noise	Particular specifications for computed radiography device YY/T 0794-2010 5.16		2023-02-14
		17	Appearance	Particular specifications for computed radiography device YY/T 0794-2010 5.17		2023-02-14
		18	Environmental testing	Particular specifications for computed radiography device YY/T 0794-2010 5.18		2023-02-14
		19	Safty	Particular specifications for computed radiography device YY/T 0794-2010 5.19		2023-02-14
291	Oral cavity X-ray equipment for digital tomography	1	All Parameters	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010		2023-02-14
		2	Maximum output power	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.2.1		2023-02-14
		3	Nominal power	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.2.2		2023-02-14
		4	X-ray tube voltage	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.3.1		2023-02-14
		5	X-ray tube current	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.3.2		2023-02-14
		6	Loading time	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.3.3		2023-02-14
		7	Current time product	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.3.4		2023-02-14
		8	Overload protection	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.3.5		2023-02-14
		9	Signal-to-noise of image	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.4.1		2023-02-14
		10	Spatial resolution	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Low contrast resolution	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.4.3		2023-02-14
		12	The uniformity of the image grey value	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.4.4		2023-02-14
		13	Image reconstruction time	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.4.5		2023-02-14
		14	Choose layer thickness	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.4.6		2023-02-14
		15	Range of mechanical movement	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.5.1		2023-02-14
		16	Indicated value of length	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.5.2		2023-02-14
		17	Indicated value of Angle	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.5.3		2023-02-14
		18	Bearing	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.6		2023-02-14
		19	Noise	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.7		2023-02-14
		20	Software functions	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.8		2023-02-14
		21	Appearance	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.9		2023-02-14
		22	Environmental testing	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.10		2023-02-14
		23	Safty	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2010 5.11		2023-02-14
292	Digital X-ray imaging	1	All Parameters	Medical electrical equipment. Exposure index of digital X-ray imaging systems. Part 1:Definitions and requirements for general		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	systems			radiography YY/T0796.1-2010 IEC 62494-1:2008		
		2	Creation of ORIGINAL DATA	Medical electrical equipment. Exposure index of digital X-ray imaging systems. Part 1:Definitions and requirements for general radiography YY/T0796.1-2010 IEC 62494-1:2008 4.1		2023-02-14
		3	Determination of the RELEVANT IMAGE REGION and the VALUE OF INTEREST	Medical electrical equipment. Exposure index of digital X-ray imaging systems. Part 1:Definitions and requirements for general radiography YY/T0796.1-2010 IEC 62494-1:2008 4.2		2023-02-14
		4	Requirements for the EXPOSURE INDEX	Medical electrical equipment. Exposure index of digital X-ray imaging systems. Part 1:Definitions and requirements for general radiography YY/T0796.1-2010 IEC 62494-1:2008 4.3		2023-02-14
		5	Calibration of the EXPOSURE INDEX	Medical electrical equipment. Exposure index of digital X-ray imaging systems. Part 1:Definitions and requirements for general radiography YY/T0796.1-2010 IEC 62494-1:2008 4.4		2023-02-14
		6	Determination of the CALIBRATION FUNCTION	Medical electrical equipment. Exposure index of digital X-ray imaging systems. Part 1:Definitions and requirements for general radiography YY/T0796.1-2010 IEC 62494-1:2008 4.5		2023-02-14
		7	Determination of the INVERSE CALIBRATION FUNCTION	Medical electrical equipment. Exposure index of digital X-ray imaging systems. Part 1:Definitions and requirements for general radiography YY/T0796.1-2010 IEC 62494-1:2008 4.6		2023-02-14
		8	Requirements for the DEVIATION INDEX	Medical electrical equipment. Exposure index of digital X-ray imaging systems. Part 1:Definitions and requirements for general radiography YY/T0796.1-2010 IEC 62494-1:2008 4.7		2023-02-14
293	Medical X-ray tube	1	All Parameters	General specifications for medical X-ray tube GB/T 13797-2009		2023-02-14
		2	Overall dimensions	General specifications for medical X-ray tube GB/T 13797-2009 4.2.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Electrode connection	General specifications for medical X-ray tube GB/T 13797-2009 4.2.2		2023-02-14
		4	Enclosure	General specifications for medical X-ray tube GB/T 13797-2009 4.3.1		2023-02-14
		5	The surface of the electrode	General specifications for medical X-ray tube GB/T 13797-2009 4.3.2		2023-02-14
		6	Connection of components	General specifications for medical X-ray tube GB/T 13797-2009 4.3.3		2023-02-14
		7	Tube clastic	General specifications for medical X-ray tube GB/T 13797-2009 4.3.4		2023-02-14
		8	Nominal X-ray tube voltage	General specifications for medical X-ray tube GB/T 13797-2009 4.4.1		2023-02-14
		9	Overvoltage	General specifications for medical X-ray tube GB/T 13797-2009 4.4.2		2023-02-14
		10	Filament voltage	General specifications for medical X-ray tube GB/T 13797-2009 4.4.3		2023-02-14
		11	The anode nominal input power	General specifications for medical X-ray tube GB/T 13797-2009 4.4.4		2023-02-14
		12	Nominal value of focus	General specifications for medical X-ray tube GB/T 13797-2009 4.4.5		2023-02-14
		13	Exposure rate	General specifications for medical X-ray tube GB/T 13797-2009 4.4.6		2023-02-14
		14	Inherent filtration	General specifications for medical X-ray tube GB/T 13797-2009 4.4.7		2023-02-14
		15	Cut-off characteristic of grid-controlled x-ray tube current	General specifications for medical X-ray tube GB/T 13797-2009 4.4.8		2023-02-14
		16	Low temperature	General specifications for medical X-ray tube GB/T 13797-2009 4.5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	High temperature	General specifications for medical X-ray tube GB/T 13797-2009 4.5.2		2023-02-14
		18	Constant damp-heat	General specifications for medical X-ray tube GB/T 13797-2009 4.5.3		2023-02-14
		19	Vibration	General specifications for medical X-ray tube GB/T 13797-2009 4.5.4		2023-02-14
		20	The intensity of lead	General specifications for medical X-ray tube GB/T 13797-2009 4.6		2023-02-14
		21	Bonding strength of pipe bedding and boot	General specifications for medical X-ray tube GB/T 13797-2009 4.7		2023-02-14
		22	Sealing of cooling system	General specifications for medical X-ray tube GB/T 13797-2009 4.8		2023-02-14
		23	Working life	General specifications for medical X-ray tube GB/T 13797-2009 4.9		2023-02-14
		24	Safty	General specifications for medical X-ray tube GB/T 13797-2009 4.10	See GB9706.1-2007、GB9706.3-2000、GB9706.10-1997、GB9706.11-1997	2023-02-14
294	Digital X-ray imaging device	1	All Parameters	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-3: Determination of the detective quantum efficiency - Detecteors used in dynamic imaging YY/T0590.3-2011 IEC 62220-1-3:2008		2023-02-14
		2	Requirements	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-3: Determination of the detective		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				quantum efficiency - Detecteors used in dynamic imaging YY/T0590.3-2011 IEC 62220-1-3:2008 4		
		3	X-RAY EQUIPMENT	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-3: Determination of the detective quantum efficiency - Detecteors used in dynamic imaging YY/T0590.3-2011 IEC 62220-1-3:2008		2023-02-14
		4	RADIATION QUALITY	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-3: Determination of the detective quantum efficiency - Detecteors used in dynamic imaging YY/T0590.3-2011 IEC 62220-1-3:2008		2023-02-14
		5	TEST DEVICE	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-3: Determination of the detective quantum efficiency - Detecteors used in dynamic imaging YY/T0590.3-2011 IEC 62220-1-3:2008		2023-02-14
		6	Geometry	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-3: Determination of the detective quantum efficiency - Detecteors used in dynamic imaging YY/T0590.3-2011 IEC 62220-1-3:2008		2023-02-14
		7	AIR KERMA measurement	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-3: Determination of the detective quantum efficiency - Detecteors used in dynamic imaging YY/T0590.3-2011 IEC 62220-1-3:2008		2023-02-14
		8	LAG EFFECTS	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-3: Determination of the detective quantum efficiency - Detecteors used in dynamic imaging YY/T0590.3-2011 IEC 62220-1-3:2008		2023-02-14
		9	IRRADIATION to obtain the CONVERSION FUNCTION	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-3: Determination of the detective quantum efficiency - Detecteors used in dynamic imaging YY/T0590.3-2011 IEC 62220-1-3:2008		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	IRRADIATION for determination of the NOISE POWER SPECTRUM and LAGEFFECTS	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-3: Determination of the detective quantum efficiency - Detecteors used in dynamic imaging YY/T0590.3-2011 IEC 62220-1-3:2008		2023-02-14
		11	IRRADIATION with TEST DEVICE in the RADIATION BEAM	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-3: Determination of the detective quantum efficiency - Detecteors used in dynamic imaging YY/T0590.3-2011 IEC 62220-1-3:2008		2023-02-14
		12	Determination of the DETECTIVE QUANTUM EFFICIENCY	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-3: Determination of the detective quantum efficiency - Detecteors used in dynamic imaging YY/T0590.3-2011 IEC 62220-1-3:2008		2023-02-14
295	Digital X-ray imaging device	1	All Parameters	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-2: Determination of the detective quantum efficiency - Detecteors used in mammography YY/T0590.2-2010 IEC 62220-1-2:2007		2023-02-14
		2	Requirements	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-2: Determination of the detective quantum efficiency - Detecteors used in mammography YY/T0590.2-2010 IEC 62220-1-2:2007 4		2023-02-14
		3	X-RAY EQUIPMENT	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-2: Determination of the detective quantum efficiency - Detecteors used in mammography YY/T0590.2-2010 IEC 62220-1-2:2007 4.2		2023-02-14
		4	RADIATION QUALITY	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-2: Determination of the detective quantum efficiency - Detecteors used in mammography YY/T0590.2-2010 IEC 62220-1-2:2007 4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	TEST DEVICE	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-2: Determination of the detective quantum efficiency - Detecteors used in mammography YY/T0590.2-2010 IEC 62220-1-2:2007 4.4		2023-02-14
		6	Geometry	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-2: Determination of the detective quantum efficiency - Detecteors used in mammography YY/T0590.2-2010 IEC 62220-1-2:2007 4.5		2023-02-14
		7	AIR KERMA measurement	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-2: Determination of the detective quantum efficiency - Detecteors used in mammography YY/T0590.2-2010 IEC 62220-1-2:2007 4.6.2		2023-02-14
		8	Avoidance of LAG EFFECTS	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-2: Determination of the detective quantum efficiency - Detecteors used in mammography YY/T0590.2-2010 IEC 62220-1-2:2007 4.6.3		2023-02-14
		9	IRRADIATION to obtain the CONVERSION FUNCTION	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-2: Determination of the detective quantum efficiency - Detecteors used in mammography YY/T0590.2-2010 IEC 62220-1-2:2007 4.6.4		2023-02-14
		10	IRRADIATION for determination of the NOISE POWER SPECTRUM	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-2: Determination of the detective quantum efficiency - Detecteors used in mammography YY/T0590.2-2010 IEC 62220-1-2:2007 4.6.5		2023-02-14
		11	IRRADIATION with TEST DEVICE in the RADIATION BEAM	Medical electrical equipment - Characteristics of digital X-ray imaging device - Part 1-2: Determination of the detective quantum efficiency - Detecteors used in mammography YY/T0590.2-2010 IEC 62220-1-2:2007 4.6.6		2023-02-14
		12	Determination of	Medical electrical equipment - Characteristics of digital X-ray		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			the DETECTIVE QUANTUM EFFICIENCY	imaging device - Part 1-2: Determination of the detective quantum efficiency - Detecteors used in mammography YY/T0590.2-2010 IEC 62220-1-2:2007 6		
296	Radiological protection in medical X-ray diagnosis	1	All Parameters	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020		2023-02-14
		2	General requirements for protective performance of x-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 4.1		2023-02-14
		3	Special requirements for protective performance of radioscopy x-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 4.2		2023-02-14
		4	Special requirements for protective performance of radiography x-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 4.3		2023-02-14
		5	Special requirements for protective performance of dental radiography x-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 4.4		2023-02-14
		6	Special requirements for	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 4.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			protective performance of breast radiography x-ray equipment			
		7	Special requirements for protective performance of mobile and portable X-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 4.6		2023-02-14
		8	Special requirements for protective performance of interventional radiology, while operating closer (not ordinary screen radioscopy) x-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 4.7		2023-02-14
		9	Requirements for protection signs and random file	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 4.8		2023-02-14
		10	Requirements for computer room protection facilities of x-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 5		2023-02-14
		11	General requirements for protective safety	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 6.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			operation of medical x-ray diagnosis			
		12	Requirements for protective safety operation of radioscopy x-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 6.2		2023-02-14
		13	Requirements for protective safety operation of radiography x-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 6.3		2023-02-14
		14	Requirements for protective safety operation of dental radiography x-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 6.4		2023-02-14
		15	Requirements for protective safety operation of breast radiography x-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 6.5		2023-02-14
		16	Requirements for protective safety operation of mobile and portable X-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 6.6		2023-02-14
		17	Requirements for protective safety operation of	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 6.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			interventional radiology, while operating closer (not ordinary screen radioscopy) x-ray equipment			
		18	Test requirements for protection performance of x-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 7.1		2023-02-14
		19	Radiation dose detection requirements for computer room protection facilities and around the room of x-ray equipment	Requirements for radiological protection in medical X-ray diagnosis GBZ 130-2020 7.2		2023-02-14
297	Digital medical X-ray image detector used in general radiography	1	All Parameters	Digital medical X-ray image detector used in general radiography YY/T 0933-2014		2023-02-14
		2	Working status indicator	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.2		2023-02-14
		3	Pixel pitch and pixel matrix	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.3		2023-02-14
		4	effect image area	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.4		2023-02-14
		5	linear dose range	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.5		2023-02-14
		6	linear dynamic range	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	line pair resolution	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.7.1		2023-02-14
		8	modulation transfer function	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.7.2		2023-02-14
		9	detective quantum efficiency	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.7.3		2023-02-14
		10	erasure thoroughness	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.7.4		2023-02-14
		11	artifact	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.7.5		2023-02-14
		12	fall	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.8.1		2023-02-14
		13	load bearing	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.8.2		2023-02-14
		14	communication	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.9		2023-02-14
		15	Appearance	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.1		2023-02-14
		16	Environmental tests	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.11		2023-02-14
		17	Safety	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 5.12		2023-02-14
		18	Markings, labels, instruction for use	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 8		2023-02-14
		19	Packaging, transportation, storage	Digital medical X-ray image detector used in general radiography YY/T 0933-2014 9.1		2023-02-14
298	Dynamic digital medical X-ray image	1	All Parameters	Dynamic digital medical X-ray image detectors YY/T 0934-2014		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	detectors	2	Pixel pitch and pixel matrix	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.2		2023-02-14
		3	effect image area	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.3		2023-02-14
		4	linear dose range	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.4		2023-02-14
		5	linear dynamic range	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.5		2023-02-14
		6	frames per second	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.6		2023-02-14
		7	line pair resolution	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.7		2023-02-14
		8	modulation transfer function	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.8		2023-02-14
		9	detective quantum efficiency	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.9		2023-02-14
		10	erasure thoroughness	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.1		2023-02-14
		11	artifact	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.11		2023-02-14
		12	Appearance	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.12		2023-02-14
		13	Environmental tests	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.13		2023-02-14
		14	Safety	Dynamic digital medical X-ray image detectors YY/T 0934-2014 5.14	see GB9706.1-2007、YY 0505-2012、YY/T	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					0708-2009	
		15	Markings, labels, instruction for use	Dynamic digital medical X-ray image detectors YY/T 0934-2014 8		2023-02-14
		16	Packaging, transportation, storage	Dynamic digital medical X-ray image detectors YY/T 0934-2014 9		2023-02-14
299	Urology X-ray equipment	1	All Parameters	Particular specifications for urology X-ray equipment YY/T 0936-2014		2023-02-14
		2	Maximum output power	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.2.1		2023-02-14
		3	Nominal input power	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.2.2		2023-02-14
		4	X-ray tube voltage	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.3.1		2023-02-14
		5	X-ray tube current	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.3.2		2023-02-14
		6	Loading time	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.3.3		2023-02-14
		7	Current time product	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.3.4		2023-02-14
		8	Against overload	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.3.5		2023-02-14
		9	radiation dosage	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.4.1		2023-02-14
		10	artifact	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.4.2		2023-02-14
		11	limiting spatial resolution	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	low contrast resolution	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.4.4		2023-02-14
		13	dynamic range	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.4.5		2023-02-14
		14	flat uniformity	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.4.6		2023-02-14
		15	stabilization of image brightness	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.4.7		2023-02-14
		16	imaging time	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.4.8		2023-02-14
		17	fluoroscopy recovery time	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.4.9		2023-02-14
		18	fluoroscopy performance in data transmission	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.4.10		2023-02-14
		19	Dose indication	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.4.11		2023-02-14
		20	Range for movement	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.5.1		2023-02-14
		21	Indicator for Length	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.5.2		2023-02-14
		22	Indicator for Angle	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.5.3		2023-02-14
		23	Display supporting device	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.5.4		2023-02-14
		24	Supporting equipment accessory	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.5.5		2023-02-14
		25	Braking force	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.5.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		26	Start force	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.5.7		2023-02-14
		27	Weight	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.5.8		2023-02-14
		28	Sport Protection	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.5.9		2023-02-14
		29	Noise	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.5.10		2023-02-14
		30	Feeding and disinfection	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.5.11		2023-02-14
		31	Software	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.6		2023-02-14
		32	Image signal interface	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.7		2023-02-14
		33	X-ray high-voltage cable plug and socket	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.8		2023-02-14
		34	Appearance	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.9		2023-02-14
		35	Environmental tests	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.1		2023-02-14
		36	Safety	Particular specifications for urology X-ray equipment YY/T 0936-2014 5.11		2023-02-14
300	Medical diagnostic X-ray tube assemblies	1	All Parameters	Methods for the measurement of leakage radiation of medical diagnostic X-ray tube assemblies YY/T 0892-2013		2023-02-14
		2	Spherical probe method	Methods for the measurement of leakage radiation of medical diagnostic X-ray tube assemblies YY/T 0892-2013 4.2		2023-02-14
		3	Locating test	Methods for the measurement of leakage radiation of medical diagnostic X-ray tube assemblies YY/T 0892-2013 4.3		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
301	Medical Digital X-ray image detector used in mammography	1	All Parameters	Medical Digital X-ray image detector used in mammography YY/T 1307-2016		2023-02-14
		2	Pixel pitch and pixel matrix	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.2		2023-02-14
		3	effect image area	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.3		2023-02-14
		4	linear dose range	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.4		2023-02-14
		5	linear dynamic range	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.5		2023-02-14
		6	line pair resolution	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.6		2023-02-14
		7	low contrast resolution	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.7		2023-02-14
		8	modulation transfer function	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.8		2023-02-14
		9	detective quantum efficiency	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.9		2023-02-14
		10	Image uniformity	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.10		2023-02-14
		11	erasure thoroughness	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.11		2023-02-14
		12	artifact	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.12		2023-02-14
		13	Appearance	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.13		2023-02-14
		14	Environmental tests	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.14		2023-02-14
		15	Safety	Medical Digital X-ray image detector used in mammography YY/T 1307-2016 5.15		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
302	X-ray equipment for 64 slice helical computed tomography	1	All Parameters	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016		2023-02-14
		2	System performance	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.2		2023-02-14
		3	Image noise	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.2.1		2023-02-14
		4	CT value's uniformity	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.2.2		2023-02-14
		5	CT value's accuracy	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.2.3		2023-02-14
		6	CT value's Linearity	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.2.4		2023-02-14
		7	Spatial resolution	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.2.5		2023-02-14
		8	low contrast resolution	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.2.6		2023-02-14
		9	Artifacts	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.2.7		2023-02-14
		10	Slice thickness	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.2.8		2023-02-14
		11	Image reconstruction speed	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.2.9		2023-02-14
		12	Image scanning layers	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.2.10		2023-02-14
		13	Spiral scan	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.3		2023-02-14
		14	Pitch coefficient	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.3.1		2023-02-14
		15	Continuous spiral scan time	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.3.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Continuous spiral scanning distance	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.3.3		2023-02-14
		17	Gantry	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.4		2023-02-14
		18	Patient support	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.5		2023-02-14
		19	X-ray generator	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.6		2023-02-14
		20	X-ray tube voltage	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.6.1		2023-02-14
		21	X-ray tube current	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.6.2		2023-02-14
		22	Loading time	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.6.3		2023-02-14
		23	Current time product	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.6.4		2023-02-14
		24	X-ray high-voltage cable plug and socket	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.6.5		2023-02-14
		25	Software	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.7		2023-02-14
		26	Running noise	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.8		2023-02-14
		27	Appearance	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.9		2023-02-14
		28	Environmental tests	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.10	GB/T 14710-2009	2023-02-14
		29	Safety	Specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016 5.11		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
303	Digital medical X-ray equipment	1	All Parameters	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017		2023-02-14
		2	Evaluation of AEC under X-ray photography	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017 5		2023-02-14
		3	Measurement of AEC's nominal minimum irradiation time	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017 5.2		2023-02-14
		4	AEC repeatability evaluation method	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017 5.3		2023-02-14
		5	Air Kernel Energy Method	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017 5.3.1		2023-02-14
		6	Image data evaluation method	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017 5.3.2		2023-02-14
		7	Evaluation method of AEC stability	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017 5.4		2023-02-14
		8	Evaluation method of standby timer and safety shut-off device	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017 5.5		2023-02-14
		9	Evaluation method of AEC air kerma kinetic energy adjustment increment	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017 5.6		2023-02-14
		10	Evaluation of automatic control function under X-ray fluoroscopy	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017 6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Evaluation method of X-ray tube voltage repeatability under automatic control mode	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017 6.2		2023-02-14
		12	Evaluation method of air kerma rate of incident surface under automatic control mode	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017 6.3		2023-02-14
		13	Evaluation method of the maximum incident air kerma rate under automatic control mode	Evaluation method of automatie exposure control in digital medical X-ray equipment YY/T 1542-2017 6.4		2023-02-14
304	Mobile X-ray equipment for computed tomography	1	All Parameters	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018		2023-02-14
		2	Performance	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2		2023-02-14
		3	Image noise	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.1		2023-02-14
		4	CT value's uniformity	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.2		2023-02-14
		5	CT value's accuracy	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.3		2023-02-14
		6	Spatial resolution	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.4		2023-02-14
		7	low contrast resolution	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Running noise	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.6		2023-02-14
		9	Artifacts	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.7		2023-02-14
		10	Slice thickness	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.2.8		2023-02-14
		11	Gantry	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.3		2023-02-14
		12	Patient support	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.4		2023-02-14
		13	Mobile performance	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.5		2023-02-14
		14	Braking force	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.5.1		2023-02-14
		15	Start force	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.5.2		2023-02-14
		16	Stability while scanning	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.5.3		2023-02-14
		17	Overcoming obstacles	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.5.4		2023-02-14
		18	Accompanying documents	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.5.5		2023-02-14
		19	X-ray generator	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.6		2023-02-14
		20	X-ray tube voltage	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.6.1		2023-02-14
		21	X-ray tube current	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.6.2		2023-02-14
		22	Loading time	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.6.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Dose	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.6.4		2023-02-14
		24	X-ray high-voltage cable plug and socket	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.6.5		2023-02-14
		25	Software	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.7		2023-02-14
		26	Internal electrical power source	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.8		2023-02-14
		27	Protection against STRAY RADIATION	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.9		2023-02-14
		28	Child Agreement Unit (if any)	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.10		2023-02-14
		29	Appearance	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.11		2023-02-14
		30	Environmental tests	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.12	GB/T 14710-2009	2023-02-14
		31	Safety	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018 5.13		2023-02-14
305	Dental panoramic X-ray equipment	1	All Parameters	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020		2023-02-14
		2	Electric power	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.2		2023-02-14
		3	Maximum output power	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.2.1		2023-02-14
		4	Nominal power	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.2.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Loading factors and control	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.3		2023-02-14
		6	X-ray tube voltage	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.3.1		2023-02-14
		7	X-ray tube current	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.3.2		2023-02-14
		8	Irradiation time	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.3.3		2023-02-14
		9	Current time product	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.3.4		2023-02-14
		10	Against overload	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.3.5		2023-02-14
		11	Imaging performance	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.4		2023-02-14
		12	General	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.4.1		2023-02-14
		13	Focal layer symmetry	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.4.2		2023-02-14
		14	Spatial resolution	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.4.3		2023-02-14
		15	low contrast resolution	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.4.4		2023-02-14
		16	Homogeneity	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.4.5		2023-02-14
		17	Magnification consistency and distortion	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.4.6		2023-02-14
		18	erasure thoroughness	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.4.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	Measurement function	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.4.8		2023-02-14
		20	Dose indication	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.4.9		2023-02-14
		21	Performance of mechanical devices	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.5		2023-02-14
		22	Range for Mechanical movement	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.5.1		2023-02-14
		23	Noise	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.5.2		2023-02-14
		24	Patient positioning light	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.5.3		2023-02-14
		25	Software	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.6		2023-02-14
		26	Management function	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.6.1		2023-02-14
		27	control function	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.6.2		2023-02-14
		28	Network communication function	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.6.3		2023-02-14
		29	Connection of external INTERLOCKS	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.7		2023-02-14
		30	Environmental tests	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.8	GB/T 14710-2009	2023-02-14
		31	Safety	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		32	Electromagnetic compatibility	Particular specification of dental panoramic X-ray equipment YY/T 1732-2020 5.10	YY0505-2012	2023-02-14
306	X-ray equipment for radiographic and radioscopic systems	1	All Parameters	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999		2023-02-14
		2	Test methods for RADIOGRAPHY EQUIPMENT	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5		2023-02-14
		3	Visual and functional tests	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.1		2023-02-14
		4	X-ray tube voltage	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.2		2023-02-14
		5	total filtration	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.3		2023-02-14
		6	X-ray tube focus	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.4		2023-02-14
		7	Limitation and indication of the extent of the X-RAY BEAM	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Accuracy of marked and written indications of the X-RAY FIELD size	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.5.1		2023-02-14
		9	Accuracy of indication of the LIGHT FIELD-INDICATOR	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.5.2		2023-02-14
		10	"Correspondence between the X-RAY FIELD and IMAGE RECEPTION AREA with automatic adjustment of the RADIATION APERTURE"	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.5.3		2023-02-14
		11	Linearity and reproducibility of TRANSMISSION KERMA or RADIATION OUTPUT	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.6		2023-02-14
		12	ATTENUATION RATIO of material between the PATIENT and the X-RAY IMAGE RECEPTOR	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.7		2023-02-14
		13	Automatic Exposure	Evaluation and routine testing in medical imaging departments –		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Control (AEC)	Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.8		
		14	NOMINAL SHORTEST IRRADIATION TIME with AUTOMATIC EXPOSURE CONTROL	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.8.1		2023-02-14
		15	Performance of the AEC	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.8.2		2023-02-14
		16	Back-up timer and security cut-out	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.8.3		2023-02-14
		17	LINE PAIR RESOLUTION for DIRECT RADIOGRAPHY	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.9		2023-02-14
		18	Test methods for RADIOSCOPY EQUIPMENT	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6		2023-02-14
		19	AIR KERMA area product indicator	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		20	Test methods for RADIOSCOPY EQUIPMENT	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6		2023-02-14
		21	Visual and functional tests	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.1		2023-02-14
		22	X-ray tube voltage	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.2		2023-02-14
		23	TOTAL FILTRATION	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.3		2023-02-14
		24	X-ray tube focus	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.4		2023-02-14
		25	Functioning of the AUTOMATIC EXPOSURE RATE CONTROL (AERC)	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.5		2023-02-14
		26	Limitation and indication of the extent of the X-RAY BEAM	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.6		2023-02-14
		27	"Correspondence between the X-RAY	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			FIELD, the IMAGE RECEPTION AREA of X-RAY IMAGE INTENSIFIERS and the image display"	equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.6.3		
		28	Correspondence between the X-RAY FIELD and the IMAGE RECEPTION AREA using a SPOTFILM DEVICE	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.6.2		2023-02-14
		29	ATTENUATION RATIO of material between the PATIENT and the X-RAY IMAGE RECEPTOR	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.7		2023-02-14
		30	AIR KERMA RATE at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER for RADIOSCOPY	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.8		2023-02-14
		31	Entrance AIR KERMA RATE for RADIOSCOPY with X-RAY	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.9		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			IMAGE INTENSIFIER			
		32	"AIR KERMA at the ENTRANCE PLANE of the X-RAY IMAGE INTENSIFIER for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)"	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.10		2023-02-14
		33	"Entrance AIR KERMA for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)"	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.11		2023-02-14
		34	"LINE PAIR RESOLUTION for RADIOSCOPY with X-RAY IMAGE INTENSIFIER and for CINERADIOGRAPHY or other INDIRECT	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.12		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			RADIOGRAPHY systems (excluding digital systems)"			
		35	"LOW CONTRAST RESOLUTION for RADIOSCOPY with X-RAY IMAGE INTENSIFIER and for CINERADIOGRAPHY or other INDIRECT RADIOGRAPHY systems (excluding digital systems)"	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.13		2023-02-14
		36	AIR KERMA area product indicator	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 6.14		2023-02-14
		37	Additional tests required for TOMOGRAPHY EQUIPMENT	Evaluation and routine testing in medical imaging departments – Part 3-1:Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems IEC 61223-3-1:1999 7		2023-02-14
307	Mammographic X-ray equipment	1	All Parameters	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996		2023-02-14
		2	Test methods for mammography X-ray equipment	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Visual and functional tests	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.1		2023-02-14
		4	X-ray tube voltage	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.2		2023-02-14
		5	TOTAL FILTRATION	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.3		2023-02-14
		6	X-ray tube focus	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.4		2023-02-14
		7	Light field indicator, X-ray field limit and X-ray beam collimation	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.5		2023-02-14
		8	Linearity and repeatability of radiation output	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.6		2023-02-14
		9	Automatic Exposure Control (AEC)	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.7		2023-02-14
		10	Minimum current time product (mA•s)	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.7.1		2023-02-14
		11	Performance of the AEC	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.7.2		2023-02-14
		12	Backup timer and safety cut-off device	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				mammographic X-ray equipment IEC 61223-3-2:1996 5.7.3		
		13	The attenuation rate of the material between the upper surface of the patient stent and the plane of the image receiver	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.8		2023-02-14
		14	Compression device	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.9		2023-02-14
		15	Tissue artifacts	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.10		2023-02-14
		16	Lightening of active anti-scatter grid shadow	Evaluation and routine testing in medical imaging departments—Part 3-2:Acceptance tests—Imaging performance of mammographic X-ray equipment IEC 61223-3-2:1996 5.11		2023-02-14
308	X-ray equipment for digital subtraction angiography(DSA)	1	All Parameters	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996		2023-02-14
		2	Test methods for X-RAY EQUIPMENT for DSA	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5		2023-02-14
		3	Marking	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Check of documents	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5.2		2023-02-14
		5	Decision on representative DSA operation modes	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5.3		2023-02-14
		6	Visual and functional tests	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5.4		2023-02-14
		7	AIR KERMA measurements	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5.5		2023-02-14
		8	Dynamic range	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5.6		2023-02-14
		9	DSA CONTRAST SENSITIVITY	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5.7		2023-02-14
		10	DSA VISUAL SPATIAL RESOLUTION	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5.8		2023-02-14
		11	Artifacts	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5.9		
		12	Mis-registration ARTIFACTS	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5.9.1		2023-02-14
		13	Irradiation related ARTIFACTS	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5.9.2		2023-02-14
		14	Compensation for ATTENUATION non-linearity (optional)	Evaluation and routine testing in medical imaging departments—Part 3-3:Acceptance tests—Imaging performance of X-ray equipment for digital subtraction angiography(DSA) IEC 61223-3-3:1996 5.10		2023-02-14
309	Dental X-ray equipment	1	All Parameters	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000		2023-02-14
		2	Test method for dental X-ray equipment with intraoral X-ray image receptor	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 5		2023-02-14
		3	Visual and functional tests	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 5.1		2023-02-14
		4	X-ray tube voltage	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 5.2		2023-02-14
		5	TOTAL FILTRATION	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				equipment IEC 61223-3-4:2000 5.3		
		6	FOCAL SPOT of the X-RAY TUBE	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 5.4		2023-02-14
		7	Limitation and alignment of the X-RAY BEAM	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 5.5		2023-02-14
		8	FOCAL SPOT TO SKIN DISTANCE	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 5.6		2023-02-14
		9	"Reproducibility of the RADIATION output"	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 5.7		2023-02-14
		10	line pair resolution	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 5.8		2023-02-14
		11	LOW CONTRAST RESOLUTION	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 5.9		2023-02-14
		12	Test method of dental panoramic X-ray equipment with external X-ray image receiver	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6		2023-02-14
		13	Visual and functional tests	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6.1		2023-02-14
		14	X-ray tube voltage	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				equipment IEC 61223-3-4:2000 6.2		
		15	TOTAL FILTRATION	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6.3		2023-02-14
		16	X-ray tube focus	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6.4		2023-02-14
		17	Limitation and alignment of the X-RAY BEAM	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6.5		2023-02-14
		18	FOCAL SPOT TO SKIN DISTANCE	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6.6		2023-02-14
		19	Reproducibility of the RADIATION output	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6.7		2023-02-14
		20	line pair resolution	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6.8		2023-02-14
		21	low contrast resolution	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6.9		2023-02-14
		22	RADIOGRAPHIC FILM cassettes with INTENSIFYING SCREENS	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6.10		2023-02-14
		23	Image homogeneity	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6.11		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		24	Indicators for patients' positioning	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6.12		2023-02-14
		25	Panorama layer	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 6.13		2023-02-14
		26	"Test methods for dental cephalometric X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR"	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 7		2023-02-14
		27	Visual and functional tests	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 7.1		2023-02-14
		28	X-ray tube voltage	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 7.2		2023-02-14
		29	TOTAL FILTRATION	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 7.3		2023-02-14
		30	X-ray tube focus	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 7.4		2023-02-14
		31	Limitation and alignment of the X-RAY BEAM	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 7.5		2023-02-14
		32	FOCAL SPOT TO SKIN DISTANCE	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				equipment IEC 61223-3-4:2000 7.6		
		33	Reproducibility of the RADIATION output	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 7.7		2023-02-14
		34	line pair resolution	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 7.8		2023-02-14
		35	low contrast resolution	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 7.9		2023-02-14
		36	RADIOGRAPHIC FILM cassettes with INTENSIFYING SCREENS	Evaluation and routine testing in medical imaging departments—Part 3-4:Acceptance tests—Imaging performance of X-ray equipment IEC 61223-3-4:2000 7.10		2023-02-14
310	X-ray equipment for computed tomography	1	All Parameters	Evaluation and routine testing in medical imaging departments—Part 3-5:Acceptance tests—Imaging performance of computed tomography X-ray equipment IEC 61223-3-5:2004		2023-02-14
		2	Test method of CT scanning device	Evaluation and routine testing in medical imaging departments—Part 3-5:Acceptance tests—Imaging performance of computed tomography X-ray equipment IEC 61223-3-5:2004 5		2023-02-14
		3	Positioning of the patient support	Evaluation and routine testing in medical imaging departments—Part 3-5:Acceptance tests—Imaging performance of computed tomography X-ray equipment IEC 61223-3-5:2004 5.1		2023-02-14
		4	Patient positioning accuracy	Evaluation and routine testing in medical imaging departments—Part 3-5:Acceptance tests—Imaging performance of computed tomography X-ray equipment IEC 61223-3-5:2004 5.2		2023-02-14
		5	Axial patient positioning accuracy	Evaluation and routine testing in medical imaging departments—Part 3-5:Acceptance tests—Imaging performance of computed tomography X-ray equipment IEC 61223-3-5:2004 5.2.1		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Sagittal and coronal positioning lamp accuracy (if applicable)	Evaluation and routine testing in medical imaging departments—Part 3-5:Acceptance tests—Imaging performance of computed tomography X-ray equipment IEC 61223-3-5:2004 5.2.2		2023-02-14
		7	Slice thickness	Evaluation and routine testing in medical imaging departments—Part 3-5:Acceptance tests—Imaging performance of computed tomography X-ray equipment IEC 61223-3-5:2004 5.3		2023-02-14
		8	Axial scan tomographic slice thickness	Evaluation and routine testing in medical imaging departments—Part 3-5:Acceptance tests—Imaging performance of computed tomography X-ray equipment IEC 61223-3-5:2004 5.3.1		2023-02-14
		9	Tomographic slice thickness of spiral scan	Evaluation and routine testing in medical imaging departments—Part 3-5:Acceptance tests—Imaging performance of computed tomography X-ray equipment IEC 61223-3-5:2004 5.3.2		2023-02-14
		10	Dose	Evaluation and routine testing in medical imaging departments—Part 3-5:Acceptance tests—Imaging performance of computed tomography X-ray equipment IEC 61223-3-5:2004 5.4		2023-02-14
		11	Noise, average CT value and uniformity	Evaluation and routine testing in medical imaging departments—Part 3-5:Acceptance tests—Imaging performance of computed tomography X-ray equipment IEC 61223-3-5:2004 5.5		2023-02-14
		12	Spatial resolution	Evaluation and routine testing in medical imaging departments—Part 3-5:Acceptance tests—Imaging performance of computed tomography X-ray equipment IEC 61223-3-5:2004 5.6		2023-02-14
311	Medical X-ray diagnostic equipment	1	All Parameters	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020		2023-02-14
		2	General test items and test methods for radioscopy X-ray equipment	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 4		2023-02-14
		3	Typical air kerma rates of incidence	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			body surface			
		4	The maximum air kerma rates of incidence body surface	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 4.2		2023-02-14
		5	High contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 4.3		2023-02-14
		6	Low contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 4.4		2023-02-14
		7	Air kerma rates of incident surface	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 4.5		2023-02-14
		8	Automatic brightness control	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 4.6		2023-02-14
		9	Dose rate around fluoroscopic protection area	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 4.7		2023-02-14
		10	Special items and testing methods for direct fluorescent screen radioscopy equipment	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 5		2023-02-14
		11	Sensitivity of direct fluorescent screen radioscopy	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 5.1		2023-02-14
		12	The distance between table and screen when the maximum exposure field is the same as	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 5.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			screen size			
		13	Special items and testing methods for DSA medical	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 6		2023-02-14
		14	DSA dynamic range	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 6.1		2023-02-14
		15	DSA contrast sensitivity	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 6.2		2023-02-14
		16	Artifact	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 6.3		2023-02-14
		17	General items and methods of quality control testing for X-ray photography equipment	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 7		2023-02-14
		18	Indicated deviation of tube voltage	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 7.1		2023-02-14
		19	Reproducibility of radiation output	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 7.2		2023-02-14
		20	The linearity of the radiation output	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 7.3		2023-02-14
		21	Half-value layer of useful rays	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 7.4		2023-02-14
		22	Indicated deviation of exposure time	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 7.5		2023-02-14
		23	Reproducibility of AEC	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 7.6		2023-02-14
		24	Response of AEC	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 7.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		25	Consistency of AEC ionization chamber	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 7.8		2023-02-14
		26	Verticality deviation of useful rays	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 7.9		2023-02-14
		27	Special items and testing methods for screen X-ray photography equipment	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 8		2023-02-14
		28	Center alignment between focused grid and useful rays	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 8.1		2023-02-14
		29	Special items and testing methods for digital X-ray photography equipment	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 9		2023-02-14
		30	Detector dose indication	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 9.1		2023-02-14
		31	Signal transmission properties	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 9.2		2023-02-14
		32	Response uniformity	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 9.3		2023-02-14
		33	Distance-measuring error	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 9.4		2023-02-14
		34	Image retention	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 9.5		2023-02-14
		35	Artifact	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 9.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		36	High contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 9.7		2023-02-14
		37	Low contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 9.8		2023-02-14
		38	Special items and testing methods for computed radiography	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 10		2023-02-14
		39	IP dark noise	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 10.1		2023-02-14
		40	Detector dose indication	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 10.2		2023-02-14
		41	IP response uniformity	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 10.3		2023-02-14
		42	IP response consistency	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 10.4		2023-02-14
		43	IP response linearity	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 10.5		2023-02-14
		44	Distance-measuring error	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 10.6		2023-02-14
		45	IP erasure completeness	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 10.7		2023-02-14
		46	High contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 10.8		2023-02-14
		47	Low contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 10.9		2023-02-14
		48	Test items and test methods for dental X-ray equipment	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 11		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		49	Indicated deviation of tube voltage	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 11.1		2023-02-14
		50	Reproducibility of radiation output	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 11.2		2023-02-14
		51	The linearity of the radiation output	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 11.3		2023-02-14
		52	Half-value layer of useful rays	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 11.4		2023-02-14
		53	High contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 11.5		2023-02-14
		54	Low contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 11.6		2023-02-14
		55	General test items and test methods for mammographic X-ray equipment	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 12		2023-02-14
		56	Consistency between radiation field on chest wall and detector	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 12.1		2023-02-14
		57	Consistency between Light field and radiation field	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 12.2		2023-02-14
		58	Indicated deviation of tube voltage	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 12.3		2023-02-14
		59	Half-value layer	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 12.4		2023-02-14
		60	Reproducibility of radiation output	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 12.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		61	Special radiation output	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 12.6		2023-02-14
		62	Reproducibility of AEC	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 12.7		2023-02-14
		63	Average mammary glandular dose	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 12.8		2023-02-14
		64	Special testing items and testing methods for mammographic screen X-ray equipment	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 13		2023-02-14
		65	Standard Photo Density	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 13.1		2023-02-14
		66	AEC Response	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 13.2		2023-02-14
		67	High contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 13.3		2023-02-14
		68	Special testing items and testing methods for digital mammography equipment	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 14		2023-02-14
		69	Response of detector	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 14.1		2023-02-14
		70	Uniformity of detector	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 14.2		2023-02-14
		71	Artifact	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 14.3		2023-02-14
		72	High contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 14.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		73	Low contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 14.5		2023-02-14
		74	Special testing items and testing methods for mammary computer X-ray radiography equipment	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 15		2023-02-14
		75	IP dark noise	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 15.1		2023-02-14
		76	IP response linearity	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 15.2		2023-02-14
		77	IP response uniformity	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 15.3		2023-02-14
		78	IP response consistency	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 15.4		2023-02-14
		79	IP erasure completeness	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 15.5		2023-02-14
		80	Artifact	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 15.6		2023-02-14
		81	High contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 15.7		2023-02-14
		82	Low contrast resolution	Specification for testing of quality control in medical X-ray diagnostic equipment WS 76-2020 15.8		2023-02-14
312	X-ray computed tomography	1	All Parameters	Specification for testing of quality control in X-ray computed tomography WS 519-2019		2023-02-14
		2	Quality control test items and methods	Specification for testing of quality control in X-ray computed tomography WS 519-2019 5		2023-02-14
		3	Positioning accuracy of	Specification for testing of quality control in X-ray computed tomography WS 519-2019 5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			diagnostic table			
		4	Positioning light accuracy	Specification for testing of quality control in X-ray computed tomography WS 519-2019 5.2		2023-02-14
		5	Inclination precision of scanning frame	Specification for testing of quality control in X-ray computed tomography WS 519-2019 5.3		2023-02-14
		6	Reconstruction layer thickness deviation	Specification for testing of quality control in X-ray computed tomography WS 519-2019 5.4		2023-02-14
		7	CTDIw	Specification for testing of quality control in X-ray computed tomography WS 519-2019 5.5		2023-02-14
		8	CT value (water), noise and uniformity	Specification for testing of quality control in X-ray computed tomography WS 519-2019 5.6		2023-02-14
		9	High contrast resolution	Specification for testing of quality control in X-ray computed tomography WS 519-2019 5.7		2023-02-14
		10	Low contrast resolution	Specification for testing of quality control in X-ray computed tomography WS 519-2019 5.8		2023-02-14
		11	Linearity of CT value	Specification for testing of quality control in X-ray computed tomography WS 519-2019 5.9		2023-02-14
313	Medical ultrasonic nebulizer	1	All Parameters	Medical ultrasonic nebulizer YY/T 0109-2013		2023-02-14
		2	The frequency of ultrasonic oscillation and nominal frequency deviation	Medical ultrasonic nebulizer YY/T 0109-2013 4.1		2023-02-14
		3	The maximum rate of atomization	Medical ultrasonic nebulizer YY/T 0109-2013 4.2		2023-02-14
		4	The temperature of the water in the	Medical ultrasonic nebulizer YY/T 0109-2013 4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			water tank			
		5	total noise of centrifuge	Medical ultrasonic nebulizer YY/T 0109-2013 4.4		2023-02-14
		6	Droplet diameter distribution	Medical ultrasonic nebulizer YY/T 0109-2013 4.5		2023-02-14
		7	control function	Medical ultrasonic nebulizer YY/T 0109-2013 4.6		2023-02-14
		8	continuous operating time	Medical ultrasonic nebulizer YY/T 0109-2013 4.7		2023-02-14
		9	Power supply ability	Medical ultrasonic nebulizer YY/T 0109-2013 4.8		2023-02-14
		10	Appearance and structure	Medical ultrasonic nebulizer YY/T 0109-2013 4.9		2023-02-14
		11	safety requirements	Medical ultrasonic nebulizer YY/T 0109-2013 4.10	see GB9706.1	2023-02-14
		12	environmental test	Medical ultrasonic nebulizer YY/T 0109-2013 4.11		2023-02-14
314	Environmental requirement and test methods for medical ultrasonic equipment	1	All Parameters	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016		2023-02-14
		2	Fixed equipment and the special requirements of permanently installed equipment and methods	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.4		2023-02-14
		3	The special requirements of medical ultrasound systems and methods	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	The special requirements of mobile devices and methods	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.6		2023-02-14
		5	By the special requirements of a battery-powered device and method	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.7		2023-02-14
		6	With the special requirements of water equipment and methods	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.8		2023-02-14
		7	The special requirements of ultrasonic transducer and the method	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.9		2023-02-14
		8	Containing liquid crystal displays the special requirements of medical ultrasound equipment and methods	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.10		2023-02-14
		9	Environmental Test Group	Environmental requirement and test methods for medical ultrasonic equipment YY/T 1420-2016 4.2	GB/T 14710-2009	2023-02-14
		10	The test items	Environmental requirement and test methods for medical ultrasonic equipment YY/T 1420-2016 4.3		2023-02-14
	B mode	1	All Parameters	B mode ultrasonic diagnostic equipment GB 10152-2009		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	ultrasonic diagnostic equipment	2	Acousticworking frequency	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.1		2023-02-14
		3	depth of penetration	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.2		2023-02-14
		4	lateral resolution	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.3		2023-02-14
		5	axial resolution	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.4		2023-02-14
		6	dead zone	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.5		2023-02-14
		7	slice thickness	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.6		2023-02-14
		8	lateral geometric location accuracy	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.7		2023-02-14
		9	axial geometric location accuracy	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.8		2023-02-14
		10	perimeter and area measurement deviation	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.9		2023-02-14
		11	M mode performance	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.10		2023-02-14
		12	3 d reconstruction volume calculation deviation	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.11		2023-02-14
		13	The power supply voltage range	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.12		2023-02-14
		14	Continuous working time	B mode ultrasonic diagnostic equipment GB 10152-2009 4.2.13		2023-02-14
		15	The appearance and structure requirements	B mode ultrasonic diagnostic equipment GB 10152-2009 4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Use function requirements	B mode ultrasonic diagnostic equipment GB 10152-2009 4.4		2023-02-14
		17	environmental test	B mode ultrasonic diagnostic equipment GB 10152-2009 4.5		2023-02-14
316	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment	1	All Parameters	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000		2023-02-14
		2	Marking on the outside of equipment or equipment parts	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 6.1		2023-02-14
		3	Instructions for use	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 6.8.2		2023-02-14
		4	Power Input	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 7		2023-02-14
		5	summary	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 13		2023-02-14
		6	Mechanical strength	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 21		2023-02-14
		7	Sound energy (including ultrasound)	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 35		2023-02-14
		8	ELECTROMAGNETIC COMPATIBILITY	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 36		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Excessive temperatures	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 42		2023-02-14
		10	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 44.6		2023-02-14
		11	Control the accuracy of the instruments and meters	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 50.1		2023-02-14
		12	Protection against hazardous output	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 51		2023-02-14
		13	Incorrect output	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 51.5		2023-02-14
		14	The output control device	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 51.101		2023-02-14
		15	The output stability of the power wave	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 51.102		2023-02-14
		16	The timer	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 51.103		2023-02-14
		17	The uniformity of the radiation field	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				2008IEC 60601-2-5：2000 51.104		
		18	The time stability of the output	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 51.105		2023-02-14
		19	Sound working frequency	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 51.106		2023-02-14
		20	Connection - overview	medical electrical equipment part2-5 particular requirements for the safety of ultrasonic physiotherapy equipment GB9706.7-2008IEC 60601-2-5：2000 56.3		2023-02-14
317	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment	1	All Parameters	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001		2023-02-14
		2	Marking on the outside of equipment or equipment parts	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001 6.1		2023-02-14
		3	Marking of controls and instruments	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001 6.3		2023-02-14
		4	Instructions for use	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001 6.8.2		2023-02-14
		5	Technical description	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001 6.8.3		2023-02-14
		6	the leakage current	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				equipment GB9706.9-2008IEC 60601-2-37：2001 19		
		7	dielectric strength	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001 20		2023-02-14
		8	Sound energy (including ultrasound)	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001 35		2023-02-14
		9	ELECTROMAGNETIC COMPATIBILITY	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001 36		2023-02-14
		10	Excessive temperatures	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001 42.3		2023-02-14
		11	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001 44.6		2023-02-14
		12	Control the accuracy of the instruments and meters	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001 50.2		2023-02-14
		13	The parameters of safety instructions	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001 51.2		2023-02-14
		14	Protection against hazardous output	medical electrical equipment part2-37 particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB9706.9-2008IEC 60601-2-37：2001 51.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
318	General technical requirements for Ultrasound Bladder Scanner	1	All Parameters	General technical requirements for Ultrasound Bladder Scanner YY/T1476-2016		2023-02-14
		2	Acousticworking frequency	General technical requirements for Ultrasound Bladder Scanner YY/T1476-2016 4.2.1		2023-02-14
		3	Volume measurement range	General technical requirements for Ultrasound Bladder Scanner YY/T1476-2016 4.2.2		2023-02-14
		4	Volume measurement accuracy	General technical requirements for Ultrasound Bladder Scanner YY/T1476-2016 4.2.3		2023-02-14
		5	Volume measurement result display	General technical requirements for Ultrasound Bladder Scanner YY/T1476-2016 4.2.4		2023-02-14
		6	function	General technical requirements for Ultrasound Bladder Scanner YY/T1476-2016 4.2.5		2023-02-14
		7	Continuous normal work time	General technical requirements for Ultrasound Bladder Scanner YY/T1476-2016 4.2.6		2023-02-14
		8	The structure and appearance	General technical requirements for Ultrasound Bladder Scanner YY/T1476-2016 4.3		2023-02-14
		9	Environmental testing requirements	General technical requirements for Ultrasound Bladder Scanner YY/T1476-2016 4.4		2023-02-14
		10	Safety requirements	General technical requirements for Ultrasound Bladder Scanner YY/T1476-2016 4.5	seeGB9706.1	2023-02-14
319	Environmental requirement and test methods for medical ultrasonic equipment	1	All Parameters	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016		2023-02-14
		2	Fixed equipment and the special requirements of permanently installed equipment and methods	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.4		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	The special requirements of medical ultrasound systems and methods	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.5		2023-02-14
		4	The special requirements of mobile devices and methods	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.6		2023-02-14
		5	By the special requirements of a battery-powered device and method	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.7		2023-02-14
		6	With the special requirements of water equipment and methods	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.8		2023-02-14
		7	The special requirements of ultrasonic transducer and the method	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.9		2023-02-14
		8	Containing liquid crystal displays the special requirements of medical ultrasound equipment and methods	Environmental requirement and test methods for medical ultrasonic equipment YY/T1420-2016 4.10		2023-02-14
		9	Environmental Test	Environmental requirement and test methods for medical	GB/T	2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Group	ultrasonic equipment YY/T 1420-2016 4.2	14710-2009	
		10	The test items	Environmental requirement and test methods for medical ultrasonic equipment YY/T 1420-2016 4.3		2023-02-14
320	Ultrasound physiotherapy equipment	1	All Parameters	Ultrasonics-Physiotherapy systems-Field specifications and methods of measurement in the frequency range 0.5MHz to 5MHz YY/T 0750-2018		2023-02-14
		2	Ultrasound field requirements	Ultrasonics-Physiotherapy systems-Field specifications and methods of measurement in the frequency range 0.5MHz to 5MHz YY/T 0750-2018 5		2023-02-14
		3	Measuring conditions and test equipment	Ultrasonics-Physiotherapy systems-Field specifications and methods of measurement in the frequency range 0.5MHz to 5MHz YY/T 0750-2018 6		2023-02-14
		4	Type test reference steps and measurement methods	Ultrasonics-Physiotherapy systems-Field specifications and methods of measurement in the frequency range 0.5MHz to 5MHz YY/T 0750-2018 7		2023-02-14
		5	General measurement steps	Ultrasonics-Physiotherapy systems-Field specifications and methods of measurement in the frequency range 0.5MHz to 5MHz YY/T 0750-2018 8		2023-02-14
		6	Sampling and uncertainty determination	Ultrasonics-Physiotherapy systems-Field specifications and methods of measurement in the frequency range 0.5MHz to 5MHz YY/T 0750-2018 9		2023-02-14
321	ultrasonically tissue-mimicking materials	1	All Parameters	Measurement methods for acoustic properties of ultrasonically tissue-mimicking materials GB/T15261-2008		2023-02-14
		2	Measuring step	Measurement methods for acoustic properties of ultrasonically tissue-mimicking materials GB/T15261-2008 6		2023-02-14
		3	Uncertainty in measurement of sound velocity and	Measurement methods for acoustic properties of ultrasonically tissue-mimicking materials GB/T15261-2008 7		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			sound attenuation coefficient			
322	Ultrasound bone sonometers	1	All Parameters	Ultrasound bone sonometers- Test method of Broadband ultrasound attenuation (BUA) YY/T 0939-2014		2023-02-14
		2	experiment method	Ultrasound bone sonometers- Test method of Broadband ultrasound attenuation (BUA) YY/T 0939-2014 4		2023-02-14
323	Acoustics-characterisation of ultrasonic fields	1	All Parameters	Acoustics-Measurement and characterisation of ultrasonic fields in the frequency range 0.5MHz to 15MHz-Hydrophone method GB/T16540-1996		2023-02-14
		2	Measurement requirements	Acoustics-Measurement and characterisation of ultrasonic fields in the frequency range 0.5MHz to 15MHz-Hydrophone method GB/T16540-1996 5		2023-02-14
		3	Performance specifications for hydrophones and amplifiers	Acoustics-Measurement and characterisation of ultrasonic fields in the frequency range 0.5MHz to 15MHz-Hydrophone method GB/T16540-1996 6		2023-02-14
		4	Measuring step	Acoustics-Measurement and characterisation of ultrasonic fields in the frequency range 0.5MHz to 15MHz-Hydrophone method GB/T16540-1996 7		2023-02-14
		5	Measurement of sound beam characteristics	Acoustics-Measurement and characterisation of ultrasonic fields in the frequency range 0.5MHz to 15MHz-Hydrophone method GB/T16540-1996 8		2023-02-14
		6	Acoustic output characteristics and signs	Acoustics-Measurement and characterisation of ultrasonic fields in the frequency range 0.5MHz to 15MHz-Hydrophone method GB/T16540-1996 9		2023-02-14
324	medical ultrasound equipment	1	All Parameters	Ultrasonics-field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic equipment YY/T 0642-2014		2023-02-14
		2	Overview	Ultrasonics-field characterization- Test methods for the determination of thermal and mechanical indices related to		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				medical diagnostic ultrasonic equipment YY/T 0642-2014 5.1		
		3	Determination of mechanical index	Ultrasonics-field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic equipment YY/T 0642-2014 5.2		2023-02-14
		4	Determination of heat index - general rule	Ultrasonics-field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic equipment YY/T 0642-2014 5.3		2023-02-14
		5	Determination of heat index in non-scan mode	Ultrasonics-field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic equipment YY/T 0642-2014 5.4		2023-02-14
		6	Determination of thermal index in scan mode	Ultrasonics-field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic equipment YY/T 0642-2014 5.5		2023-02-14
		7	Composite working mode calculation	Ultrasonics-field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic equipment YY/T 0642-2014 5.6		2023-02-14
		8	An overview of the measured values in the index determination	Ultrasonics-field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic equipment YY/T 0642-2014 5.7		2023-02-14
325	Ultrasonics-pulsed Doppler diagnostic system	1	All Parameters	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008		2023-02-14
		2	General	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.1		2023-02-14
		3	Initial conditions	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.2		2023-02-14
		4	Zero signal noise level	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.3		2023-02-14
		5	Doppler frequency	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			response	determine performance YY/T 0704-2008 5.4		
		6	Spatial response	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.5		2023-02-14
		7	Sampling area position coincidence error	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.6		2023-02-14
		8	Sound beam position and orientation	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.7		2023-02-14
		9	Intrinsic spectrum broadening	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.8		2023-02-14
		10	Blind zone	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.9		2023-02-14
		11	Acoustic operating frequency	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.10		2023-02-14
		12	Flow direction separation	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.11		2023-02-14
		13	Speed estimation accuracy	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.12		2023-02-14
		14	Volume flow estimation accuracy	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.13		2023-02-14
		15	Maximum, average, value, and median frequency estimation accuracy	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.14		2023-02-14
		16	Speed waveform index estimation accuracy	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 5.15		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	Test piece	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 6.1		2023-02-14
		18	Electronic test piece	Ultrasonics-pulsed Doppler diagnostic system -Test procedures to determine performance YY/T 0704-2008 6.2		2023-02-14
326	Ultrasonics-continuous-wave Doppler systems	1	All Parameters	Ultrasonics-continuous-wave Doppler systems -Test procedures YY/T 0705-2008		2023-02-14
		2	General	Ultrasonics-continuous-wave Doppler systems -Test procedures YY/T 0705-2008 2.1		2023-02-14
		3	Initial conditions	Ultrasonics-continuous-wave Doppler systems -Test procedures YY/T 0705-2008 2.2		2023-02-14
		4	Doppler frequency response	Ultrasonics-continuous-wave Doppler systems -Test procedures YY/T 0705-2008 2.3		2023-02-14
		5	Spatial response	Ultrasonics-continuous-wave Doppler systems -Test procedures YY/T 0705-2008 2.4		2023-02-14
		6	working frequency	Ultrasonics-continuous-wave Doppler systems -Test procedures YY/T 0705-2008 2.5		2023-02-14
		7	Flow direction recognition	Ultrasonics-continuous-wave Doppler systems -Test procedures YY/T 0705-2008 2.6		2023-02-14
		8	Doppler spectral response	Ultrasonics-continuous-wave Doppler systems -Test procedures YY/T 0705-2008 2.7		2023-02-14
		9	Doppler test piece	Ultrasonics-continuous-wave Doppler systems -Test procedures YY/T 0705-2008 3.1		2023-02-14
327	medical ultrasound equipment	1	All Parameters	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011		2023-02-14
		2	Requirements for hydrophones and amplifiers	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 5.1		2023-02-14
		3	Positioning system and sink	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			requirements	YY/T0865.1-2011 5.2		
		4	Requirements for data acquisition and analysis systems	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 5.3		2023-02-14
		5	Advice for the ultrasound equipment being tested	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 5.4		2023-02-14
		6	general	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 6.1		2023-02-14
		7	Preparation and alignment	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 6.2		2023-02-14
		8	measuring	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 6.3		2023-02-14
		9	analysis	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 6.4		2023-02-14
		10	general	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 7.1		2023-02-14
		11	Basic sound pressure parameter	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 7.2		2023-02-14
		12	general	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 8.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Diagnostic sound field	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 8.2		2023-02-14
		14	Treatment sound field	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 8.3		2023-02-14
		15	Surgical sound field	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 8.4		2023-02-14
		16	Sound field for other medical applications	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 8.5		2023-02-14
		17	general	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 9.1		2023-02-14
		18	Maximum possible value	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 9.2		2023-02-14
		19	sampling	Ultrasonic-hydrophone- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz YY/T0865.1-2011 9.3		2023-02-14
328	ultrasonic pulse-echo diagnostic equipment	1	All Parameters	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment YY/T 0643-2008		2023-02-14
		2	Sound frequency	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment YY/T 0643-2008 3		2023-02-14
		3	Echo detection capability	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment YY/T 0643-2008 4		2023-02-14
		4	Gain-distance correlation	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment YY/T 0643-2008 5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Display characteristics	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment YY/T 0643-2008 6		2023-02-14
		6	Geometric resolution	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment YY/T 0643-2008 7		2023-02-14
		7	Geometric adjustment accuracy	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment YY/T 0643-2008 8		2023-02-14
329	Ultrasonics - Real-time pulse-echo systems	1	All Parameters	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008		2023-02-14
		2	instrument	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008 6.1		2023-02-14
		3	Test setup	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008 6.2		2023-02-14
		4	Test parameters	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008 6.3		2023-02-14
		5	Acoustic operating frequency bandwidth	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008 6.3.1		2023-02-14
		6	Resolution	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008 6.3.2		2023-02-14
		7	Blind zone	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008 6.3.3		2023-02-14
		8	Slice thickness	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008 6.3.4		2023-02-14
		9	Probing depth	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008 6.3.5		2023-02-14
		10	Display dynamic range	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008 6.3.6		2023-02-14
		11	Display and recording error	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008 6.3.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Measuring system accuracy	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008 6.3.8		2023-02-14
		13	M mode calibration	Ultrasonics - Real-time pulse-echo systems -Test procedures to determine performance specifications YY/T 0703-2008 6.3.9		2023-02-14
330	B-mode ultrasonic diagnostic equipment	1	All Parameters	performance testing methods for B-mode ultrasonic diagnostic equipment with intra-cavity probe YY/T 0906-2013		2023-02-14
		2	depth of penetration	performance testing methods for B-mode ultrasonic diagnostic equipment with intra-cavity probe YY/T 0906-2013 5.1		2023-02-14
		3	axial resolution	performance testing methods for B-mode ultrasonic diagnostic equipment with intra-cavity probe YY/T 0906-2013 5.2		2023-02-14
		4	lateral resolution	performance testing methods for B-mode ultrasonic diagnostic equipment with intra-cavity probe YY/T 0906-2013 5.3		2023-02-14
		5	lateral geometric location accuracy	performance testing methods for B-mode ultrasonic diagnostic equipment with intra-cavity probe YY/T 0906-2013 5.4		2023-02-14
		6	perimeter and area measurement deviation	performance testing methods for B-mode ultrasonic diagnostic equipment with intra-cavity probe YY/T 0906-2013 5.5		2023-02-14
331	diagnostic ultrasonic equipment	1	All Parameters	Measurement methods of ultrasonic output power for medical diagnostic ultrasonic equipments YY/T 1084-2015		2023-02-14
		2	Measurement requirements and measurement systems	Measurement methods of ultrasonic output power for medical diagnostic ultrasonic equipments YY/T 1084-2015 4		2023-02-14
		3	Measuring step	Measurement methods of ultrasonic output power for medical diagnostic ultrasonic equipments YY/T 1084-2015 5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Measurement uncertainty	Measurement methods of ultrasonic output power for medical diagnostic ultrasonic equipments YY/T 1084-2015 6		2023-02-14
332	Ultrasound bone dsonometers	1	All Parameters	Ultrasound bone sonometers YY/T 0774-2019		2023-02-14
		2	Acoustic working frequency	Ultrasound bone sonometers YY/T 0774-2019 4.1.1		2023-02-14
		3	Ultrasonic speed	Ultrasound bone sonometers YY/T 0774-2019 4.1.2		2023-02-14
		4	Broadband ultrasonic attenuation	Ultrasound bone sonometers YY/T 0774-2019 4.1.3		2023-02-14
		5	Power supply voltage adaptability	Ultrasound bone sonometers YY/T 0774-2019 4.2		2023-02-14
		6	Continuous working time	Ultrasound bone sonometers YY/T 0774-2019 4.3		2023-02-14
		7	Functional requirements	Ultrasound bone sonometers YY/T 0774-2019 4.4		2023-02-14
		8	Appearance and structure	Ultrasound bone sonometers YY/T 0774-2019 4.5		2023-02-14
		9	General safety requirements	Ultrasound bone sonometers YY/T 0774-2019 4.6		2023-02-14
		10	Special safety requirements	Ultrasound bone sonometers YY/T 0774-2019 4.7		2023-02-14
		11	Environmental test requirements	Ultrasound bone sonometers YY/T 0774-2019 4.8		2023-02-14
333	requirement for the declaration of the acoustic output of medical	1	All Parameters	requirement for the declaration of the acoustic output of medical diagnostic Ultrasonic equipment GB/T 16846-2008		2023-02-14
		2	General	requirement for the declaration of the acoustic output of medical diagnostic Ultrasonic equipment GB/T 16846-2008 4.1		2023-02-14
		3	Acoustic output data	requirement for the declaration of the acoustic output of medical		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	diagnostic Ultrasonic equipment		published requirements	diagnostic Ultrasonic equipment GB/T 16846-2008 4.2		
		4	Information published in the technical data sheet	requirement for the declaration of the acoustic output of medical diagnostic Ultrasonic equipment GB/T 16846-2008 4.2.1		2023-02-14
		5	Information published in documents/manuals	requirement for the declaration of the acoustic output of medical diagnostic Ultrasonic equipment GB/T 16846-2008 4.2.2		2023-02-14
		6	Background information	requirement for the declaration of the acoustic output of medical diagnostic Ultrasonic equipment GB/T 16846-2008 4.2.3		2023-02-14
		7	Sampling of published value	requirement for the declaration of the acoustic output of medical diagnostic Ultrasonic equipment GB/T 16846-2008 5		2023-02-14
		8	Exemption from publication	requirement for the declaration of the acoustic output of medical diagnostic Ultrasonic equipment GB/T 16846-2008 6		2023-02-14
		9	experiment method	requirement for the declaration of the acoustic output of medical diagnostic Ultrasonic equipment GB/T 16846-2008 7		2023-02-14
		10	mark	requirement for the declaration of the acoustic output of medical diagnostic Ultrasonic equipment GB/T 16846-2008 8		2023-02-14
334	Ultrasonic physiotherapy equipment	1	All Parameters	Ultrasonic physiotherapy equipment YY/T1090-2018		2023-02-14
		2	Ultrasonic output power accuracy	Ultrasonic physiotherapy equipment YY/T1090-2018 4.1		2023-02-14
		3	Effective radiation area	Ultrasonic physiotherapy equipment YY/T1090-2018 4.2		2023-02-14
		4	Effective sound intensity	Ultrasonic physiotherapy equipment YY/T1090-2018 4.3		2023-02-14
		5	Sound pressure at the farthest axial maximum (zN)	Ultrasonic physiotherapy equipment YY/T1090-2018 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Acoustic working frequency	Ultrasonic physiotherapy equipment YY/T1090-2018 4.5		2023-02-14
		7	Beam type	Ultrasonic physiotherapy equipment YY/T1090-2018 4.6		2023-02-14
		8	Appearance and structural requirements	Ultrasonic physiotherapy equipment YY/T1090-2018 4.7		2023-02-14
		9	random files	Ultrasonic physiotherapy equipment YY/T1090-2018 4.8		2023-02-14
		10	Safety requirements	Ultrasonic physiotherapy equipment YY/T1090-2018 4.9		2023-02-14
		11	Environmental test requirements	Ultrasonic physiotherapy equipment YY/T1090-2018 4.10		2023-02-14
335	ultrasonic diagnostic equipment	1	All Parameters	testing methods for M- mode of ultrasonic diagnostic equipment YY/T 0108-2008		2023-02-14
		2	Acoustic working frequency	testing methods for M- mode of ultrasonic diagnostic equipment YY/T 0108-2008 5.1		2023-02-14
		3	depth of penetration	testing methods for M- mode of ultrasonic diagnostic equipment YY/T 0108-2008 5.2		2023-02-14
		4	axial resolution	testing methods for M- mode of ultrasonic diagnostic equipment YY/T 0108-2008 5.3		2023-02-14
		5	lateral resolution	testing methods for M- mode of ultrasonic diagnostic equipment YY/T 0108-2008 5.4		2023-02-14
		6	Distance display error	testing methods for M- mode of ultrasonic diagnostic equipment YY/T 0108-2008 5.5		2023-02-14
		7	time display error	testing methods for M- mode of ultrasonic diagnostic equipment YY/T 0108-2008 5.6		2023-02-14
336	ultrasonic diagnostic equipment	1	All Parameters	Ultrasound-Test methods of performance for quasi-static strain sonoelasticity YY/T1419-2016		2023-02-14
		2	Maximum penetration	Ultrasound-Test methods of performance for quasi-static strain sonoelasticity YY/T1419-2016 5.1		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Strain-ratio Strain-ratio	Ultrasound-Test methods of performance for quasi-static strain sonoelasticity YY/T1419-2016 5.2.1		2023-02-14
		4	Shear wave velocity accuracy	Ultrasound-Test methods of performance for quasi-static strain sonoelasticity YY/T1419-2016 5.2.2		2023-02-14
		5	Shear wave velocity repeatability	Ultrasound-Test methods of performance for quasi-static strain sonoelasticity YY/T1419-2016 5.2.3		2023-02-14
		6	Spatial resolution	Ultrasound-Test methods of performance for quasi-static strain sonoelasticity YY/T1419-2016 5.3		2023-02-14
		7	Precision of geometric imaging	Ultrasound-Test methods of performance for quasi-static strain sonoelasticity YY/T1419-2016 5.4		2023-02-14
337	ultrasonic diagnostic equipment	1	All Parameters	Test method for performance of three-dimensional ultrasonography YY/T1279-2015		2023-02-14
		2	depth of penetration	Test method for performance of three-dimensional ultrasonography YY/T1279-2015 4.4		2023-02-14
		3	dead zone	Test method for performance of three-dimensional ultrasonography YY/T1279-2015 4.5		2023-02-14
		4	lateral resolution	Test method for performance of three-dimensional ultrasonography YY/T1279-2015 4.6		2023-02-14
		5	axial resolution	Test method for performance of three-dimensional ultrasonography YY/T1279-2015 4.7		2023-02-14
		6	geometric location accuracy	Test method for performance of three-dimensional ultrasonography YY/T1279-2015 4.8		2023-02-14
		7	3 d reconstruction volume calculation deviation	Test method for performance of three-dimensional ultrasonography YY/T1279-2015 4.9		2023-02-14
338	Ultrasound transcranial Doppler	1	All Parameters	Ultrasound transcranial Doppler system YY/T 0593-2022		2023-02-14
		2	Acoustic working frequency	Ultrasound transcranial Doppler system YY/T 0593-2022 5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	system	3	Flow rate measurement range	Ultrasound transcranial Doppler system YY/T 0593-2022 5.2		2023-02-14
		4	Velocity measurement error	Ultrasound transcranial Doppler system YY/T 0593-2022 5.3		2023-02-14
		5	Working distance	Ultrasound transcranial Doppler system YY/T 0593-2022 5.4		2023-02-14
		6	Distance gating error	Ultrasound transcranial Doppler system YY/T 0593-2022 5.5		2023-02-14
		7	Ultrasonic output power	Ultrasound transcranial Doppler system YY/T 0593-2022 5.6		2023-02-14
		8	Work status and function settings	Ultrasound transcranial Doppler system YY/T 0593-2022 5.7		2023-02-14
		9	Appearance and structure	Ultrasound transcranial Doppler system YY/T 0593-2022 5.8		2023-02-14
		10	Safety	Ultrasound transcranial Doppler system YY/T 0593-2022 5.9		2023-02-14
		11	Environmental test	Ultrasound transcranial Doppler system YY/T 0593-2022 5.10		2023-02-14
339	ultrasonic elasticity imaging equipment	1	All Parameters	Test methods of performance for ultrasonic elasticity imaging equipment based on acoustic radiation force YY/T1480-2016		2023-02-14
		2	Maximum depth of elastic imaging	Test methods of performance for ultrasonic elasticity imaging equipment based on acoustic radiation force YY/T1480-2016 5.1		2023-02-14
		3	shear wave speed	Test methods of performance for ultrasonic elasticity imaging equipment based on acoustic radiation force YY/T1480-2016 5.2		2023-02-14
		4	accuracy of measurements	Test methods of performance for ultrasonic elasticity imaging equipment based on acoustic radiation force YY/T1480-2016 5.2.1		2023-02-14
		5	repeatability of measurements	Test methods of performance for ultrasonic elasticity imaging equipment based on acoustic radiation force YY/T1480-2016		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				5.2.2		
		6	spatial resolution	Test methods of performance for ultrasonic elasticity imaging equipment based on acoustic radiation force YY/T1480-2016 5.3		2023-02-14
		7	Geometric error of elastic imaging	Test methods of performance for ultrasonic elasticity imaging equipment based on acoustic radiation force YY/T1480-2016 5.4		2023-02-14
340	Ultrasound colour flow imaging systems	1	All Parameters	Ultrasound colour flow imaging systems YY/T 0767-2009		2023-02-14
		2	Color flow imaging mode performance requirements	Ultrasound colour flow imaging systems YY/T 0767-2009 4.2		2023-02-14
		3	Spectrum Doppler mode performance requirements	Ultrasound colour flow imaging systems YY/T 0767-2009 4.3		2023-02-14
		4	Safety requirements	Ultrasound colour flow imaging systems YY/T 0767-2009 4.4		2023-02-14
		5	Environmental test requirements	Ultrasound colour flow imaging systems YY/T 0767-2009 4.5		2023-02-14
341	medical ultrasound equipment	1	All Parameters	measuring methods for beam area of medical ultrasound equipment transducer YY/T 1278-2015		2023-02-14
		2	Diagnostic equipment	measuring methods for beam area of medical ultrasound equipment transducer YY/T 1278-2015 4.1		2023-02-14
		3	Treatment equipment	measuring methods for beam area of medical ultrasound equipment transducer YY/T 1278-2015 4.2		2023-02-14
		4	High intensity focused ultrasound therapy equipment	measuring methods for beam area of medical ultrasound equipment transducer YY/T 1278-2015 4.3		2023-02-14
		5	Measuring device	measuring methods for beam area of medical ultrasound equipment transducer YY/T 1278-2015 5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Requirements for the device under test at the time of measurement	measuring methods for beam area of medical ultrasound equipment transducer YY/T 1278-2015 5.2		2023-02-14
		7	Measurement environment	measuring methods for beam area of medical ultrasound equipment transducer YY/T 1278-2015 5.3		2023-02-14
		8	Measurement methods	measuring methods for beam area of medical ultrasound equipment transducer YY/T 1278-2015 6		2023-02-14
		9	uncertainty	measuring methods for beam area of medical ultrasound equipment transducer YY/T 1278-2015 7		2023-02-14
342	medical ultrasonic equipment and probe	1	All Parameters	methods of measuring the frequency of medical ultrasonic equipment and probe YY/T 1142-2013		2023-02-14
		2	Test Conditions	methods of measuring the frequency of medical ultrasonic equipment and probe YY/T 1142-2013 4		2023-02-14
		3	experiment method	methods of measuring the frequency of medical ultrasonic equipment and probe YY/T 1142-2013 5		2023-02-14
343	Ultrasound Doppler Fetal Heart beat detector	1	All Parameters	Ultrasound Doppler Fetal Heart beat detector YY/T 0448-2019		2023-02-14
		2	Acoustic working frequency	Ultrasound Doppler Fetal Heart beat detector YY/T 0448-2019 4.1		2023-02-14
		3	Comprehensive sensitivity	Ultrasound Doppler Fetal Heart beat detector YY/T 0448-2019 4.2		2023-02-14
		4	Fetal heart rate measurement and display range	Ultrasound Doppler Fetal Heart beat detector YY/T 0448-2019 4.3		2023-02-14
		5	Fetal heart rate measurement error	Ultrasound Doppler Fetal Heart beat detector YY/T 0448-2019 4.4		2023-02-14
		6	Appearance and structure	Ultrasound Doppler Fetal Heart beat detector YY/T 0448-2019 4.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Features	Ultrasound Doppler Fetal Heart beat detector YY/T 0448-2019 4.6		2023-02-14
		8	Safety	Ultrasound Doppler Fetal Heart beat detector YY/T 0448-2019 4.7	GB9706.1	2023-02-14
		9	Environmental test	Ultrasound Doppler Fetal Heart beat detector YY/T 0448-2019 4.8		2023-02-14
344	intravascular ultrasound （IVUS） diagnostic equipment	1	All Parameters	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019		2023-02-14
		2	Acoustic working frequency	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.1		2023-02-14
		3	Imaging radius	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.2		2023-02-14
		4	Axial resolution	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.3		2023-02-14
		5	Lateral resolution	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.4		2023-02-14
		6	Resolution of retracement direction	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.5		2023-02-14
		7	Longitudinal geometric position accuracy	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.6		2023-02-14
		8	Horizontal geometric position accuracy	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.7		2023-02-14
		9	Geometric position accuracy in retraction direction	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.8		2023-02-14
		10	Image geometric distortion	General technical requirements for intravascular ultrasound		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				（IVUS）diagnostic equipment YY/T1659-2019 4.9		
		11	Appearance and structure	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.10		2023-02-14
		12	Use function	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.11		2023-02-14
		13	catheter	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.12		2023-02-14
		14	Safety	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.13		2023-02-14
		15	Environmental test	General technical requirements for intravascular ultrasound （IVUS）diagnostic equipment YY/T1659-2019 4.14		2023-02-14
345	Ultrasonic surgical equipment for osseous tissue	1	All Parameters	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018		2023-02-14
		2	technical requirement	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4		2023-02-14
		3	Appearance and structure	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.1		2023-02-14
		4	Temperature display and control performance	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.2		2023-02-14
		5	Principal amplitude of tip	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.3		2023-02-14
		6	Tip transverse amplitude	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.4		2023-02-14
		7	Excitation frequency	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.5		2023-02-14
		8	Tip vibration frequency	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Duty cycle	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.8		2023-02-14
		10	Static (no load) electric power	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.9		2023-02-14
		11	Maximum electric power	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.10		2023-02-14
		12	Power reserve index	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.11		2023-02-14
		13	Main sound output area	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.12		2023-02-14
		14	Acoustic output area of secondary transverse vibration	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.13		2023-02-14
		15	Liquid flow rate	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.14		2023-02-14
		16	Noise	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.15		2023-02-14
		17	Characteristics to be published in the specification	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.16		2023-02-14
		18	safety requirements	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.17		2023-02-14
		19	environmental test	Ultrasonic surgical equipment for osseous tissue YY/T1601-2018 4.18		2023-02-14
346	ultrasound endoscope	1	All parameters	ultrasound endoscope YY/T1676-2020		2023-02-14
		2	requirement	ultrasound endoscope YY/T1676-2020 4		2023-02-14
		3	Acoustic working frequency	ultrasound endoscope YY/T1676-2020 4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Detection depth	ultrasound endoscope YY/T1676-2020 4.2		2023-02-14
		5	Lateral resolution	ultrasound endoscope YY/T1676-2020 4.3		2023-02-14
		6	Axial resolution	ultrasound endoscope YY/T1676-2020 4.4		2023-02-14
		7	blind area	ultrasound endoscope YY/T1676-2020 4.5		2023-02-14
		8	Slice thickness	ultrasound endoscope YY/T1676-2020 4.6		2023-02-14
		9	Lateral geometric position accuracy	ultrasound endoscope YY/T1676-2020 4.7		2023-02-14
		10	Longitudinal geometric position accuracy	ultrasound endoscope YY/T1676-2020 4.8		2023-02-14
		11	Perimeter and area measurement deviation	ultrasound endoscope YY/T1676-2020 4.9		2023-02-14
		12	M-mode performance index	ultrasound endoscope YY/T1676-2020 4.10		2023-02-14
		13	Three dimensional imaging performance	ultrasound endoscope YY/T1676-2020 4.11		2023-02-14
		14	Geometric position accuracy of the retreat direction	ultrasound endoscope YY/T1676-2020 4.12		2023-02-14
		15	Geometric distortion of ultrasonic imaging	ultrasound endoscope YY/T1676-2020 4.13		2023-02-14
		16	Performance of ultrasound color	ultrasound endoscope YY/T1676-2020 4.14		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			flow imaging			
		17	Ultrasonic visual field angle	ultrasound endoscope YY/T1676-2020 4.15		2023-02-14
		18	safety requirements	ultrasound endoscope YY/T1676-2020 4.16		2023-02-14
		19	Environmental test requirements	ultrasound endoscope YY/T1676-2020 4.17		2023-02-14
347	ultrasound biopsy guide	1	All Parameters	ultrasound biopsy guide YY/T1671-2020		2023-02-14
		2	requirement	ultrasound biopsy guide YY/T1671-2020 5		2023-02-14
		3	appearance	ultrasound biopsy guide YY/T1671-2020 5.1		2023-02-14
		4	Performance	ultrasound biopsy guide YY/T1671-2020 5.2		2023-02-14
		5	Puncture precision of in plane puncture	ultrasound biopsy guide YY/T1671-2020 5.3		2023-02-14
		6	Puncture precision of out of plane puncture	ultrasound biopsy guide YY/T1671-2020 5.4		2023-02-14
		7	Special requirements for reusable puncture frame	ultrasound biopsy guide YY/T1671-2020 5.5		2023-02-14
		8	Special requirements for disposable puncture frame	ultrasound biopsy guide YY/T1671-2020 5.6		2023-02-14
		9	Biological evaluation	ultrasound biopsy guide YY/T1671-2020 5.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
348	ultrasonic surgical equipment for soft tissue excision and hemostasia	1	All Parameters	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020		2023-02-14
		2	requirement	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4		2023-02-14
		3	Principal amplitude of tip	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.1		2023-02-14
		4	Tip lateral amplitude	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.2		2023-02-14
		5	Excitation frequency	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.3		2023-02-14
		6	Static electric power	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.5		2023-02-14
		7	Maximum electric power	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.6		2023-02-14
		8	Appearance and structure	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.9		2023-02-14
		9	The appearance of the equipment shall be clean and tidy without scratches, cracks and other defects	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.9.1		2023-02-14
		10	The words and signs for prompt operation shall be clear, easy to recognize and durable	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.9.2		2023-02-14
		11	The control and adjustment	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.9.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			mechanism shall be flexible and reliable, and the fastening parts shall not be loose			
		12	Use function	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.10		2023-02-14
		13	Publication of output characteristics	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.11		2023-02-14
		14	Foot switch	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.12		2023-02-14
		15	safety requirements	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.13		2023-02-14
		16	environmental test	ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T1750-2020 4.14		2023-02-14
349	external-vibration based ultrasonic elasticity measurement equipment for liver tissue	1	All Parameters	external-vibration based ultrasonic elasticity measurement equipment for liver tissue YY/T1749-2020		2023-02-14
		2	safety requirements	external-vibration based ultrasonic elasticity measurement equipment for liver tissue YY/T1749-2020 4.1		2023-02-14
		3	Ultrasonic working frequency	external-vibration based ultrasonic elasticity measurement equipment for liver tissue YY/T1749-2020 4.2		2023-02-14
		4	Ultrasonic detection depth	external-vibration based ultrasonic elasticity measurement equipment for liver tissue YY/T1749-2020 4.3		2023-02-14
		5	Measurement accuracy of Young's modulus	external-vibration based ultrasonic elasticity measurement equipment for liver tissue YY/T1749-2020 4.4		2023-02-14
		6	Repeatability of Young's modulus measurement	external-vibration based ultrasonic elasticity measurement equipment for liver tissue YY/T1749-2020 4.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	function	external-vibration based ultrasonic elasticity measurement equipment for liver tissue YY/T1749-2020 4.6		2023-02-14
		8	Accompanying documents	external-vibration based ultrasonic elasticity measurement equipment for liver tissue YY/T1749-2020 4.7		2023-02-14
		9	environmental test	external-vibration based ultrasonic elasticity measurement equipment for liver tissue YY/T1749-2020 4.8		2023-02-14
350	pulse-echo ultrasonic array transducers	1	All Parameters	Electroacoustic characteristics and measurement methods of pulse-echo ultrasonic array transducers YY/T1668-2019		2023-02-14
		2	Characterization parameters	Electroacoustic characteristics and measurement methods of pulse-echo ultrasonic array transducers YY/T1668-2019 4		2023-02-14
		3	Measurement conditions	Electroacoustic characteristics and measurement methods of pulse-echo ultrasonic array transducers YY/T1668-2019 5		2023-02-14
		4	Measuring instruments and equipment	Electroacoustic characteristics and measurement methods of pulse-echo ultrasonic array transducers YY/T1668-2019 5.1		2023-02-14
		5	Measurement environment and other conditions	Electroacoustic characteristics and measurement methods of pulse-echo ultrasonic array transducers YY/T1668-2019 5.2		2023-02-14
		6	Measurement methods and procedures	Electroacoustic characteristics and measurement methods of pulse-echo ultrasonic array transducers YY/T1668-2019 6		2023-02-14
		7	Measurement of maximum response frequency, center frequency and bandwidth of pulse echo	Electroacoustic characteristics and measurement methods of pulse-echo ultrasonic array transducers YY/T1668-2019 6.1		2023-02-14
		8	Measurement of maximum response frequency, center	Electroacoustic characteristics and measurement methods of pulse-echo ultrasonic array transducers YY/T1668-2019 6.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			frequency and bandwidth of pulse echo spectrum analysis method			
		9	Relative sensitivity of pulse echo	Electroacoustic characteristics and measurement methods of pulse-echo ultrasonic array transducers YY/T1668-2019 6.3		2023-02-14
		10	Echo pulse duration	Electroacoustic characteristics and measurement methods of pulse-echo ultrasonic array transducers YY/T1668-2019 6.4		2023-02-14
		11	Mutual coupling degree of array elements	Electroacoustic characteristics and measurement methods of pulse-echo ultrasonic array transducers YY/T1668-2019 6.5		2023-02-14
		12	Resonance equivalent resistance	Electroacoustic characteristics and measurement methods of pulse-echo ultrasonic array transducers YY/T1668-2019 6.6		2023-02-14
351	Ultrasonic-surgical system	1	All Parameters	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008		2023-02-14
		2	General measurement requirements	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 5		2023-02-14
		3	Working conditions	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 5.1		2023-02-14
		4	Load conditions	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 5.2		2023-02-14
		5	Preparation for measurement	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 5.3		2023-02-14
		6	Measurement steps	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 6		2023-02-14
		7	Principal amplitude of tip	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 6.1		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Tip transverse amplitude	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 6.2		2023-02-14
		9	Excitation frequency	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 6.3		2023-02-14
		10	Tip vibration frequency	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 6.4		2023-02-14
		11	Tip dominant amplitude modulation	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 6.7		2023-02-14
		12	Duty cycle	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 6.8		2023-02-14
		13	Static (no load) electric power	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 6.9		2023-02-14
		14	Maximum electric power	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 6.10		2023-02-14
		15	Main sound output area	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 6.11		2023-02-14
		16	Acoustic output area of secondary transverse vibration	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 6.12		2023-02-14
		17	Power reserve index	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 6.13		2023-02-14
		18	Publication of output characteristics	Ultrasonic-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008 7		2023-02-14
352	Ultrasonic Doppler fetal monitor	1	All Parameters	Guide for the check of Ultrasonic Doppler fetal monitor YY/T 1481-2016		2023-02-14
		2	Check the content	Guide for the check of Ultrasonic Doppler fetal monitor YY/T 1481-2016 4		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Receiving inspection	Guide for the check of Ultrasonic Doppler fetal monitor YY/T 1481-2016 4.1		2023-02-14
		4	Periodic inspection	Guide for the check of Ultrasonic Doppler fetal monitor YY/T 1481-2016 4.2		2023-02-14
		5	Inspection records	Guide for the check of Ultrasonic Doppler fetal monitor YY/T 1481-2016 4.3		2023-02-14
		6	Verification conclusion	Guide for the check of Ultrasonic Doppler fetal monitor YY/T 1481-2016 4.4		2023-02-14
353	Ultrasonic Doppler fetal monitor	1	All Parameters	Ultrasonic Doppler fetal monitor YY/T 0449—2018		2023-02-14
		2	Requirements	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4		2023-02-14
		3	Ultrasonic operating frequency	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.1		2023-02-14
		4	Fetal heart rate measurement and display range	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.2		2023-02-14
		5	Fetal heart rate measurement error	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.3		2023-02-14
		6	Alarm function	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.4		2023-02-14
		7	Systole pressure measurement range	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.5		2023-02-14
		8	Temperature drift of the value of the contraction pressure	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.6		2023-02-14
		9	Storage record function	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.7		2023-02-14
		10	Power supply voltage adaptability	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.8		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Normal continuous working hours	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.9		2023-02-14
		12	Appearance and structure	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.10		2023-02-14
		13	Functional requirements	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.11		2023-02-14
		14	Safety requirements	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.12	See GB9706.1 和 GB9706.9	2023-02-14
		15	Environmental test requirements	Ultrasonic Doppler fetal monitor YY/T 0449—2018 4.13		2023-02-14
354	B mode ultrasound disgnostic equipment	1	All Parameters	Medical ultrasound equipment class series-Part 1: B mode ultrasound disgnostic equipment YY/T 0162. 1—2009		2023-02-14
		2	Classification method and requirements of equipment of each grade	Medical ultrasound equipment class series-Part 1: B mode ultrasound disgnostic equipment YY/T 0162. 1—2009 4		2023-02-14
		3	The test method	Medical ultrasound equipment class series-Part 1: B mode ultrasound disgnostic equipment YY/T 0162. 1—2009 5		2023-02-14
		4	Technical requirements of body mold for testing	Medical ultrasound equipment class series-Part 1: B mode ultrasound disgnostic equipment YY/T 0162. 1—2009 5.1		2023-02-14
		5	Test methods for performance requirements	Medical ultrasound equipment class series-Part 1: B mode ultrasound disgnostic equipment YY/T 0162. 1—2009 5.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	About what you should have	Medical ultrasound equipment class series-Part 1: B mode ultrasound disgnostic equipment YY/T 0162. 1—2009 5.3		2023-02-14
355	B mode ultrasound disgnostic equipment	1	All Parameters	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014		2023-02-14
		2	Check the content	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 4		2023-02-14
		3	Receiving inspection	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 4.1		2023-02-14
		4	Weekly inspection	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 4.2		2023-02-14
		5	The annual inspection	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 4.3		2023-02-14
		6	Inspection records	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 4.4		2023-02-14
		7	Inspection conclusion	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 4.5		2023-02-14
		8	Test method for	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5		2023-02-14
		9	The device under test	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.1		2023-02-14
		10	Test set	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.2		2023-02-14
		11	B ultrasonic host and probe appearance inspection	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.3		2023-02-14
		12	B ultrasound host appearance inspection	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.3.1		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Inspection of probe appearance	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.3.2		2023-02-14
		14	Depth test	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.4		2023-02-14
		15	Transverse geometric position accuracy test	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.5		2023-02-14
		16	Longitudinal geometric position accuracy test	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.6		2023-02-14
		17	Lateral resolution test	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.7		2023-02-14
		18	Axial resolution test	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.8		2023-02-14
		19	Blind test	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.9		2023-02-14
		20	Monitor check	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.10		2023-02-14
		21	Verification of image printing device	Guide for the check of B mode ultrasonic diagnostic equipment YY/T 0938—2014 5.11		2023-02-14
356	Utrasound disgnostic equipment	1	All Parameters	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008		2023-02-14
		2	Reliability test and test plan	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 4		2023-02-14
		3	Type of reliability test	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 4.1		2023-02-14
		4	Reliability test	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 4.1.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Reliability verification test	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 4.1.2		2023-02-14
		6	Laboratory reliability test	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 4.1.3		2023-02-14
		7	Field reliability test	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 4.1.4		2023-02-14
		8	Test plan	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 4.2		2023-02-14
		9	Timing truncation test scheme	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 4.2.1		2023-02-14
		10	Truncated sequential test scheme	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 4.2.2		2023-02-14
		11	Selection of test scheme	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 4.3		2023-02-14
		12	Test requirements	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 5		2023-02-14
		13	Reliability prediction	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 5.1		2023-02-14
		14	Pretreatment	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 5.2		2023-02-14
		15	Determination of test samples	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 5.3		2023-02-14
		16	Test of time	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 5.4		2023-02-14
		17	Test preparation	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 5.5		2023-02-14
		18	Check and test function and performance	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 5.5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	Requirements for test equipment, instruments and meters	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 5.5.2		2023-02-14
		20	Formulate the implementation plan of reliability test	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 5.5.3		2023-02-14
		21	Test stress	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 6		2023-02-14
		22	Test stress	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 6.1		2023-02-14
		23	Climatic conditions	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 6.1.1		2023-02-14
		24	The electric stress	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 6.1.2		2023-02-14
		25	Test sequence diagram	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 6.2		2023-02-14
		26	Failure classification and criteria	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 7		2023-02-14
		27	Judgment of acceptance and rejection	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 8		2023-02-14
		28	Receive	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 8.1		2023-02-14
		29	Conditional acceptance	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 8.2		2023-02-14
		30	Refuse to accept	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 8.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		31	Test data processing	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 9		2023-02-14
		32	Reliability test report and record	Requirements and methods of reliability test forultrasonic diagnostic equipment GB/T 15214—2008 10		2023-02-14
357	Ultrasound physiotherapy systems	1	All Parameters	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007		2023-02-14
		2	Check the category	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 4		2023-02-14
		3	Receiving inspection	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 4.1		2023-02-14
		4	Weekly inspection	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 4.2		2023-02-14
		5	The annual inspection	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 4.3		2023-02-14
		6	Performance test	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5		2023-02-14
		7	Acceptance test	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.1		2023-02-14
		8	Visual inspection	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.1.1		2023-02-14
		9	Manufacturer's Statement	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.1.2		2023-02-14
		10	Quantitative testing of ultrasonic output	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.1.3		2023-02-14
		11	Beam inhomogeneity and output test	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.1.4		2023-02-14
		12	Overview	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.1.4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Steps	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.1.4.2		2023-02-14
		14	Records of receiving inspection results	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.1.5		2023-02-14
		15	Request (Suggestion)	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.1.6		2023-02-14
		16	Weekly inspection	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.2		2023-02-14
		17	Visual inspection	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.2.1		2023-02-14
		18	Tests on ultrasonic output	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.2.2		2023-02-14
		19	Beam inhomogeneity and output test	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.2.3		2023-02-14
		20	Records of weekly inspections	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.2.4		2023-02-14
		21	Request (Suggestion)	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.2.5		2023-02-14
		22	The annual inspection	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.3		2023-02-14
		23	Output power test	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.3.1		2023-02-14
		24	Effective radiation area	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.3.2		2023-02-14
		25	Beam inhomogeneity test	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.3.3		2023-02-14
		26	Pulse mode accuracy test	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.3.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		27	Ultrasonic power meter method was used	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.3.4.1		2023-02-14
		28	Oscilloscope method is used	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.3.4.2		2023-02-14
		29	Timer accuracy test	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.3.5		2023-02-14
		30	Record annual inspection results	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.3.6		2023-02-14
		31	Maintenance requirements	Ultrasonics--Output test-Guide for the maintenance of ultrasound physiotherapy systems IEC 62462 : 2007 5.4		2023-02-14
358	Ultrasonics Hydrophones	1	All Parameters	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007		2023-02-14
		2	Characteristics of hydrophones	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5		2023-02-14
		3	Overview	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.1		2023-02-14
		4	Basic information	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.2		2023-02-14
		5	The sensitivity	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.3		2023-02-14
		6	Frequency response	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.4		2023-02-14
		7	Nominal frequency	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.4.1		2023-02-14
		8	Frequency dependence	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.4.2		2023-02-14
		9	Directional response	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Overview	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.5.1		2023-02-14
		11	Symmetry of directional response	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.5.2		2023-02-14
		12	Effective radius of	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.6		2023-02-14
		13	Dynamic range, linearity and electromagnetic interference	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.7		2023-02-14
		14	Electrical output characteristic	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.8		2023-02-14
		15	Overview	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.8.1		2023-02-14
		16	Hydrophone without preamplifier	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.8.2		2023-02-14
		17	Hydrophone assembly	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.8.3		2023-02-14
		18	Output wire configuration	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.8.4		2023-02-14
		19	Environmental considerations	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.9		2023-02-14
		20	Temperature range	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.9.1		2023-02-14
		21	Water tightness	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.9.2		2023-02-14
		22	Water quality and incompatible materials	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.9.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Exposed material	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.9.4		2023-02-14
		24	Instruction manual	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.10		2023-02-14
		25	List of hydrophone features	Ultrasonics- -Hydrophones-Part3: Properties of hydrophones for ultrasonic fields u to 40 MHz IEC 62127-3 :2007 5.11		2023-02-14
359	Ultrasonic Doppler transducer	1	All Parameters	Technical requirements and test methods for ultrasonic Doppler transducer YY/T 0111—2005		2023-02-14
		2	Product categories	Technical requirements and test methods for ultrasonic Doppler transducer YY/T 0111—2005 4		2023-02-14
		3	Requirements	Technical requirements and test methods for ultrasonic Doppler transducer YY/T 0111—2005 5		2023-02-14
		4	The test conditions	Technical requirements and test methods for ultrasonic Doppler transducer YY/T 0111—2005 6		2023-02-14
		5	Test method for	Technical requirements and test methods for ultrasonic Doppler transducer YY/T 0111—2005 7		2023-02-14
		6	Deviation of FP from nominal frequency and measurement of relative bandwidth	Technical requirements and test methods for ultrasonic Doppler transducer YY/T 0111—2005 7.1		2023-02-14
		7	Tone burst method	Technical requirements and test methods for ultrasonic Doppler transducer YY/T 0111—2005 7.1.1		2023-02-14
		8	Spectral analysis	Technical requirements and test methods for ultrasonic Doppler transducer YY/T 0111—2005 7.1.2		2023-02-14
		9	Measurement of relative sensitivity and serial mixing of sending and receiving signals	Technical requirements and test methods for ultrasonic Doppler transducer YY/T 0111—2005 7.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Measurement of compound directional main lobe beam width and side lobe stage	Technical requirements and test methods for ultrasonic Doppler transducer YY/T 0111—2005 7.3		2023-02-14
		11	Measurement of electrical impedance (or admittance) deviation	Technical requirements and test methods for ultrasonic Doppler transducer YY/T 0111—2005 7.4		2023-02-14
360	Ultrasonics-Dental descaler systems	1	All Parameters	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993		2023-02-14
		2	General condition of measurement	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 5		2023-02-14
		3	The working conditions	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 5.1		2023-02-14
		4	Load conditions	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 5.2		2023-02-14
		5	Device cleaning	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 5.3		2023-02-14
		6	Rinse water temperature	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 5.4		2023-02-14
		7	Measuring steps	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 6		2023-02-14
		8	Tip vibration migration	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 6.1		2023-02-14
		9	Optical microscopy	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 6.1.1		2023-02-14
		10	Slide method	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 6.1.2		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Tip frequency	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 6.2		2023-02-14
		12	The vibration meter method	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 6.2.1		2023-02-14
		13	Method of frequency meter	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 6.2.2		2023-02-14
		14	Half deviation force	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 6.3		2023-02-14
		15	Publish requirements for basic output characteristics	Ultrasonics- Dental descaler systems-Measurement and declaration of the output characteristics IEC 61205:1993 7		2023-02-14
361	Ultrasonics-Dental descaler systems	1	All Parameters	Ultrasonics-Dental descaler systems YY/T 0460-2009		2023-02-14
		2	requirements	Ultrasonics-Dental descaler systems YY/T 0460-2009 4		2023-02-14
		3	Tip principal vibration shift	Ultrasonics-Dental descaler systems YY/T 0460-2009 4.1		2023-02-14
		4	Tip frequency	Ultrasonics-Dental descaler systems YY/T 0460-2009 4.2		2023-02-14
		5	Half deviation force	Ultrasonics-Dental descaler systems YY/T 0460-2009 4.3		2023-02-14
		6	Adjustment of the principal vibration offset of the tip	Ultrasonics-Dental descaler systems YY/T 0460-2009 4.4		2023-02-14
		7	Adjustment of flushing water pressure or flow rate	Ultrasonics-Dental descaler systems YY/T 0460-2009 4.5		2023-02-14
		8	Safety requirements	Ultrasonics-Dental descaler systems YY/T 0460-2009 4.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Power supply voltage adaptability	Ultrasonics-Dental descaler systems YY/T 0460-2009 4.7		2023-02-14
		10	Continuous working time	Ultrasonics-Dental descaler systems YY/T 0460-2009 4.8		2023-02-14
		11	Appearance and structure requirements	Ultrasonics-Dental descaler systems YY/T 0460-2009 4.9		2023-02-14
		12	Functional requirements	Ultrasonics-Dental descaler systems YY/T 0460-2009 4.10		2023-02-14
		13	Environmental test requirements	Ultrasonics-Dental descaler systems YY/T 0460-2009 4.11		2023-02-14
362	A mode ultrasonic biometer for ophthalmolog scanner	1	All Parameters	A mode ultrasonic biometer for ophthalmolog scanner YY/T 0107—2015		2023-02-14
		2	Requirements	A mode ultrasonic biometer for ophthalmolog scanner YY/T 0107—2015 4		2023-02-14
		3	Measuring range	A mode ultrasonic biometer for ophthalmolog scanner YY/T 0107—2015 4.1		2023-02-14
		4	Measurement error	A mode ultrasonic biometer for ophthalmolog scanner YY/T 0107—2015 4.2		2023-02-14
		5	Effective display digit	A mode ultrasonic biometer for ophthalmolog scanner YY/T 0107—2015 4.3		2023-02-14
		6	Additional features	A mode ultrasonic biometer for ophthalmolog scanner YY/T 0107—2015 4.4		2023-02-14
		7	Normal continuous working hours	A mode ultrasonic biometer for ophthalmolog scanner YY/T 0107—2015 4.5		2023-02-14
		8	Appearance and structure	A mode ultrasonic biometer for ophthalmolog scanner YY/T 0107—2015 4.6		2023-02-14
		9	Power supply voltage adaptability	A mode ultrasonic biometer for ophthalmolog scanner YY/T 0107—2015 4.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Environmental test requirements	A mode ultrasonic biometer for ophthalmolog scanner YY/T 0107—2015 4.8		2023-02-14
		11	Safety requirements	A mode ultrasonic biometer for ophthalmolog scanner YY/T 0107—2015 4.9		2023-02-14
363	Ophthalmic ultrasound B-mode scan	1	All Parameters	General technical requirements for ophthalmic ultrasound B-mode scan YY/T 0773-2010		2023-02-14
		2	Requirements	General technical requirements for ophthalmic ultrasound B-mode scan YY/T 0773-2010 4		2023-02-14
		3	The working conditions	General technical requirements for ophthalmic ultrasound B-mode scan YY/T 0773-2010 4.1		2023-02-14
		4	Performance	General technical requirements for ophthalmic ultrasound B-mode scan YY/T 0773-2010 4.2		2023-02-14
		5	Function	General technical requirements for ophthalmic ultrasound B-mode scan YY/T 0773-2010 4.3		2023-02-14
		6	Security	General technical requirements for ophthalmic ultrasound B-mode scan YY/T 0773-2010 4.4		2023-02-14
		7	Appearance and structure	General technical requirements for ophthalmic ultrasound B-mode scan YY/T 0773-2010 4.5		2023-02-14
		8	Environmental testing	General technical requirements for ophthalmic ultrasound B-mode scan YY/T 0773-2010 4.6		2023-02-14
364	Ophthalmic high frequency ultrasound scanner	1	All Parameters	Ophthalmic high frequency ultrasound scanner YY/T 0849-2011		2023-02-14
		2	Requirements	Ophthalmic high frequency ultrasound scanner YY/T 0849-2011 4		2023-02-14
		3	The working conditions	Ophthalmic high frequency ultrasound scanner YY/T 0849-2011 4.1		2023-02-14
		4	Performance	Ophthalmic high frequency ultrasound scanner YY/T 0849-2011 4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Function	Ophthalmic high frequency ultrasound scanner YY/T 0849-2011 4.3		2023-02-14
		6	Security	Ophthalmic high frequency ultrasound scanner YY/T 0849-2011 4.4		2023-02-14
		7	Appearance and structure	Ophthalmic high frequency ultrasound scanner YY/T 0849-2011 4.5		2023-02-14
		8	Environmental testing	Ophthalmic high frequency ultrasound scanner YY/T 0849-2011 4.6		2023-02-14
365	Ultrasonically blood-mimicking Doppler phantom	1	All Parameters	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001		2023-02-14
		2	Technical requirements of blood - like fluid mold	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 6		2023-02-14
		3	Overview	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 6.1		2023-02-14
		4	Imitation of the blood	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 6.2		2023-02-14
		5	The pipe	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 6.3		2023-02-14
		6	The inner diameter	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 6.3.1		2023-02-14
		7	Inlet pipe length	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 6.3.2		2023-02-14
		8	The wall	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 6.3.3		2023-02-14
		9	Tissue like material	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 6.4		2023-02-14
		10	Geometric configuration	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 6.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Measures to prevent the change of blood composition and eliminate bubbles	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 7		2023-02-14
		12	Technical specifications identification content	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 8		2023-02-14
		13	Measuring method for main technical parameters of blood fluid mold	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 9		2023-02-14
		14	Density measurement	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 9.1		2023-02-14
		15	Sound velocity measurement	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 9.2		2023-02-14
		16	Attenuation coefficient measurement	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 9.3		2023-02-14
		17	Imitated blood viscosity measurement	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 9.4		2023-02-14
		18	Measurement of pipeline cross section area	Technical requirements for ultrasonically blood-mimicking Doppler phantom IEC 61685:2001 9.5		2023-02-14
366	Ultrasonic medical diagnostic and monitoring equipment	1	All Parameters	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	General requirements	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.4		2023-02-14
		3	General requirements for ME equipment testing	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.5	See GB 9706.1-2020	2023-02-14
		4	Classification of ME devices and ME systems	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.6	See GB 9706.1-2020	2023-02-14
		5	ME device identification, tags, and files	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.7		2023-02-14
		6	ME equipment protection against electric shock hazard	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.8	See GB 9706.1-2020	2023-02-14
		7	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.9	See GB 9706.1-2020	2023-02-14
		8	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.10	See GB 9706.1-2020	2023-02-14
		9	Protection against unwanted or	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			excessive radiation hazards (sources)	medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.11		
		10	Control and instrument accuracy and hazard output protection	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.12		2023-02-14
		11	ME Device danger status and fault status	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.13	See GB 9706.1-2020	2023-02-14
		12	Programmable electrical medical system	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.14	See GB 9706.1-2020	2023-02-14
		13	Equipment structure of ME	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.15	See GB 9706.1-2020	2023-02-14
		14	The ME system	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.16	See GB 9706.1-2020	2023-02-14
		15	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 201.17	See GB 9706.1-2020	2023-02-14
		16	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2015 202.6	See YY 9706.102	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
367	Ultrasonic physiotherapy equipment	1	All Parameters	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009		2023-02-14
		2	General requirements	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.4	See GB 9706.1-2020	2023-02-14
		3	General requirements for ME equipment testing	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.5	See GB 9706.1-2020	2023-02-14
		4	Classification of ME devices and ME systems	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.6	See GB 9706.1-2020	2023-02-14
		5	ME device identification, tags, and files	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.7		2023-02-14
		6	ME equipment shock hazard protection	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.8	See GB 9706.1-2020	2023-02-14
		7	Protection of ME equipment and ME systems against mechanical hazards	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.9	See GB 9706.1-2020	2023-02-14
		8	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.10		2023-02-14
		9	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.11		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Control and instrument accuracy and hazard output protection	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.12		2023-02-14
		11	ME Device danger status and fault status	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.13	See GB 9706.1-2020	2023-02-14
		12	Programmable electrical medical system	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.14	See GB 9706.1-2020	2023-02-14
		13	ME device structure	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.15	See GB 9706.1-2020	2023-02-14
		14	The ME system	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.16	See GB 9706.1-2020	2023-02-14
		15	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 201.17	See GB 9706.1-2020	2023-02-14
		16	Electromagnetic compatibility of ME devices and ME systems	Medical electrical equipment Part 2-5:Particular requirements for ultrasonic physiotherapy equipment IEC 60601-2-5:2009 202.6	See YY 9706.102	2023-02-14
Non-electrical Medical Devices						
Non-electrical Medical Devices						
1	Protective face mask for medical use	1	Part Parameters	Technical requirements for protective face mask for medical use GB19083-2010		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	Basic requirements of masks	Technical requirements for protective face mask for medical use GB19083-2010 4.1		2023-02-14
		3	air-flow resistance	Protective face mask for medical use GB 19083-2010 4.5		2023-02-14
		4	Penetrability of Synthetic blood	Technical requirements for protective face mask for medical use GB19083-2010 4.6		2023-02-14
		5	filtration efficiency	Protective face mask for medical use GB 19083-2010 4.4		2023-02-14
		6	Humidity resistance of surface	Technical requirements for protective face mask for medical use GB19083-2010 4.7		2023-02-14
		7	mouth-piece tape	Protective face mask for medical use GB 19083-2010 4.3		2023-02-14
		8	Microbiological indicator	Technical requirements for protective face mask for medical use GB19083-2010 4.7		2023-02-14
		9	noseclip	Protective face mask for medical use GB 19083-2010 4.2		2023-02-14
		10	Residual of ethylene oxide	Technical requirements for protective face mask for medical use GB19083-2010 4.9		2023-02-14
		11	Performance of antiflaming	Technical requirements for protective face mask for medical use GB19083-2010 4.10		2023-02-14
		12	Adaptation	Technical requirements for protective face mask for medical use GB19083-2010 4.12		2023-02-14
		13	Derma irritancy	Technical requirements for protective face mask for medical use GB 19083-2010 4.11		2023-02-14
2	Surgical mask	1	Part Parameters	Surgical mask YY0469-2011		2023-02-14
		2	Appearance	Surgical mask YY0469-2011 4.1		2023-02-14
		3	Structure and size	Surgical mask YY0469-2011 4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Nose clip	Surgical mask YY0469-2011 4.3		2023-02-14
		5	Belt of mask	Surgical mask YY0469-2011 4.4		2023-02-14
		6	Penetrability of Synthetic blood	Surgical mask YY0469-2011 4.5		2023-02-14
		7	Fillter efficiency	Surgical mask YY0469-2011 4.6		2023-02-14
		8	Pressure difference	Surgical mask YY0469-2011 4.7		2023-02-14
		9	Performance of antiflaming	Surgical mask YY0469-2011 4.8		2023-02-14
		10	Microbiological indicator（Total bacterial count，Coliform，Pseudomonas aeruginosa，Staphylococcus aureus，Streptococcus haemolyticus，Total fungal colonies）	Surgical mask YY0469-2011 4.9		2023-02-14
		11	Residual of ethylene oxide	Surgical mask YY0469-2011 4.10		2023-02-14
		12	Cytotoxicity	Surgical mask YY0469-2011 4.12		2023-02-14
		13	Derma irritancy	Surgical mask YY0469-2011 4.11		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Delayed-type Hypersensitivity	Surgical mask YY0469-2011 4.13		2023-02-14
3	Single-use medical face mask	1	PartParameters	Single-use medical face mask YY/T0969-2013		2023-02-14
		2	Appearance	Single-use medical face mask YY/T0969-2013 4.1		2023-02-14
		3	Structure and size	Single-use medical face mask YY/T0969-2013 4.2		2023-02-14
		4	Nose clip	Single-use medical face mask YY/T0969-2013 4.3		2023-02-14
		5	Belt of mask	Single-use medical face mask YY/T0969-2013 4.4		2023-02-14
		6	Bacterial filtration efficiency	Single-use medical face mask YY/T0969-2013 4.5		2023-02-14
		7	Ventilation resistance	Single-use medical face mask YY/T0969-2013 4.6		2023-02-14
		8	Microbiological indicator（Total bacterial count，Coliform，Pseudomonas aeruginosa，Staphylococcus aureus，Streptococcus haemolyticus，Total fungal colonies）	Single-use medical face mask YY/T0969-2013 4.7		2023-02-14
		9	Residual of ethylene oxide	Single-use medical face mask YY/T0969-2013 4.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Skin irritation	Single-use medical face mask YY/T0969-2013 4.9.1		2023-02-14
		11	Derma irritancy	single-use medical face mask YY/T0969-2013 4.9.2		2023-02-14
		12	Delayed-type Hypersensitivity	single-use medical face mask YY/T0969-2013 4.9.3		2023-02-14
4	Infusion sets for single use,gravity feed	1	PartParameters	infusion sets for single use,gravity feed GB 8368-2018		2023-02-14
		2	Particle Pollution	infusion sets for single use,gravity feed GB 8368-2018 6.1		2023-02-14
		3	Leakage	infusion sets for single use,gravity feed GB 8368-2018 6.2		2023-02-14
		4	Tensile Strength	infusion sets for single use,gravity feed GB 8368-2018 6.3		2023-02-14
		5	Cork Puncture Outfit	infusion sets for single use,gravity feed GB 8368-2018 6.4		2023-02-14
		6	Air Inflow Ware	infusion sets for single use,gravity feed GB 8368-2018 6.5		2023-02-14
		7	Pipeline	infusion sets for single use,gravity feed GB 8368-2018 6.6		2023-02-14
		8	Liquid Medicine Filter	infusion sets for single use,gravity feed GB 8368-2018 6.7		2023-02-14
		9	Drip Chamber and Dropper	infusion sets for single use,gravity feed GB 8368-2018 6.8		2023-02-14
		10	Flow Regulator	infusion sets for single use,gravity feed GB 8368-2018 6.9		2023-02-14
		11	Flow Velocity of Transfusion	infusion sets for single use,gravity feed GB 8368-2018 6.10		2023-02-14
		12	Injection Ware	infusion sets for single use,gravity feed GB 8368-2018 6.11		2023-02-14
		13	External Cone Splice	infusion sets for single use,gravity feed GB 8368-2018 6.12		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Protective Jacket	infusion sets for single use,gravity feed GB 8368-2018 6.13		2023-02-14
		15	Revivification Matter	infusion sets for single use,gravity feed GB 8368-2018 7.1		2023-02-14
		16	Metal Ion	infusion sets for single use,gravity feed GB 8368-2018 7.2		2023-02-14
		17	Titration of PH Value	infusion sets for single use,gravity feed GB 8368-2018 7.3		2023-02-14
		18	Residue of Evaporation	infusion sets for single use,gravity feed GB 8368-2018 7.4		2023-02-14
		19	Ultraviolet Absorbance of Extracted	infusion sets for single use,gravity feed GB 8368-2018 7.5		2023-02-14
		20	Residual Quantity of Oxirane	infusion sets for single use,gravity feed GB 8368-2018 7.6		2023-02-14
		21	sterile	infusion sets for single use,gravity feed GB 8368-2018 8.2		2023-02-14
		22	bacterial endotoxin	infusion sets for single use,gravity feed GB 8368-2018 8.3		2023-02-14
		23	Pyrogen rabbit method	infusion sets for single use，gravity feed GB 8368-2018 8.3		2023-02-14
		24	Hemolysis	infusion sets for single use，gravity feed GB 8368-2018 8.5		2023-02-14
		25	Sensitization	infusion sets for single use，gravity feed GB 8368-2018 8.5		2023-02-14
		26	Acute Systemic Toxic	infusion sets for single use，gravity feed GB 8368-2018 8.5		2023-02-14
		27	Intracutaneous Reactivity	infusion sets for single use，gravity feed GB 8368-2018 8.5		2023-02-14
5	Intravenous needles for	1	PartParameters	Intravenous needles for single use GB 18671-2009		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	single use	2	Shade Guide	Intravenous needles for single use GB 18671-2009 6.1		2023-02-14
		3	Particle Pollution	Intravenous needles for single use GB 18671-2009 6.2		2023-02-14
		4	Link Firmness	Intravenous needles for single use GB 18671-2009 6.3		2023-02-14
		5	Leakage	Intravenous needles for single use GB 18671-2009 6.4		2023-02-14
		6	Flow	Intravenous needles for single use GB 18671-2009 6.5		2023-02-14
		7	Length of Syringe	Intravenous needles for single use GB 18671-2009 6.6		2023-02-14
		8	Needle Tip	Intravenous needles for single use GB 18671-2009 6.7		2023-02-14
		9	Lubricant	Intravenous needles for single use GB 18671-2009 6.8		2023-02-14
		10	Joint Pedestal	Intravenous needles for single use GB 18671-2009 6.9		2023-02-14
		11	Needle Handle	Intravenous needles for single use GB 18671-2009 6.10		2023-02-14
		12	Hosepipe	Intravenous needles for single use GB 18671-2009 6.11		2023-02-14
		13	Protective Jacket、Protective Cap	Intravenous needles for single use GB 18671-2009 6.12		2023-02-14
		14	Revivification Matter	Intravenous needles for single use GB 18671-2009 7.1		2023-02-14
		15	Metal Ion	Intravenous needles for single use GB 18671-2009 7.2		2023-02-14
		16	PH Value	Intravenous needles for single use GB 18671-2009 7.3		2023-02-14
		17	Residue of Evaporation	Intravenous needles for single use GB 18671-2009 7.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	Ultraviolet Absorbance	Intravenous needles for single use GB 18671-2009 7.5		2023-02-14
		19	sterile	Intravenous needles for single use GB 18671-2009 8.2		2023-02-14
		20	Bacterial endotoxin	Intravenous needles for single use GB 18671-2009 8.3		2023-02-14
		21	Hemolysis	intravenous needles for single use GB 18671-2009 8.1		2023-02-14
		22	Sensitization	intravenous needles for single use GB 18671-2009 8.1		2023-02-14
		23	Acute Systemic Toxic	intravenous needles for single use GB 18671-2009 8.1		2023-02-14
		24	Intracutaneous Reactivity	intravenous needles for single use GB 18671-2009 8.1		2023-02-14
6	Flow rate-setting and adjustable infusion sets for single use	1	Part Parameters	Special infusion sets-Part6:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009		2023-02-14
		2	Particle Pollution	Special infusion sets-Part6:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009		2023-02-14
		3	Leakage	Special infusion sets-Part7:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 6.1		2023-02-14
		4	Tensile Strength	Special infusion sets-Part8:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 6.1		2023-02-14
		5	Cork Puncture Outfit	Special infusion sets-Part9:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 6.1		2023-02-14
		6	Air Inflow Ware	Special infusion sets-Part10:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 6.1		2023-02-14
		7	Pipeline	Special infusion sets-Part11:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 6.1		2023-02-14
		8	Liquid Medicine Filter	Special infusion sets-Part12:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 6.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Drip Chamber and Dropper	Special infusion sets-Part13:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 6.1		2023-02-14
		10	Flow Regulator	Special infusion sets-Part14:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 6.1		2023-02-14
		11	Flow Velocity of Transfusion	Special infusion sets-Part15:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 6.1		2023-02-14
		12	Injection Ware	Special infusion sets-Part16:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 6.1		2023-02-14
		13	External Cone Splice	Special infusion sets-Part17:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 6.1		2023-02-14
		14	Protective Jacket	Special infusion sets-Part18:Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 6.1		2023-02-14
		15	Setting Reliable Property	Infusion Bottles Made of Middle Borosilicate Glass YY 0286.6-2009 6.2.1		2023-02-14
		16	Adjustable Joint	Infusion Bottles Made of Middle Borosilicate Glass YY 0286.6-2009 6.2.2		2023-02-14
		17	Graded and Mark	Infusion Bottles Made of Middle Borosilicate Glass YY 0286.6-2009 6.2.3		2023-02-14
		18	Flow Indication Basic Error	Infusion Bottles Made of Middle Borosilicate Glass YY 0286.6-2009 6.2.4.1		2023-02-14
		19	Flow Controlled Stability	Infusion Bottles Made of Middle Borosilicate Glass YY 0286.6-2009 6.2.4.2		2023-02-14
		20	Flow Velocity of Transfusion	Infusion Bottles Made of Middle Borosilicate Glass YY 0286.6-2009 6.3		2023-02-14
		21	Suspend Stream Clamp and Switch	Infusion Bottles Made of Middle Borosilicate Glass YY 0286.6-2009 6.4		2023-02-14
		22	Chemical Require	Infusion Bottles Made of Middle Borosilicate Glass YY 0286.6-2009 7		2023-02-14
		23	Biological Require	Infusion Bottles Made of Middle Borosilicate Glass YY 0286.6-2009 8		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		24	Hemolysis	special infusion sets-Part 6：Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 8		2023-02-14
		25	Sensitization	special infusion sets-Part 6：Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 8		2023-02-14
		26	Acute Systemic Toxic	special infusion sets-Part 6：Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 8		2023-02-14
		27	Intracutaneous Reactivity	special infusion sets-Part 6：Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 8		2023-02-14
		28	Cytotoxicity	special infusion sets-Part 6：Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 8		2023-02-14
		29	Pyrogen rabbit method	special infusion sets-Part 6：Flow rate-setting and adjustable infusion sets for single use YY 0286.6-2009 8		2023-02-14
7	Light-resistant infusion sets for single use	1	PartParameters	Special infusion sets-Part3:Light-resistant infusion sets for single use YY/T 0286.3-2017		2023-02-14
		2	general rules	Special infusion sets-Part3:Light-resistant infusion sets for single use YY/T 0286.3-2017 5.1	See chapter 6 gb8368-2005 all the requirements	2023-02-14
		3	Lucifuge Property	Special infusion sets-Part3:Light-resistant infusion sets for single use YY/T 0286.3-2017 5.2		2023-02-14
		4	Decoloration	Special infusion sets-Part3:Light-resistant infusion sets for single use YY/T 0286.3-2017 5.3		2023-02-14
		5	Chemical Require	Special infusion sets-Part4:Light-resistant infusion sets for single use YY/T 0286.3-2017 6		2023-02-14
		6	Biological Require	Special infusion sets-Part5:Light-resistant infusion sets for single use YY/T 0286.3-2017 8		2023-02-14
		7	Hemolysis	special infusion sets-Part 6：light-resistant infusion sets for single use YY/T 0286.3-2017		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Sensitization	special infusion sets-Part 6：light-resistant infusion sets for single use YY/T 0286.3-2017		2023-02-14
		9	Acute Systemic Toxic	special infusion sets-Part 6：light-resistant infusion sets for single use YY/T 0286.3-2017		2023-02-14
		10	Intracutaneous Reactivity	special infusion sets-Part 6：light-resistant infusion sets for single use YY/T 0286.3-2017		2023-02-14
		11	Cytotoxicity	special infusion sets-Part 6：light-resistant infusion sets for single use YY/T 0286.3-2017		2023-02-14
		12	Pyrogen rabbit method	special infusion sets-Part 6：light-resistant infusion sets for single use YY/T 0286.3-2017		2023-02-14
8	Transfusion sets for single use	1	Part Parameters	Transfusion sets for single use GB 8369.1-2019		2023-02-14
		2	Particle Pollution	Transfusion sets for single use GB 8369.1-2019 5.1		2023-02-14
		3	Leakage	Transfusion sets for single use GB 8369.1-2019 5.2		2023-02-14
		4	Tensile Strength	Transfusion sets for single use GB 8369.1-2019 5.3		2023-02-14
		5	Blood Transfusion Cannula	Transfusion sets for single use GB 8369.1-2019 5.4		2023-02-14
		6	Pipe Line	Transfusion sets for single use GB 8369.1-2019 5.5		2023-02-14
		7	Filter for blood and blood components	Transfusion sets for single use GB 8369.1-2019 5.6		2023-02-14
		8	Dropper and dropper	Transfusion sets for single use GB 8369.1-2019 5.7		2023-02-14
		9	Flow regulator	Transfusion sets for single use GB 8369.1-2019 5.8		2023-02-14
		10	Blood and blood composition	Transfusion sets for single use GB 8369.1-2019 5.9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Injection part	Transfusion sets for single use GB 8369.1-2019 5.10		2023-02-14
		12	External taper joint	Transfusion sets for single use GB 8369.1-2019 5.11		2023-02-14
		13	Protective Cover	Transfusion sets for single use GB 8369.1-2019 5.12		2023-02-14
		14	Revivification Matter	Transfusion sets for single use GB 8369.1-2019 6.1		2023-02-14
		15	Metal Ion	Transfusion sets for single use GB 8369.1-2019 6.2		2023-02-14
		16	Titration of PH Value	Transfusion sets for single use GB 8369.1-2019 6.3		2023-02-14
		17	Residue of Evaporation	Transfusion sets for single use GB 8369.1-2019 6.4		2023-02-14
		18	Ultraviolet Absorbance of Extracted	Transfusion sets for single use GB 8369.1-2019 6.5		2023-02-14
		19	Residual Quantity of Oxirane	Transfusion sets for single use GB 8369.1-2019 6.6		2023-02-14
		20	sterile	Transfusion sets for single use GB 8369.1-2019 7.2		2023-02-14
		21	bacterial endotoxin	Transfusion sets for single use GB 8369.1-2019 7.3		2023-02-14
		22	Biological Require	Transfusion sets for single use GB 8369.1-2019 7		2023-02-14
		23	Hemolysis	transfusion sets for single use GB 8369.1-2019 7.4		2023-02-14
		24	Sensitization	transfusion sets for single use GB 8369.1-2019 7		2023-02-14
		25	Acute Systemic Toxic	transfusion sets for single use GB 8369.1-2019 7.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		26	Intracutaneous Reactivity	transfusion sets for single use GB 8369.1-2019 7.5		2023-02-14
		27	Cytotoxicity	transfusion sets for single use GB 8369.1-2019 7.5		2023-02-14
		28	Pyrogen rabbit method	transfusion sets for single use GB 8369.1-2019 7.5		2023-02-14
9	Sterile hypodermic syringes for single use	1	PartParameters	Sterile hypodermic syringes for single use GB 15810-2019		2023-02-14
		2	Physical requirements	Sterile hypodermic syringes for single use GB 15810-2019 5		2023-02-14
		3	Chemical requirement	Sterile hypodermic syringes for single use GB 15810-2019 6		2023-02-14
		4	sterile	Sterile hypodermic syringes for single use GB 15810-2019 5.12.1		2023-02-14
		5	bacterial endotoxin	Sterile hypodermic syringes for single use GB 15810-2019 5.12.2		2023-02-14
		6	Pyrogen rabbit method	sterile hypodermic syringes for single use GB 15810-2019 5.12.3		2023-02-14
		7	Hemolysis	sterile hypodermic syringes for single use GB 15810-2019 5.12.3		2023-02-14
		8	Acute Systemic Toxic	sterile hypodermic syringes for single use GB 15810-2019 5.12.4		2023-02-14
10	Sterile urethral catheter for single use	1	PartParameters	Sterile urethral catheter for single use YY 0325-2016		2023-02-14
		2	Appearance	Sterile urethral catheter for single use YY 0325-2016 4.2		2023-02-14
		3	Size	Sterile urethral catheter for single use YY 0325-2016 4.3		2023-02-14
		4	Strength	Sterile urethral catheter for single use YY 0325-2016 4.4		2023-02-14
		5	Separating Force of	Sterile urethral catheter for single use YY 0325-2016 4.5		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Connector			
		6	Reliable Property of Sacculus	Sterile urethral catheter for single use YY 0325-2016 4.6		2023-02-14
		7		Sterile urethral catheter for single use YY 0325-2016 4.7		2023-02-14
		8	Flow	Sterile urethral catheter for single use YY 0325-2016 4.8		2023-02-14
		9	sterile	Sterile vagina dilator for single use YY 0325-2016 4.10		2023-02-14
		10		Sterile urethral catheter for single use YY 0325-2016 4.11		2023-02-14
		11	Residual Quantity of EO	Sterile vagina dilator for single use YY 0325-2016 4.12		2023-02-14
		12	Hemolysis	sterile urethral catheter for single use YY 0325-2016 4.9		2023-02-14
		13	Sensitization	sterile urethral catheter for single use YY 0325-2016 4.9		2023-02-14
		14	Acute Systemic Toxic	sterile urethral catheter for single use YY 0325-2016 4.9		2023-02-14
		15	Intracutaneous Reactivity	sterile urethral catheter for single use YY 0325-2016 4.9		2023-02-14
11	Sterile urethral catheter for single use	1	PartParameters	Sterile urethral catheter for single use YY/T 0325-2022		2023-02-14
		2	Apparence	Sterile urethral catheter for single use YY/T 0325-2022 5.4		2023-02-14
		3	Dimension indentification	Sterile urethral catheter for single use YY/T 0325-2022 5.5		2023-02-14
		4	Sterilization	Sterile urethral catheter for single use YY/T 0325-2022 5.8		2023-02-14
		5	Ethylene oxide	Sterile urethral catheter for single use YY/T 0325-2022 5.9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			（EO）residue			
		6	strength	Sterile urethral catheter for single use YY/T 0325-2022 6.1		2023-02-14
		7	connector security	Sterile vagina dilator for single use YY/T 0325-2022 6.2		2023-02-14
		8	balloon reliability	Sterile urethral catheter for single use YY/T 0325-2022 6.3		2023-02-14
		9	Integrity and volume maintenance of of catheter filling chamber	Sterile vagina dilator for single use YY/T 0325-2022 6.4		2023-02-14
		10	flow	sterile urethral catheter for single use YY/T 0325-2022 6.5		2023-02-14
		11	Corrosion Resistance	sterile urethral catheter for single use YY/T 0325-2022 6.6		2023-02-14
		12	kink stability	sterile urethral catheter for single use YY/T 0325-2022 6.7		2023-02-14
		13	peak tension	sterile urethral catheter for single use YY/T 0325-2022 6.8		2023-02-14
		14	tensile property of inflation ballon	YY/T 0325-2022 6.9		2023-02-14
12	Sterile vagina dilator for single use	1	PartParameters	Sterile vagina dilator for single use YY 0336-2020		2023-02-14
		2	appearance	Sterile vagina dilator for single use YY 0336-2020 4.1		2023-02-14
		3	size	Sterile vagina dilator for single use YY 0336-2020 4.2		2023-02-14
		4	Using Property	Sterile vagina dilator for single use YY 0336-2020 4.3		2023-02-14
		5	Resistance to deformation ability	Sterile vagina dilator for single use YY 0336-2020 4.4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	The structural strength	Sterile vagina dilator for single use YY 0336-2020 4.4.2		2023-02-14
		7	sterile	Sterile vagina dilator for single use YY 0336-2020 4.5		2023-02-14
		8	Residual Quantity of Oxirane	Sterile vagina dilator for single use YY 0336-2020 4.6		2023-02-14
		9	cytotoxicity	Sterile vagina dilator for single use YY 0336-2020 5.7.1		2023-02-14
		10	Delayed-type Hypersensitivity	sterile vaginal dilatory for single use YY 0336-2020 4.7.2		2023-02-14
		11	Vaginal mucosal irritation test	sterile vaginal dilatory for single use YY 0336-2020 4.7.3		2023-02-14
13	Suction catheter for use in the respiratory tract	1	All Parameters	Suction catheter for use in the respiratory tract YY/T 0339-2019		2023-02-14
		2	General requirements for development and closed suction conduits	Suction catheter for use in the respiratory tract YY/T 0339-2019 4		2023-02-14
		3	Specific requirements for open and closed suction catheters	Suction catheter for use in the respiratory tract YY/T 0339-2019 5		2023-02-14
		4	Material	Suction catheter for use in the respiratory tract YY/T 0339-2019 6		2023-02-14
		5	Design	Suction catheter for use in the respiratory tract YY/T 0339-2019 7		2023-02-14
		6	Link Firmness Property	Suction catheter for use in the respiratory tract YY/T 0339-2019 8.1		2023-02-14
		7	Barrel performance	Suction catheter for use in the respiratory tract YY/T 0339-2019 8.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Vacuum control device performance	Medical polymer products-Test methods of radiopacity YY/T 0339-2019 8.3		2023-02-14
		9	Leakage	Suction catheter for use in the respiratory tract YY/T 0339-2019 8.4		2023-02-14
		10	Air Resistance	Suction catheter for use in the respiratory tract YY/T 0339-2019 8.5		2023-02-14
		11	Ray impermeability	Suction catheter for use in the respiratory tract YY/T 0339-2019 8.6		2023-02-14
		12	Requirements for a suction catheter provided in aseptic form	Suction catheters for use in the respiratory tract YY/T 0339-2019 9		2023-02-14
		13	Mark	Suction catheter for use in the respiratory tract YY/T 0339-2019 10		2023-02-14
14	absorbent cotton gauze and absorbent cotton and gauze	1	All Parameters	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006		2023-02-14
		2	Fiber Identify	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.1		2023-02-14
		3	PH Value	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.2		2023-02-14
		4	Outside Fiber	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.3		2023-02-14
		5	Fluorescent Material	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.4		2023-02-14
		6	Amount of Yarn	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.5		2023-02-14
		7	Quality of Every Centiare	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.6		2023-02-14
		8	Minimum Breakage Force	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Sinked Time	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.8		2023-02-14
		10	Soluble Matter in Ether	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.9		2023-02-14
		11	Liveness Matter in Surface	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.10		2023-02-14
		12	Soluble Matter in Water	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.11		2023-02-14
		13	Starch and Dextrin	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.12		2023-02-14
		14	Extracted Tinting Matter	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.13		2023-02-14
		15	Desiccation Weightlessness	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.14		2023-02-14
		16	Sulfate Ash	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze YY/T 0331-2006 4.15		2023-02-14
15	surgical gauze dressings	1	All Parameters	Gereral requirements for surgical gauze dressings YY 0594-2006		2023-02-14
		2	Gauze Material	Gereral requirements for surgical gauze dressings YY 0594-2006 4.1	See Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and gauze	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Dye	Gereral requirements for surgical gauze dressings YY 0594-2006 4.2		2023-02-14
		4	Fold and Tailor	Gereral requirements for surgical gauze dressings YY 0594-2006 4.3		2023-02-14
		5	Sterility	Gereral requirements for surgical gauze dressings YY 0594-2006 4.4		2023-02-14
		6	Residual Quantity of Oxirane	Gereral requirements for surgical gauze dressings YY 0594-2006 4.5		2023-02-14
		7	X-ray Detectable Module	Gereral requirements for surgical gauze dressings YY 0594-2006 5.1		2023-02-14
		8	Colour Fasthess	Gereral requirements for surgical gauze dressings YY 0594-2006 5.2		2023-02-14
		9	Suture	Gereral requirements for surgical gauze dressings YY 0594-2006 5.3		2023-02-14
		10	Abdomen Scarf Belt	Gereral requirements for surgical gauze dressings YY 0594-2006 5.4		2023-02-14
16	Medical absorbent cotton	1	All Parameters	Medical absorbent cotton YY/T 0330-2015		2023-02-14
		2	Character	Medical absorbent cotton YY/T 0330-2015 3.1		2023-02-14
		3	Identify	Medical absorbent cotton YY/T 0330-2015 3.2		2023-02-14
		4	Outside Fiber	Medical absorbent cotton YY/T 0330-2015 3.3		2023-02-14
		5	Cotton Knot	Medical absorbent cotton YY/T 0330-2015 3.4		2023-02-14
		6	Soluble Matter in Water	Medical absorbent cotton YY/T 0330-2015 3.5		2023-02-14
		7	PH Value	Medical absorbent cotton YY/T 0330-2015 3.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Sinked Time	Medical absorbent cotton YY/T 0330-2015 3.7		2023-02-14
		9	Amount of Absorb Water	Medical absorbent cotton YY/T 0330-2015 3.8		2023-02-14
		10	Soluble Matter in Ether	Medical absorbent cotton YY/T 0330-2015 3.9		2023-02-14
		11	Fluorescent Material	Medical absorbent cotton YY/T 0330-2015 3.10		2023-02-14
		12	Desiccation Weightlessness	Medical absorbent cotton YY/T 0330-2015 3.11		2023-02-14
		13	Sulfate Ash	Medical absorbent cotton YY/T 0330-2015 3.12		2023-02-14
		14	Liveness Matter in Surface	Medical absorbent cotton YY/T 0330-2015 3.13		2023-02-14
		15	Extracted Tinting Matter	Medical absorbent cotton YY/T 0330-2015 3.14		2023-02-14
		16	Residual Quantity of Oxirane	Medical absorbent cotton YY/T 0330-2015 3.15		2023-02-14
		17	Biological load	medical absorbent cotton YY/T 0330-2015 4.14		2023-02-14
				Microbiological methods for sterilization of medical devices Part I Determination of total number of microorganisms on products GB/T 19973.1		2023-02-14
17	Spinal needle	1	All Parameters	Spinal needle YY/T 1148-2009		2023-02-14
		2	Classification and marking	Spinal needle YY/T 1148-2009 3		2023-02-14
		3	Materials	Spinal needle YY/T 1148-2009 4		2023-02-14
		4	Demands	Spinal needle YY/T 1148-2009 5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
18	Single-use puncture set local anaesthesia	1	All Parameters	Single-use puncture set local anaesthesia YY0321.1-2009		2023-02-14
		2	One-time Anesthesia Needle	Single-use puncture set local anaesthesia YY0321.1-2009 5.1	See Single-use puncture set local anaesthesia	2023-02-14
		3	One-time Anesthesia Filter	Single-use puncture set local anaesthesia YY0321.1-2009 5.2	See Single-use puncture set local anaesthesia	2023-02-14
		4	Conduit and Structure of Splice	Single-use puncture set local anaesthesia YY0321.1-2009 5.3.1		2023-02-14
		5	Size of Conduit	Single-use puncture set local anaesthesia YY0321.1-2009 5.3.2		2023-02-14
		6	X-ray Display Image	Single-use puncture set local anaesthesia YY0321.1-2009 5.3.3		2023-02-14
		7	Hole in Flank Conduit	Single-use puncture set local anaesthesia YY0321.1-2009 5.3.4		2023-02-14
		8	Graded Line of Conduit	Single-use puncture set local anaesthesia YY0321.1-2009 5.3.5		2023-02-14
		9	Flow of Conduit	Single-use puncture set local anaesthesia YY0321.1-2009 5.3.6		2023-02-14
		10	Breakage Force of Conduit	Single-use puncture set local anaesthesia YY0321.1-2009 5.3.7		2023-02-14
		11	Conduit Structure	Single-use puncture set local anaesthesia YY0321.1-2009 5.3.8		2023-02-14
		12	Particle Pollution	Single-use puncture set local anaesthesia YY0321.1-2009 5.3.9		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Link Firmness	Single-use puncture set local anaesthesia YY0321.1-2009 5.3.10		2023-02-14
		14	Sealing	Single-use puncture set local anaesthesia YY0321.1-2009 5.3.11		2023-02-14
		15	Revivification Matter	Single-use puncture set local anaesthesia YY0321.1-2009 6.1		2023-02-14
		16	Metal Ion	Single-use puncture set local anaesthesia YY0321.1-2009 6.2		2023-02-14
		17	PH Value	Single-use puncture set local anaesthesia YY0321.1-2009 6.3		2023-02-14
		18	Residual Quantity of Oxirane	Single-use puncture set local anaesthesia YY0321.1-2009 6.4		2023-02-14
		19	sterile	Single-use puncture set local anaesthesia YY0321.1-2009 7.1		2023-02-14
		20	Bacterial endotoxin	Single-use puncture set local anaesthesia YY0321.1-2009 7.2		2023-02-14
19	Single-use needle for anaesthesia	1	All Parameters	Single-use needle for anaesthesia YY0321.2-2009		2023-02-14
		2	Physical Properties Require	Single-use needle for anaesthesia YY0321.2-2009 5		2023-02-14
		3	Chemical Properties Require	Single-use needle for anaesthesia YY0321.2-2009 6		2023-02-14
		4	sterile	Single-use puncture set local anaesthesia YY0321.2-2009 7.1		2023-02-14
		5	Bacterial endotoxin	Single-use puncture set local anaesthesia YY0321.2-2009 7.2		2023-02-14
20	Single-use filter for anaesthesia	1	All Parameters	Single-use filter for anaesthesia YY0321.3-2009		2023-02-14
		2	Appearance	Single-use filter for anaesthesia YY0321.3-2009 5.1		2023-02-14
		3	Splice	Single-use filter for anaesthesia YY0321.3-2009 5.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Filtering Rate	Single-use filter for anaesthesia YY0321.3-2009 5.3		2023-02-14
		5	Sealing	Single-use filter for anaesthesia YY0321.3-2009 5.4		2023-02-14
		6	Particle Pollution	Single-use filter for anaesthesia YY0321.3-2009 5.5		2023-02-14
		7	Flow of Liquor	Single-use filter for anaesthesia YY0321.3-2009 5.6		2023-02-14
		8	Revivification Matter	Single-use filter for anaesthesia YY0321.3-2009 6.2		2023-02-14
		9	Metal Ion	Single-use filter for anaesthesia YY0321.3-2009 6.3		2023-02-14
		10	PH Value	Single-use filter for anaesthesia YY0321.3-2009 6.4		2023-02-14
		11	Residual Quantity of Oxirane	Single-use filter for anaesthesia YY0321.3-2009 6.5		2023-02-14
		12	sterile	Single-use puncture set local anaesthesia YY0321.3-2009 7.1		2023-02-14
		13	Bacterial endotoxin	Single-use puncture set local anaesthesia YY0321.3-2009 7.2		2023-02-14
21	Single-use sterile rubber surgical gloves	1	All Parameters	Single-use sterile rubber surgical gloves GB 7543-2020 ISO 10282-2014		2023-02-14
		2	Size	Single-use sterile rubber surgical gloves GB 7543-2020 ISO 10282-2014 6.1		2023-02-14
		3	Water no-penetrate Properties	Single-use sterile rubber surgical gloves GB 7543-2020 ISO 10282-2014 6.2		2023-02-14
		4	Tensile Properties	Single-use sterile rubber surgical gloves GB 7543-2020 ISO 10282-2014 6.3		2023-02-14
		5	Sterilization	Single-use sterile rubber surgical gloves GB 7543-2020 ISO 10282-2014 6.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
22	Single-use medical rubber examination gloves	1	All Parameters	Single-use medical rubber examination gloves GB10213-2006 ISO 11193.1：2002		2023-02-14
		2	Size	Single-use medical rubber examination gloves GB10213-2006 ISO 11193.1：2002 6.1		2023-02-14
		3	Water no-penetrate Properties	Single-use medical rubber examination gloves GB10213-2006 ISO 11193.1：2002 6.2		2023-02-14
		4	Tensile Properties	Single-use medical rubber examination gloves GB10213-2006 ISO 11193.1：2002 6.3		2023-02-14
		5	Sterilization	Single-use medical rubber examination gloves GB10213-2006 ISO 11193.1：2002 6.4		2023-02-14
23	Natural latex rubber condoms	1	All Parameters	Natural latex rubber condoms-Requirments and test methods GB/T7544-2019 ISO 4074：2015		2023-02-14
		2	Design	Natural latex rubber condoms-Requirments and test methods GB/T7544-2019 ISO 4074：2015 9		2023-02-14
		3	Blasting volume and pressure	Natural latex rubber condoms-Requirments and test methods GB/T7544-2019 ISO 4074：2015 10		2023-02-14
		4	Stability and shelf life	Natural latex rubber condoms-Requirments and test methods GB/T7544-2019 ISO 4074：2015 11		2023-02-14
		5	Pinhole	Natural latex rubber condoms-Requirments and test methods GB/T7544-2019 ISO 4074：2015 12		2023-02-14
		6	Visible defect	Natural latex rubber condoms-Requirments and test methods GB/T7544-2019 ISO 4074：2015 13		2023-02-14
		7	Packaging integrity of a single package	Natural latex rubber condoms-Requirments and test methods GB/T7544-2019 ISO 4074：2015 14		2023-02-14
		8	Packaging and labelling	Natural latex rubber condoms-Requirments and test methods GB/T7544-2019 ISO 4074：2015 15		2023-02-14
24	Medical adhesive bandages	1	Part Parameters	Medical adhesive bandages-General requirments YY/T 0148-2006		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	Size	Medical adhesive bandages-General requirments YY/T 0148-2006 5.1		2023-02-14
		3	Maintain Glue Property	Medical adhesive bandages-General requirments YY/T 0148-2006 5.2.1		2023-02-14
		4	Peeled Strength	Medical adhesive bandages-General requirments YY/T 0148-2006 5.2.2		2023-02-14
		5	Comfort （extensible）	Medical adhesive bandages-General requirments YY/T 0148-2006 6.1		2023-02-14
		6	Water Vapor Transit Property	Medical adhesive bandages-General requirments YY/T 0148-2006 6.2		2023-02-14
		7	Preventing Water Property	Medical adhesive bandages-General requirments YY/T 0148-2006 6.3		2023-02-14
		8	Specific Matter	Medical adhesive bandages-General requirments YY/T 0148-2006 6.4		2023-02-14
		9	Elasticity	Medical adhesive bandages-General requirments YY/T 0148-2006 6.5		2023-02-14
		10	Dye	Medical adhesive bandages-General requirments YY/T 0148-2006 6.6		2023-02-14
		11	Sterility	Medical adhesive bandages-General requirments YY/T 0148-2006 6.7		2023-02-14
		12	Hemolysis	medical adhesive bandages-General requirements YY/T 0148-2006 5.3		2023-02-14
		13	Sensitization	medical adhesive bandages-General requirements YY/T 0148-2006 5.3		2023-02-14
		14	Acute Systemic Toxic	medical adhesive bandages-General requirements YY/T 0148-2006 5.3		2023-02-14
		15	Derma irritancy	medical adhesive bandages-General requirements YY/T 0148-2006 5.3		2023-02-14
25	Single-use protective	1	Part Parameters	Technical requirments for single-use protective clothing for medical use GB 19082-2009		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	clothing for medical use	2	appearance	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.1		2023-02-14
		3	Structure	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.2		2023-02-14
		4	Model Specification	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.3		2023-02-14
		5	Water Permeability Resist Property	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.4.1		2023-02-14
		6	Amount of Moisture Penetrate	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.4.2		2023-02-14
		7	Synthesis Blood Penetrate	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.4.3		2023-02-14
		8	Resist Moisture Property in Surface	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.4.4		2023-02-14
		9	Breakage Mightiness	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.5		2023-02-14
		10	Breakage Elongation	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.6		2023-02-14
		11	Filter Rate	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.7		2023-02-14
		12	Hinder Burn Property	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.8		2023-02-14
		13	Static Attenuation Property	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.10		2023-02-14
		14	antistatic	single-use protective clothing for medical use GB19082-2009 4.9		2023-02-14
		15	Microbiological indicator（Total bacterial count，Coliform，	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.12		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Pseudomonas aeruginosa，Staphylococcus aureus，Streptococcus haemolyticus，Total fungal colonies）			
		16	Residual Quantity of Oxirane	Technical requirments for single-use protective clothing for medical use GB 19082-2009 4.13		2023-02-14
		17	Derma irritancy	technical requirements for single-use protective clothing for medical use GB 19082-2009 4.11		2023-02-14
26	Sterile insulin syringe for single use	1	Part Parameters	Sterile insulin syringe for single use YY/T 0497-2018		2023-02-14
		2	appearance	YY/T 0497-2018 6.1		2023-02-14
		3	Lubricant	YY/T 0497-2018 6.2		2023-02-14
		4	Size range	YY/T 0497-2018 6.3		2023-02-14
		5	Graduated scale	YY/T 0497-2018 6.4		2023-02-14
		6	jacket	YY/T 0497-2018 6.5		2023-02-14
		7	Scale piston rod assembly	YY/T 0497-2018 6.6		2023-02-14
		8	cone	YY/T 0497-2018 6.7		2023-02-14
		9	Needle tube and needle	YY/T 0497-2018 6.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Syringe assembly performance	YY/T 0497-2018 6.9		2023-02-14
		11	PH Value	YY/T 0497-2018 7.1		2023-02-14
		12	Extraction metal	YY/T 0497-2018 7.2		2023-02-14
		13	Readily Oxidizable Substance	YY/T 0497-2018 7.3		2023-02-14
		14	Residual Quantity of Oxirane	YY/T 0497-2018 7.4		2023-02-14
		15	biological properties	Sterile insulin syringe for single use YY/T 0497-2018 5.11		2023-02-14
		16	Cytotoxicity	sterile insulin syringe for single use YY/T 0497-2018 8		2023-02-14
		17	Delayed-type Hypersensitivity	sterile insulin syringe for single use YY/T 0497-2018 8		2023-02-14
		18	Intradermal reaction	sterile insulin syringe for single use YY/T 0497-2018 8		2023-02-14
		19	Hemolysis	sterile insulin syringe for single use YY/T 0497-2018 8		2023-02-14
		20	Acute Systemic Toxic	sterile insulin syringe for single use YY/T 0497-2018 8		2023-02-14
27	Sterile dental injection needles for single use	1	All Parameters	Sterile dental injection needles for single use YY//T 0587-2018		2023-02-14
		2	color batch	Sterile dental injection needles for single use YY//T 0587-2018 6.1		2023-02-14
		3	Connecting fastness	Sterile dental injection needles for single use YY//T 0587-2018 6.2		2023-02-14
		4	Pinhole smooth general characteristic	Sterile dental injection needles for single use YY//T 0587-2018 6.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Appearance	Sterile dental injection needles for single use YY//T 0587-2018 6.4		2023-02-14
		6	The length of the needle	Sterile dental injection needles for single use YY//T 0587-2018 6.5.1		2023-02-14
		7	The length of end-to-end of the needle	Sterile dental injection needles for single use YY//T 0587-2018 6.5.2		2023-02-14
		8	The needle diameter	Sterile dental injection needles for single use YY//T 0587-2018 6.5.3		2023-02-14
		9	The needle features	Sterile dental injection needles for single use YY//T 0587-2018 6.5.4		2023-02-14
		10	Pinpoint	Sterile dental injection needles for single use YY//T 0587-2018 6.6		2023-02-14
		11	Needle bed	Sterile dental injection needles for single use YY//T 0587-2018 6.7		2023-02-14
		12	pH	Sterile dental injection needles for single use YY//T 0587-2018 7.2		2023-02-14
		13	Extraction metal content	Sterile dental injection needles for single use YY//T 0587-2018 7.3		2023-02-14
		14	General Rules	Sterile dental injection needles for single use YY//T 0587-2018 8.1		2023-02-14
		15	Sterility test	Sterile dental injection needles for single use YY//T 0587-2018 8.2		2023-02-14
		16	Bacterial endotoxins test	Sterile dental injection needles for single use YY//T 0587-2018 8.3		2023-02-14
28	A.V.fistula needle sets for single use	1	Part Parameters	A.V.fistula needle sets for single use YY/T 0328-2015		2023-02-14
		2	Particle Pollution	A.V.fistula needle sets for single use YY/T 0328-2015 5.1		2023-02-14
		3	Sealing	A.V.fistula needle sets for single use YY/T 0328-2015 5.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Link Strength	A.V.fistula needle sets for single use YY/T 0328-2015 5.3		2023-02-14
		5	Flow	A.V.fistula needle sets for single use YY/T 0328-2015 5.4		2023-02-14
		6	Hosepipe	A.V.fistula needle sets for single use YY/T 0328-2015 5.5		2023-02-14
		7	Puncture Needle	A.V.fistula needle sets for single use YY/T 0328-2015 5.6		2023-02-14
		8	Suspend Stream Clamp	A.V.fistula needle sets for single use YY/T 0328-2015 5.7		2023-02-14
		9	Inner Cone Splice	A.V.fistula needle sets for single use YY/T 0328-2015 5.8		2023-02-14
		10	Protective Jacket	A.V.fistula needle sets for single use YY/T 0328-2015 5.9		2023-02-14
		11	Prevent Needling Protector	A.V.fistula needle sets for single use YY/T 0328-2015 5.10		2023-02-14
		12	Revivification Matter	A.V.fistula needle sets for single use YY/T 0328-2015 6.2		2023-02-14
		13	Metal Ion	A.V.fistula needle sets for single use YY/T 0328-2015 6.3		2023-02-14
		14	PH Value	A.V.fistula needle sets for single use YY/T 0328-2015 6.4		2023-02-14
		15	Residue of Evaporation	A.V.fistula needle sets for single use YY/T 0328-2015 6.5		2023-02-14
		16	Ultraviolet Absorbance	A.V.fistula needle sets for single use YY/T 0328-2015 6.6		2023-02-14
		17	Residual Quantity of Oxirane	A.V.fistula needle sets for single use YY/T 0328-2015 6.7		2023-02-14
		18	Sterility	A.V.fistula needle sets for single use YY/T 0328-2015 7.2		2023-02-14
		19	Bacterial endotoxins	A.V.fistula needle sets for single use YY/T 0328-2015 7.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		20	Hemolysis	A.V.fistula needle sets for single use YY/T 0328-2015 7.1		2023-02-14
		21	Sensitization	A.V.fistula needle sets for single use YY/T 0328-2015 7.1		2023-02-14
		22	Acute Systemic Toxic	A.V.fistula needle sets for single use YY/T 0328-2015 7.1		2023-02-14
		23	Intracutaneous Reactivity	A.V.fistula needle sets for single use YY/T 0328-2015 7.1		2023-02-14
29	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment	1	All Parameters	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 1:General requirement GB/T 1962.1-2015		2023-02-14
		2	size	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 1:General requirement GB/T 1962.1-2015 4.1		2023-02-14
		3	weeping	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 1:General requirement GB/T 1962.1-2015 4.2		2023-02-14
		4	air leakage	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 1:General requirement GB/T 1962.1-2015 4.3		2023-02-14
		5	separating force	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 1:General requirement GB/T 1962.1-2015 4.4		2023-02-14
		6	stress cracking	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 1:General requirement GB/T 1962.1-2015 4.5		2023-02-14
30	Conical fittings with a 6%（Luer）taper for	1	All Parameters	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 2:Lock fittings GB/T 1962.2-2001		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	syringes,needles and certain other medical equipment	2	size	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 2:Lock fittings GB/T 1962.2-2001 4.1		2023-02-14
		3	divulge	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 2:Lock fittings GB/T 1962.2-2001 4.2		2023-02-14
		4	separating force	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 2:Lock fittings GB/T 1962.2-2001 4.3		2023-02-14
		5	torque	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 2:Lock fittings GB/T 1962.2-2001 4.4		2023-02-14
		6	Ease of assembly	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 2:Lock fittings GB/T 1962.2-2001 4.5		2023-02-14
		7	overload resistance	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 2:Lock fittings GB/T 1962.2-2001 4.6		2023-02-14
		8	stress cracking	Conical fittings with a 6%（Luer）taper for syringes,needles and certain other medical equipment-Part 2:Lock fittings GB/T 1962.2-2001 4.7		2023-02-14
31	infusion,transfusion,injection equipments	1	part Parameters	Test methods for infusion,transfusion,injection equipments for medical use-Part 1:Chemical analysis methods GB/T 14233.1-2008	non for colorimetry and atomic fluorescence method or heavy metal	2023-02-14
		2	Turbidity and colour	Test methods for infusion,transfusion,injection equipments for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				medical use-Part 1:Chemical analysis methods GB/T 14233.1-2008 5.1		
		3	Revivification Matter	Test methods for infusion,transfusion,injection equipments for medical use-Part 1:Chemical analysis methods GB/T 14233.1-2008 5.2		2023-02-14
		4	chloride	Test methods for infusion,transfusion,injection equipments for medical use-Part 1:Chemical analysis methods GB/T 14233.1-2008 5.3		2023-02-14
		5	PH Value	Test methods for infusion,transfusion,injection equipments for medical use-Part 1:Chemical analysis methods GB/T 14233.1-2008 5.4		2023-02-14
		6	Residue of Evaporation	Test methods for infusion,transfusion,injection equipments for medical use-Part 1:Chemical analysis methods GB/T 14233.1-2008 5.5		2023-02-14
		7	heavy metal	Test methods for infusion,transfusion,injection equipments for medical use-Part 1:Chemical analysis methods GB/T 14233.1-2008 5.6		2023-02-14
		8	Ultraviolet Absorbance	Test methods for infusion,transfusion,injection equipments for medical use-Part 1:Chemical analysis methods GB/T 14233.1-2008 5.7		2023-02-14
		9	ammonium	Test methods for infusion,transfusion,injection equipments for medical use-Part 1:Chemical analysis methods GB/T 14233.1-2008 5.8		2023-02-14
		10	heavy metal element	Test methods for infusion,transfusion,injection equipments for medical use-Part 1:Chemical analysis methods GB/T 14233.1-2008 5.9、6、7		2023-02-14
		11	residue on ignition	Test methods for infusion,transfusion,injection equipments for medical use-Part 1:Chemical analysis methods GB/T 14233.1-2008 8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Residual Quantity of Oxirane	Test methods for infusion,transfusion,injection equipments for medical use-Part 1:Chemical analysis methods GB/T 14233.1-2008 9		2023-02-14
32	Surgical drapes,gowns and clean air suits for patients,clinical staff and equipment	1	All Parameters	Surgical drapes,gowns and clean air suits for patients,clinical staff and equipment-Part 3:Test methods YY/T 0506.2-2016		2023-02-14
		2	Cleanliness and microorganism	Surgical drapes,gowns and clean air suits for patients,clinical staff and equipment-Part 3:Test methods YY/T 0506.2-2016		2023-02-14
		3	Water permeability resistance	Surgical drapes,gowns and clean air suits for patients,clinical staff and equipment-Part 2:Test methods YY/T 0506.2-2016		2023-02-14
		4	Bursting Strength	Surgical drapes,gowns and clean air suits for patients,clinical staff and equipment-Part 2:Test methods YY/T 0506.2-2016		2023-02-14
		5	tensile strength	Surgical drapes,gowns and clean air suits for patients,clinical staff and equipment-Part 2:Test methods YY/T 0506.2-2016		2023-02-14
		6	Falling Catkins	Surgical drapes,gowns and clean air suits for patients,clinical staff and equipment-Part 2:Test methods YY/T 0506.2-2016		2023-02-14
		7	Cleanliness-particulate matter	Surgical drapes,gowns and clean air suits for patients,clinical staff and equipment-Part 2:Test methods YY/T 0506.2-2016		2023-02-14
		8	Resistance to dry microbial penetration	Surgical drapes,gowns and clean air suits for patients,clinical staff and equipment-Part 2:Test methods YY/T 0506.2-2016		2023-02-14
		9	Penetrating resistance wet microorganisms	Surgical drapes,gowns and clean air suits for patients,clinical staff and equipment-Part 3:Test methods YY/T 0506.2-2016		2023-02-14
33	Sterile hypodermic needles for single use	1	PartParameters	Sterile hypodermic needles for single use GB 15811-2016		2023-02-14
		2	clean	Sterile hypodermic needles for single use GB 15811-2016 6.1		2023-02-14
		3	color lable	Sterile hypodermic needles for single use GB 15811-2016 6.2		2023-02-14
		4	straight	Sterile hypodermic needles for single use GB 15811-2016 6.3		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Connectivity	Sterile hypodermic needles for single use GB 15811-2016 6.4		2023-02-14
		6	smooth	Sterile hypodermic needles for single use GB 15811-2016 6.5		2023-02-14
		7	Compatibility of needle base and sheath	Sterile hypodermic needles for single use GB 15811-2016 6.6		2023-02-14
		8	pinpoint	Sterile hypodermic needles for single use GB 15811-2016 6.7		2023-02-14
		9	Needle.	Sterile hypodermic needles for single use GB 15811-2016 6.8		2023-02-14
		10	Needle Pedestal of Entry Needle	Sterile hypodermic needles for single use GB 15811-2016 6.9		2023-02-14
		11	PH Value	Sterile hypodermic needles for single use GB 15811-2016 7.2		2023-02-14
		12	Total heavy metal content	Sterile hypodermic needles for single use GB 15811-2016 7.3		2023-02-14
		13	sterile	Sterile hypodermic syringes for single use GB 15811-2016 8.2		2023-02-14
		14	Bacterial endotoxin	Sterile hypodermic syringes for single use GB 15811-2016 8.3		2023-02-14
		15	Hemolysis	sterile hypodermic needles for single use GB 15811-2016 8.4		2023-02-14
		16	Sensitization	sterile hypodermic needles for single use GB 15811-2016 8.5		2023-02-14
		17	Intracutaneous Reactivity	sterile hypodermic needles for single use GB 15811-2016 8.5		2023-02-14
		18	Cytotoxicity	sterile hypodermic needles for single use GB 15811-2016 8.5		2023-02-14
		19	Acute Systemic Toxic	sterile hypodermic needles for single use GB 15811-2016 8.5		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
34	Medical instrument of stainless steel	1	All Parameters	Medical instrument of stainless steel-Test method of corrosion resistance YY/T 0149-2006		2023-02-14
		2	Boiling water test method	Medical instrument of stainless steel-Test method of corrosion resistance YY/T 0149-2006 5		2023-02-14
		3	Sodium Chloride Solution test method	Medical instrument of stainless steel-Test method of corrosion resistance YY/T 0149-2006 6		2023-02-14
		4	Citric acid solution test method	Medical instrument of stainless steel-Test method of corrosion resistance YY/T 0149-2006 7		2023-02-14
		5	Copper sulphate test method	Medical instrument of stainless steel-Test method of corrosion resistance YY/T 0149-2006 8		2023-02-14
		6	Steam pressure test method	Medical instrument of stainless steel-Test method of corrosion resistance YY/T 0149-2006 9		2023-02-14
		7	Heating test method	Medical instrument of stainless steel-Test method of corrosion resistance YY/T 0149-2006 10		2023-02-14
35	Stainless steel needle tubing for manufacture of medical devices	1	All Parameters	Stainless steel needle tubing for manufacture of medical devices GB/T 18457-2015		2023-02-14
		2	Dimensions	Stainless steel needle tubing for manufacture of medical devices GB/T 18457-2015 4		2023-02-14
		3	Specification label	Stainless steel needle tubing for manufacture of medical devices GB/T 18457-2015 5		2023-02-14
		4	Surface	Stainless steel needle tubing for manufacture of medical devices GB/T 18457-2015 6		2023-02-14
		5	cleanliness	Stainless steel needle tubing for manufacture of medical devices GB/T 18457-2015 7		2023-02-14
		6	PH Value	Stainless steel needle tubing for manufacture of medical devices GB/T 18457-2015 8		2023-02-14
		7	Rigidity	Stainless steel needle tubing for manufacture of medical devices GB/T 18457-2015 9		2023-02-14
		8	Tenacity	Stainless steel needle tubing for manufacture of medical devices GB/T 18457-2015 10		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	corrosion resistance	Stainless steel needle tubing for manufacture of medical devices GB/T 18457-2015 11		2023-02-14
36	Hot compress spirit	1	All Parameters	Hot compress sticker（bag） YY 0060-2018		2023-02-14
		2	apparence	Hot compress sticker（bag） YY 0060-2018 5.2		2023-02-14
		3	Tightness of outer package	Hot compress sticker（bag） YY 0060-2018 5.3		2023-02-14
		4	Internal bag anti drop	Hot compress sticker（bag） YY 0060-2018 5.4		2023-02-14
		5	The intensity of inside the bag	Hot compress sticker（bag） YY 0060-2018 5.5.1		2023-02-14
		6	Outer bag strengh	Hot compress sticker（bag） YY 0060-2018 5.5.2		2023-02-14
		7	Temperature characteristic	Hot compress sticker（bag） YY 0060-2018 5.8		2023-02-14
		8	Measure	Hot compress sticker（bag） YY 0060-2018 5.1		2023-02-14
		9	Air tightness of outer bag material	Hot compress sticker（bag） YY 0060-2018 5.6		2023-02-14
		10	Paste performance	Hot compress sticker（bag） YY 0060-2018 5.7		2023-02-14
		11	Temperature characteristic of products with expiration date and near expiration date	Hot compress sticker（bag） YY 0060-2018 5.10		2023-02-14
37	Textile	1	All Parameters	Textiles-Testing and evaluation for water resistance-Hydrostatic pressure method GB/T 4744-2013		2023-02-14
		2	Testing and evaluation for water	Textiles-Testing and evaluation for water resistance-Hydrostatic pressure method GB/T 4744-2013		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	water-vapour	Textiles-Test method for water-vapour transmission of fabrics-Part 1:Desiccant method GB/T 12704.1-2009		2023-02-14
		4	evaluation for water	Textiles-Testing and evaluation for water resistance-Spray test methed GB/T 4745-2012		2023-02-14
		5	Tensile properties of fabrics	Textiles-Tensile properties of fabrics-Part1:Determination of maximum force and elongation at maximum force using the strip method GB/T 3923.1-2013		2023-02-14
		6	electrostatic properties	Textile-Evaluation for electrostatic properties-Part 3:Electric charge GB/T 12703.3-2009		2023-02-14
		7	Burning behaviour	Textiles-Burning behaviour-Vertical method GB/T 5455-2014		2023-02-14
38	Sterile rectal catheters for single use	1	All Parameters	Sterile rectal catheters for single use EN 12439:1998		2023-02-14
		2	profile	Sterile rectal catheters for single use EN 12439:1998 4.1		2023-02-14
		3	size and marking	Sterile rectal catheters for single use EN 12439:1998 4.2		2023-02-14
		4	bending resitance	Sterile rectal catheters for single use EN 12439:1998 4.4		2023-02-14
		5	appearance	Sterile rectal catheters for single use EN 12439:1998 4.5		2023-02-14
		6	scaling performace	Sterile rectal catheters for single use EN 12439:1998 4.6		2023-02-14
		7	reduced diameter	Sterile rectal catheters for single use EN 12439:1998 4.7		2023-02-14
		8	air leak	Sterile rectal catheters for single use EN 12439:1998 4.8		2023-02-14
		9	sterilization	Sterile rectal catheters for single use EN 12439:1998 4.9		2023-02-14
		10	biocompatibility	Sterile rectal catheters for single use EN 12439:1998 4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
39	Peritoneal dialysis catheters	1	All Parameters	Peritoneal dialysis catheters YY/T 0030-2004		2023-02-14
		2	general requirements	Peritoneal dialysis catheters YY/T 0030-2004 4		2023-02-14
		3	structure	Peritoneal dialysis catheters YY/T 0030-2004 5.1		2023-02-14
		4	appearance	Peritoneal dialysis catheters YY/T 0030-2004 5.2		2023-02-14
		5	size	Peritoneal dialysis catheters YY/T 0030-2004 5.3		2023-02-14
		6	flow	Peritoneal dialysis catheters YY/T 0030-2004 5.4		2023-02-14
		7	bending resitance	Peritoneal dialysis catheters YY/T 0030-2004 5.5		2023-02-14
		8	connection firmness	Peritoneal dialysis catheters YY/T 0030-2004 5.6		2023-02-14
		9	no leakage	Peritoneal dialysis catheters YY/T 0030-2004 5.7		2023-02-14
		10	Ray detectability	Peritoneal dialysis catheters YY/T 0030-2004 5.8		2023-02-14
		11	sterile	Peritoneal dialysis catheters YY/T 0030-2004 5.9		2023-02-14
40	Intravascular catheters-Sterile and single-use catheters	1	All Parameters	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013		2023-02-14
		2	profile 1	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 4.1		2023-02-14
		3	Ray detectability	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 4.2		2023-02-14
		4	biocompatibility	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 4.3		2023-02-14
		5	the outer surface	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	corrosion resistance	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 4.5		2023-02-14
		7	peak tension	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 4.6		2023-02-14
		8	no leakage	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 4.7		2023-02-14
		9	hub	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 4.8		2023-02-14
		10	flow	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 4.9		2023-02-14
		11	power injection	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 4.10		2023-02-14
		12	side hole	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 4.11		2023-02-14
		13	distal end	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 4.12		2023-02-14
		14	profile 2	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 5.1		2023-02-14
		15	outside diameter	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 5.2		2023-02-14
		16	Nominal effective length	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements ISO 10555-1:2013 5.3		2023-02-14
		17	profile	Intravascular catheters-Sterile and single-use catheters-Part 3:Central venous catheters ISO 10555-3:2013 4.1		2023-02-14
		18	distance indicator	Intravascular catheters-Sterile and single-use catheters-Part 3:Central venous catheters ISO 10555-3:2013 4.2		2023-02-14
		19	lumen identification	Intravascular catheters-Sterile and single-use catheters-Part 3:Central venous catheters ISO 10555-3:2013 4.3		2023-02-14
		20	peak tension	Intravascular catheters-Sterile and single-use catheters-Part 3:Central venous catheters ISO 10555-3:2013 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		21	information provided by the manufacturer	Intravascular catheters-Sterile and single-use catheters-Part 3:Central venous catheters ISO 10555-3:2013 4.5		2023-02-14
		22	profile	Intravascular catheters-Sterile and single-use catheters-Part 4: Balloon dilatation caterers ISO 10555-4:2013 4.1		2023-02-14
		23	Ray detectability	Intravascular catheters-Sterile and single-use catheters-Part 4: Balloon dilatation caterers ISO 10555-4:2013 4.2		2023-02-14
		24	nominal size identification	Intravascular catheters-Sterile and single-use catheters-Part 4: Balloon dilatation caterers ISO 10555-4:2013 4.3		2023-02-14
		25	physical requirements	Intravascular catheters-Sterile and single-use catheters-Part 4: Balloon dilatation caterers ISO 10555-4:2013 4.4		2023-02-14
		26	rated burst pressure of balloon	Intravascular catheters-Sterile and single-use catheters-Part 4: Balloon dilatation caterers ISO 10555-4:2013 4.4.1		2023-02-14
		27	balloon fatigue;no leakage and damage when blowing up	Intravascular catheters-Sterile and single-use catheters-Part 4: Balloon dilatation caterers ISO 10555-4:2013 4.4.2		2023-02-14
		28	balloon pressure unloading time	Intravascular catheters-Sterile and single-use catheters-Part 4: Balloon dilatation caterers ISO 10555-4:2013 4.4.3		2023-02-14
		29	relationship between balloon diameter and filling pressure	Intravascular catheters-Sterile and single-use catheters-Part 4: Balloon dilatation caterers ISO 10555-4:2013 4.4.4		2023-02-14
		30	information provided by the manufacturer	Intravascular catheters-Sterile and single-use catheters-Part 4: Balloon dilatation caterers ISO 10555-4:2013 4.5		2023-02-14
		31	profile	Intravascular catheters-Sterile and single-use catheters-Part 5: Over-needle peripheral catheters ISO 10555:5-2013 4.1		2023-02-14
		32	multicavity catheter	Intravascular catheters-Sterile and single-use catheters-Part 5: Over-needle peripheral catheters ISO 10555:5-2013 4.2		2023-02-14
		33	physical requirements	Intravascular catheters-Sterile and single-use catheters-Part 5: Over-needle peripheral catheters ISO 10555:5-2013 4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		34	color code	Intravascular catheters-Sterile and single-use catheters-Part 5: Over-needle peripheral catheters ISO 10555:5-2013 4.3.1		2023-02-14
		35	catheter unit	Intravascular catheters-Sterile and single-use catheters-Part 5: Over-needle peripheral catheters ISO 10555:5-2013 4.3.2		2023-02-14
		36	needle	Intravascular catheters-Sterile and single-use catheters-Part 5: Over-needle peripheral catheters ISO 10555:5-2013 4.3.3		2023-02-14
		37	material	Intravascular catheters-Sterile and single-use catheters-Part 5: Over-needle peripheral catheters ISO 10555:5-2013 4.3.3.1		2023-02-14
		38	needlepoint	Intravascular catheters-Sterile and single-use catheters-Part 5: Over-needle peripheral catheters ISO 10555:5-2013 4.3.3.2		2023-02-14
		39	needle hub	Intravascular catheters-Sterile and single-use catheters-Part 5: Over-needle peripheral catheters ISO 10555:5-2013 4.3.3.3		2023-02-14
		40	connection strength between needle tube and needle hub	Intravascular catheters-Sterile and single-use catheters-Part 5: Over-needle peripheral catheters ISO 10555:5-2013 4.3.3.4		2023-02-14
		41	exhaust connection	Intravascular catheters-Sterile and single-use catheters-Part 5: Over-needle peripheral catheters ISO 10555:5-2013 4.3.4		2023-02-14
		42	information provided by the manufacturer	Intravascular catheters-Sterile and single-use catheters-Part 5: Over-needle peripheral catheters ISO 10555:5-2013 4.4		2023-02-14
41	Single-use high-pressure angiographic syringes and accessories	1	All Parameters	Single-use high-pressure angiographic syringes and accessories YY/T 0614-2017		2023-02-14
		2	"general requirements "	Single-use high-pressure angiographic syringes and accessories YY/T 0614-2017 6.1		2023-02-14
		3	Additional requirements for contrast syringes	Single-use high-pressure angiographic syringes and accessories YY/T 0614-2017 6.2		2023-02-14
		4	Additional requirements for inhalers	Single-use high-pressure angiographic syringes and accessories YY/T 0614-2017 6.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Additional requirements for connecting pipelines	Single-use high-pressure angiographic syringes and accessories YY/T 0614-2017 6.4		2023-02-14
		6	Chemical requirement	Single-use high-pressure angiographic syringes and accessories YY/T 0614-2017 7		2023-02-14
		7	biological requirements	Single-use high-pressure angiographic syringes and accessories YY/T 0614-2017 8		2023-02-14
42	Surgical drapes, growns and clean air suits for patients, clincial staff and equipment	1	performance requirements	Surgical drapes, growns and clean air suits for patients, clincial staff and equipment-Part 2:Performance requirements and test methods EN 13795:2011 4		2023-02-14
		2	linting in the dry state	Surgical drapes, growns and clean air suits for patients, clincial staff and equipment-Part 4:Test method for linting in the dry state ISO 9073-10:2003 4		2023-02-14
43	Single-use maternity kits, for spontaneous labor	1	All Parameters	Single-use maternity kits, for spontaneous labor YY/T 0720-2009		2023-02-14
		2	production requirements	Single-use maternity kits, for spontaneous labor YY/T 0720-2009 4.1		2023-02-14
		3	sterilization requirements	Single-use maternity kits, for spontaneous labor YY/T 0720-2009 4.2		2023-02-14
		4	sterility guarantee	Single-use maternity kits, for spontaneous labor YY/T 0720-2009 4.2.1		2023-02-14
		5	residual ethylene oxide	Single-use maternity kits, for spontaneous labor YY/T 0720-2009 4.2.2		2023-02-14
		6	biological requirements	Single-use maternity kits, for spontaneous labor YY/T 0720-2009 4.3		2023-02-14
44	Accessory devices for sterile single-use	1	All Parameters	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014		2023-02-14
		2	sterilization	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	intravascular catheters	3	biocompatibility	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 4.2		2023-02-14
		4	surface	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 4.3		2023-02-14
		5	corrosion resistance	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 4.4		2023-02-14
		6	ray detectability	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 4.5		2023-02-14
		7	additional requirements for introducer needle	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 5		2023-02-14
		8	profile	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 5.1		2023-02-14
		9	specification mark	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 5.2		2023-02-14
		10	needlepoint	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 5.3		2023-02-14
		11	hub	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 5.4		2023-02-14
		12	taper joint	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 5.4.1		2023-02-14
		13	connection strength between needle tube and needle hub	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 5.4.2		2023-02-14
		14	additional requirements for guide casing	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 6		2023-02-14
		15	profile	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 6.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	headend	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 6.2		2023-02-14
		17	peak tension	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 6.3		2023-02-14
		18	hub	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 6.4		2023-02-14
		19	specification mark	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 6.5		2023-02-14
		20	information provided by the manufacturer	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 6.6		2023-02-14
		21	additional requirements for catheter sheaths	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 7		2023-02-14
		22	profile	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 7.1		2023-02-14
		23	specification mark	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 7.2		2023-02-14
		24	no leakage of catheter sheath	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 7.3		2023-02-14
		25	no leakage from the hemostatic	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 7.4		2023-02-14
		26	hub	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 7.5		2023-02-14
		27	peak tension	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 7.6		2023-02-14
		28	additional requirements for guide wire	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		29	profile	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 8.1		2023-02-14
		30	specification mark	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 8.2		2023-02-14
		31	safety wire	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 8.3		2023-02-14
		32	rupture test	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 8.4		2023-02-14
		33	bending test	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 8.5		2023-02-14
		34	peak guide wire tension	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 8.6		2023-02-14
		35	information provided by the manufacturer	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 8.7		2023-02-14
		36	additional requirements for dilator	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 9		2023-02-14
		37	profile	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 9.1		2023-02-14
		38	specification mark	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 9.2		2023-02-14
		39	hub	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 9.3		2023-02-14
		40	profile	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 9.3.1		2023-02-14
		41	taper joint	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 9.3.2		2023-02-14
		42	connection strength between hub and	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 9.3.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			dilator			
		43	additional requirements for complete sets containing the devices specified in this section	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 10		2023-02-14
		44	connection strength test of neelde tube and needle hub of puncture needle	Accessory devices for sterile single-use intravascular catheters-Part 1:Introducers ISO 11070:2014 11		2023-02-14
		45	profile	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters ISO 14972:1998 4.1		2023-02-14
		46	biocompatibility	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters ISO 14972:1998 4.2		2023-02-14
		47	surface	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters ISO 14972:1998 4.3		2023-02-14
		48	breaking force	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters ISO 14972:1998 4.4		2023-02-14
		49	Ruhr taper joint	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters ISO 14972:1998 4.5		2023-02-14
		50	outside diameter	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters ISO 14972:1998 4.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		51	effective length	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters ISO 14972:1998 4.7		2023-02-14
		52	color code	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters ISO 14972:1998 4.8		2023-02-14
		53	ray detectability	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters ISO 14972:1998 4.9		2023-02-14
		54	information provided by the manufacturer	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters ISO 14972:1998 4.10		2023-02-14
		55	pointer pressure gauge	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 4		2023-02-14
		56	unit of measurement	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 4.1		2023-02-14
		57	zero point	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 4.2		2023-02-14
		58	index	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 4.3		2023-02-14
		59	negative pressure indication	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 4.4		2023-02-14
		60	basic error	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 4.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		61	return difference	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 4.6		2023-02-14
		62	stability of pointer deflection	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 4.7		2023-02-14
		63	tap displacement	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 4.8		2023-02-14
		64	digital pressure gauge	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 5		2023-02-14
		65	unit of measurement	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 5.1		2023-02-14
		66	zero drift	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 5.2		2023-02-14
		67	display resolution	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 5.3		2023-02-14
		68	negative pressure indication	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 5.4		2023-02-14
		69	basic error	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 5.5		2023-02-14
		70	repeatability	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 5.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		71	return difference	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 5.7		2023-02-14
		72	stability	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 5.8		2023-02-14
		73	indicating value fluctuation	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 5.9		2023-02-14
		74	safety requirements	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 5.10		2023-02-14
		75	performance of charging device	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 6		2023-02-14
		76	positive pressure sealing	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 6.1		2023-02-14
		77	stress relief	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 6.2		2023-02-14
		78	negative pressure sealing	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 6.3		2023-02-14
		79	stress decay	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 6.4		2023-02-14
		80	reliability of release device	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 6.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		81	trun around	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 6.6		2023-02-14
		82	connectot	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 6.7		2023-02-14
		83	bubble observation and elimination	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 6.8		2023-02-14
		84	extension tube size	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 6.9		2023-02-14
		85	capacity scale	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 6.10		2023-02-14
		86	capacity tolerance	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 6.11		2023-02-14
		87	chemical properties	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 7		2023-02-14
		88	biological properties	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 8		2023-02-14
		89	sterile	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 8.1		2023-02-14
		90	biocompatibility	Accessory devices for sterile single-use intravascular catheters-Part 3:Inflation devices for balloon of balloon dilatation catheters YY/T 0450.3-2016 8.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
45	low resistance syringe for single use	1	All Parameters	low resistance syringe for single use YY/T 0909-2013		2023-02-14
		2	appearance	low resistance syringe for single use YY/T 0909-2013 5.1		2023-02-14
		3	syringe ruler	low resistance syringe for single use YY/T 0909-2013 5.2		2023-02-14
		4	the total length of the scale of the nominal capacity line	low resistance syringe for single use YY/T 0909-2013 5.3		2023-02-14
		5	scale capacity line	low resistance syringe for single use YY/T 0909-2013 5.4		2023-02-14
		6	zero line ruler position	low resistance syringe for single use YY/T 0909-2013 5.5		2023-02-14
		7	measurement figures on the ruler	low resistance syringe for single use YY/T 0909-2013 5.6		2023-02-14
		8	jacket	low resistance syringe for single use YY/T 0909-2013 5.7		2023-02-14
		9	maximum usable capacity	low resistance syringe for single use YY/T 0909-2013 5.7.1		2023-02-14
		10	crimping	low resistance syringe for single use YY/T 0909-2013 5.7.2		2023-02-14
		11	piston/core rod assembly	low resistance syringe for single use YY/T 0909-2013 5.8		2023-02-14
		12	design	low resistance syringe for single use YY/T 0909-2013		2023-02-14
		13	cooperate of piston and jacket	low resistance syringe for single use YY/T 0909-2013 5.8.2		2023-02-14
		14	baseline	low resistance syringe for single use YY/T 0909-2013 5.8.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	cone	low resistance syringe for single use YY/T 0909-2013 5.9		2023-02-14
		16	taper joint	low resistance syringe for single use YY/T 0909-2013 5.9.1		2023-02-14
		17	cone hole diameter	low resistance syringe for single use YY/T 0909-2013 5.9.2		2023-02-14
		18	cone position	low resistance syringe for single use YY/T 0909-2013 5.9.3		2023-02-14
		19	physical properties	low resistance syringe for single use YY/T 0909-2013 5.10		2023-02-14
		20	sliding properties	low resistance syringe for single use YY/T 0909-2013 5.10.1		2023-02-14
		21	body tightness	low resistance syringe for single use YY/T 0909-2013 5.10.2		2023-02-14
		22	residual capacity	low resistance syringe for single use YY/T 0909-2013 5.10.3		2023-02-14
		23	capacity tolerance	low resistance syringe for single use YY/T 0909-2013 5.10.4		2023-02-14
		24	chemical properties	low resistance syringe for single use YY/T 0909-2013 5.11		2023-02-14
		25	extractable metal content	low resistance syringe for single use YY/T 0909-2013 5.11.1		2023-02-14
		26	pH	low resistance syringe for single use YY/T 0909-2013 5.11.2		2023-02-14
		27	easy oxide(reducing substance)	low resistance syringe for single use YY/T 0909-2013 5.11.3		2023-02-14
		28	biological properties	low resistance syringe for single use YY/T 0909-2013 5.12		2023-02-14
		29	profile	low resistance syringe for single use YY/T 0909-2013 5.12.1		2023-02-14
		30	sterile	low resistance syringe for single use YY/T 0909-2013 5.12.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		31	bacterial endotoxin	low resistance syringe for single use YY/T 0909-2013 5.12.3		2023-02-14
46	Disposable abdominal trocars	1	All Parameters	Disposable abdominal trocars YY/T 1710-2020		2023-02-14
		2	Appearance	Disposable abdominal trocars YY/T 1710-2020 4.1		2023-02-14
		3	Size	Disposable abdominal trocars YY/T 1710-2020 4.2		2023-02-14
		4	Surface roughness	Disposable abdominal trocars YY/T 1710-2020 4.3		2023-02-14
		5	Hardness	Disposable abdominal trocars YY/T 1710-2020 4.4		2023-02-14
		6	Flexibility	Disposable abdominal trocars YY/T 1710-2020 4.5		2023-02-14
		7	Cooperate with the performance	Disposable abdominal trocars YY/T 1710-2020 4.6		2023-02-14
		8	Connection firmness	Disposable abdominal trocars YY/T 1710-2020 4.7		2023-02-14
		9	Gas resistance and sealing performance	Disposable abdominal trocars YY/T 1710-2020 4.8		2023-02-14
		10	Gas injection valve interface	Disposable abdominal trocars YY/T 1710-2020 4.9		2023-02-14
		11	Puncture and plug performance	Disposable abdominal trocars YY/T 1710-2020 4.10		2023-02-14
		12	Corrosion resistance	Disposable abdominal trocars YY/T 1710-2020 4.11		2023-02-14
		13	Sterile	Disposable abdominal trocars YY/T 1710-2020 4.12		2023-02-14
		14	Ethylene oxide sterilization residuals	Disposable abdominal trocars YY/T 1710-2020 4.13		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Dissolved products of some polymer materials in contact with patients	Disposable abdominal trocars YY/T 1710-2020 4.14		2023-02-14
		16	Packaing identification and instructions	Disposable abdominal trocars YY/T 1710-2020 4.15		2023-02-14
47	Plastics collapsible containers for human blood and blood components	1	All Parameters	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013		2023-02-14
		2	dimensions and markings	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 4		2023-02-14
		3	air content	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 5.2		2023-02-14
		4	pressurized emptying	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 5.3		2023-02-14
		5	blood sample recognition	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 5.4		2023-02-14
		6	acquisition speed	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 5.5		2023-02-14
		7	blood collection tube and transfer tube	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 5.6		2023-02-14
		8	Blood sampling needle	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 5.7		2023-02-14
		9	blood transfusion socket	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 5.8		2023-02-14
		10	suspension	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 5.9		2023-02-14
		11	profile	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	sterilization	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.2.2		2023-02-14
		13	extreme	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.2.3		2023-02-14
		14	colour	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.2.4		2023-02-14
		15	thermal stability	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.2.5		2023-02-14
		16	water vapor leaks	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.2.6		2023-02-14
		17	anti-leakage	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.2.7		2023-02-14
		18	particulate pollution	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.2.8		2023-02-14
		19	burning residue	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.3.1		2023-02-14
		20	reducing substance	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.3.2		2023-02-14
		21	ammonium ion	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.3.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	chloride ion	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.3.2		2023-02-14
		23	metal	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.3.2		2023-02-14
		24	heavy metal	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.3.2		2023-02-14
		25	pH	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.3.2		2023-02-14
		26	evaporation residue	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.3.2		2023-02-14
		27	turbidity	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.3.2		2023-02-14
		28	colour 2	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.3.2		2023-02-14
		29	ultraviolet(UV) absorption	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.3.2		2023-02-14
		30	alcohol extract	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.3.2		2023-02-14
		31	profile	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		32	microbial impermeability	Plastics collapsible containers for human blood and blood components-Part 1:Conventional containers ISO 3826-1:2013 6.4.2		2023-02-14
In vitro diagnostic reagents						
In vitro diagnostic reagents						
1	In vitrodiagnostic reagent (kit) for clinical chemistry	1	All Parameters	In vitrodiagnostic reagent(kit)for clinical chemistry GB/T 26124-2011		2023-02-14
		2	appearance	In vitrodiagnostic reagent(kit)for clinical chemistry GB/T 26124-2011 5.1		2023-02-14
		3	net content	In vitrodiagnostic reagent(kit)for clinical chemistry GB/T 26124-2011 5.2		2023-02-14
		4	Reagent blank	In vitrodiagnostic reagent(kit)for clinical chemistry GB/T 26124-2011 5.3		2023-02-14
		5	analytical sensitivity	In vitrodiagnostic reagent(kit)for clinical chemistry GB/T 26124-2011 5.4		2023-02-14
		6	Linear range	In vitrodiagnostic reagent(kit)for clinical chemistry GB/T 26124-2011 5.5		2023-02-14
		7	precision of measurement	In vitrodiagnostic reagent(kit)for clinical chemistry GB/T 26124-2011 5.6		2023-02-14
		8	Accuracy	In vitrodiagnostic reagent(kit)for clinical chemistry GB/T 26124-2011 5.7		2023-02-14
		9	stability	In vitrodiagnostic reagent(kit)for clinical chemistry GB/T 26124-2011 5.8		2023-02-14
2	Detection reagent (kit) for enzyme-linked immunoabsorb	1	All Parameters	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010		2023-02-14
		2	appearance	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.1.1		2023-02-14
		3	Traceability	Detection reagent (kit) for enzyme-linked immunoabsorbent		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	ent assay (ELISA)			assay (ELISA) YY/T1183-2010 5.1.2		
		4	Accuracy	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.1.3		2023-02-14
		5	limit of detection	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.1.4		2023-02-14
		6	linearity of a measuring system	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.1.5		2023-02-14
		7	Repeatability	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.1.6		2023-02-14
		8	Inter coefficients of variation	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.1.7		2023-02-14
		9	stability	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.1.8		2023-02-14
		10	appearance	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.2.1		2023-02-14
		11	coincidence rate of negative reference product	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.2.2		2023-02-14
		12	coincidence rate of positive reference product	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.2.3		2023-02-14
		13	limit of detection	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.2.4		2023-02-14
		14	Repeatability	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.2.5		2023-02-14
		15	Inter coefficients of variation	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.2.6		2023-02-14
		16	stability	Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA) YY/T1183-2010 5.2.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
3	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay)	1	All Parameters	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay) YY/T 1164-2009		2023-02-14
		2	Physical properties	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay) YY/T 1164-2009 4.1		2023-02-14
		3	Appearance	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay) YY/T 1164-2009 4.1.1		2023-02-14
		4	Width	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay) YY/T 1164-2009 4.1.2		2023-02-14
		5	Moving velocity	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay) YY/T 1164-2009 4.1.3		2023-02-14
		6	Minimum detection limit	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay) YY/T 1164-2009 4.2		2023-02-14
		7	Specificity	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay) YY/T 1164-2009 4.3		2023-02-14
		8	Negative specificity	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay) YY/T 1164-2009 4.3.1		2023-02-14
		9	Positive specificity	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay) YY/T 1164-2009 4.3.2		2023-02-14
		10	Repeatability	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay) YY/T 1164-2009 4.4		2023-02-14
		11	Stabilization	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay) YY/T 1164-2009 4.5		2023-02-14
		12	Difference between batch	Human chorionic gonadotropin (HCG) test strip (Colloidal gold immunochromatographic assay) YY/T 1164-2009 4.6		2023-02-14
4	(Creatine kinase isoenzyme MB)(CK-MB) diagnostic kit(Colloid	1	All Parameters	(Creatine kinase isoenzyme MB)(CK-MB) diagnostic kit(Colloid gold method) YY/T 1220-2013		2023-02-14
		2	Physical properties	(Creatine kinase isoenzyme MB)(CK-MB) diagnostic kit(Colloid gold method) YY/T 1220-2013 4.1		2023-02-14
		3	Appearance	(Creatine kinase isoenzyme MB)(CK-MB) diagnostic kit(Colloid gold method) YY/T 1220-2013 4.1.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	gold method)	4	Membrane strip width	(Creatine kinase isoenzyme MB)(CK-MB) diagnostic kit(Colloid gold method) YY/T 1220-2013 4.1.2		2023-02-14
		5	Liquid moving velocity	(Creatine kinase isoenzyme MB)(CK-MB) diagnostic kit(Colloid gold method) YY/T 1220-2013 4.1.3		2023-02-14
		6	Accuracy	(Creatine kinase isoenzyme MB)(CK-MB) diagnostic kit(Colloid gold method) YY/T 1220-2013 4.2		2023-02-14
		7	Repeatability	(Creatine kinase isoenzyme MB)(CK-MB) diagnostic kit(Colloid gold method) YY/T 1220-2013 4.3		2023-02-14
		8	Analytical specificity	(Creatine kinase isoenzyme MB)(CK-MB) diagnostic kit(Colloid gold method) YY/T 1220-2013 4.4		2023-02-14
		9	Minimum detection limit	(Creatine kinase isoenzyme MB)(CK-MB) diagnostic kit(Colloid gold method) YY/T 1220-2013 4.5		2023-02-14
		10	Stabilization	(Creatine kinase isoenzyme MB)(CK-MB) diagnostic kit(Colloid gold method) YY/T 1220-2013 4.6		2023-02-14
5	Cardiac troponini(cTnI) diagnostic kit(Colloid gold method)	1	All Parameters	Cardiac troponini(cTnI) diagnostic kit(Colloid gold method) YY/T 1221-2013		2023-02-14
		2	Physical properties	Cardiac troponini(cTnI) diagnostic kit(Colloid gold method) YY/T 1221-2013 4.1		2023-02-14
		3	Appearance	Cardiac troponini(cTnI) diagnostic kit(Colloid gold method) YY/T 1221-2013 4.1.1		2023-02-14
		4	Membrane strip width	Cardiac troponini(cTnI) diagnostic kit(Colloid gold method) YY/T 1221-2013 4.1.2		2023-02-14
		5	Liquid moving velocity	Cardiac troponini(cTnI) diagnostic kit(Colloid gold method) YY/T 1221-2013 4.1.3		2023-02-14
		6	Accuracy	Cardiac troponini(cTnI) diagnostic kit(Colloid gold method) YY/T 1221-2013 4.2		2023-02-14
		7	Repeatability	Cardiac troponini(cTnI) diagnostic kit(Colloid gold method) YY/T 1221-2013 4.3		2023-02-14
		8	Analytical specificity	Cardiac troponini(cTnI) diagnostic kit(Colloid gold method) YY/T 1221-2013 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Minimum detection limit	Cardiac troponini(cTnI) diagnostic kit(Colloid gold method) YY/T 1221-2013 4.5		2023-02-14
		10	Stabilization	Cardiac troponini(cTnI) diagnostic kit(Colloid gold method) YY/T 1221-2013 4.6		2023-02-14
6	Urine dry chemistry analysis control material	1	All Parameters	Urine dry chemistry analysis control material YY/T 0501-2014		2023-02-14
		2	Appearance	Urine dry chemistry analysis control material YY/T 0501-2014 3.1		2023-02-14
		3	The load	Urine dry chemistry analysis control material YY/T 0501-2014 3.2		2023-02-14
		4	Nominal value setting	Urine dry chemistry analysis control material YY/T 0501-2014 3.3		2023-02-14
		5	Quality control material test value	Urine dry chemistry analysis control material YY/T 0501-2014 3.4		2023-02-14
		6	homogeneity	Urine dry chemistry analysis control material YY/T 0501-2014 3.5		2023-02-14
		7	Stabilization	Urine dry chemistry analysis control material YY/T 0501-2014 3.6		2023-02-14
		8	Post-dissolution stability	Urine dry chemistry analysis control material YY/T 0501-2014 3.6.1		2023-02-14
		9	Validity stability	Urine dry chemistry analysis control material YY/T 0501-2014 3.6.2		2023-02-14
7	Control materials for urine formed element analyzer	1	All Parameters	Control materials for urine formed element analyzer YY/T 1530-2017		2023-02-14
		2	character	Control materials for urine formed element analyzer YY/T 1530-2017 3.1		2023-02-14
		3	Loading quantity	Control materials for urine formed element analyzer YY/T 1530-2017 3.2		2023-02-14
		4	Trace to the source	Control materials for urine formed element analyzer YY/T 1530-2017 3.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Control the setting of the material range	Control materials for urine formed element analyzer YY/T 1530-2017 3.4		2023-02-14
		6	Controlled material range	Control materials for urine formed element analyzer YY/T 1530-2017 3.5		2023-02-14
		7	uniformity	Control materials for urine formed element analyzer YY/T 1530-2017 3.6		2023-02-14
		8	Uniformity in bottle	Control materials for urine formed element analyzer YY/T 1530-2017 3.6.1		2023-02-14
		9	Bottle to bottle uniformity	Control materials for urine formed element analyzer YY/T 1530-2017 3.6.2		2023-02-14
		10	Stabilization	Control materials for urine formed element analyzer YY/T 1530-2017 3.7		2023-02-14
		11	Stability after initial dissolution	Control materials for urine formed element analyzer YY/T 1530-2017 3.7.1		2023-02-14
		12	Validity stability	Control materials for urine formed element analyzer YY/T 1530-2017 3.7.2		2023-02-14
8	Thrombin time reagent (Kit)	1	All Parameters	Thrombin time reagent (Kit) YY/T 1156-2009		2023-02-14
		2	Appearance	Thrombin time reagent (Kit) YY/T 1156-2009 4.1		2023-02-14
		3	Normal plasma measurements	Thrombin time reagent (Kit) YY/T 1156-2009 4.2		2023-02-14
		4	Repeatability	Thrombin time reagent (Kit) YY/T 1156-2009 4.3		2023-02-14
		5	Difference between batch	Thrombin time reagent (Kit) YY/T 1156-2009 4.4		2023-02-14
		6	Stabilization	Thrombin time reagent (Kit) YY/T 1156-2009 4.5		2023-02-14
9	Actived partial thromboplastin time reagent	1	All Parameters	Actived partial thromboplastin time reagent (kit) YY/T 1157-2009		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	(kit)	2	Appearance	Actived partial thromboplastin time reagent (kit) YY/T 1157-2009 4.1		2023-02-14
		3	Normal plasma measurements	Actived partial thromboplastin time reagent (kit) YY/T 1157-2009 4.2		2023-02-14
		4	Repeatability	Actived partial thromboplastin time reagent (kit) YY/T 1157-2009 4.3		2023-02-14
		5	Difference between batch	Actived partial thromboplastin time reagent (kit) YY/T 1157-2009 4.4		2023-02-14
		6	Stabilization	Actived partial thromboplastin time reagent (kit) YY/T 1157-2009 4.5		2023-02-14
10	Prothrombin time reagent(Kit)	1	All Parameters	Prothrombin time reagent(Kit) YY/T 1158-2009		2023-02-14
		2	Appearance	Prothrombin time reagent(Kit) YY/T 1158-2009 4.1		2023-02-14
		3	Normal plasma measurements	Prothrombin time reagent(Kit) YY/T 1158-2009 4.2		2023-02-14
		4	The ISI value	Prothrombin time reagent(Kit) YY/T 1158-2009 4.3		2023-02-14
		5	Repeatability	Prothrombin time reagent(Kit) YY/T 1158-2009 4.4		2023-02-14
		6	Difference between batch	Prothrombin time reagent(Kit) YY/T 1158-2009 4.5		2023-02-14
		7	Stabilization	Prothrombin time reagent(Kit) YY/T 1158-2009 4.6		2023-02-14
11	Fibrinogen reagent (Kit)	1	All Parameters	Fibrinogen reagent (Kit) YY/T 1159-2009		2023-02-14
		2	Appearance	Fibrinogen reagent (Kit) YY/T 1159-2009 4.1		2023-02-14
		3	Accuracy	Fibrinogen reagent (Kit) YY/T 1159-2009 4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	linear	Fibrinogen reagent (Kit) YY/T 1159-2009 4.3		2023-02-14
		5	Repeatability	Fibrinogen reagent (Kit) YY/T 1159-2009 4.4		2023-02-14
		6	Difference between batch	Fibrinogen reagent (Kit) YY/T 1159-2009 4.5		2023-02-14
		7	Stabilization	Fibrinogen reagent (Kit) YY/T 1159-2009 4.6		2023-02-14
12	Quantitative detection reagent(kit) for tumor markers-Chemiluminescent immunoassay	1	All Parameters	Quantitative detection reagent(kit) for tumor markers-Chemiluminescent immunoassay YY/T 1175-2010		2023-02-14
		2	Appearance	Quantitative detection reagent(kit) for tumor markers-Chemiluminescent immunoassay YY/T 1175-2010 5.1		2023-02-14
		3	traceability	Quantitative detection reagent(kit) for tumor markers-Chemiluminescent immunoassay YY/T 1175-2010 5.2		2023-02-14
		4	Degree of accuracy	Quantitative detection reagent(kit) for tumor markers-Chemiluminescent immunoassay YY/T 1175-2010 5.3		2023-02-14
		5	Minimum detection limit	Quantitative detection reagent(kit) for tumor markers-Chemiluminescent immunoassay YY/T 1175-2010 5.4		2023-02-14
		6	linear	Quantitative detection reagent(kit) for tumor markers-Chemiluminescent immunoassay YY/T 1175-2010 5.5		2023-02-14
		7	Repeatability	Quantitative detection reagent(kit) for tumor markers-Chemiluminescent immunoassay YY/T 1175-2010 5.6		2023-02-14
		8	Difference between batch	Quantitative detection reagent(kit) for tumor markers-Chemiluminescent immunoassay YY/T 1175-2010 5.7		2023-02-14
		9	Stabilization	Quantitative detection reagent(kit) for tumor markers-Chemiluminescent immunoassay YY/T 1175-2010 5.8		2023-02-14
13	Follicle stimulating hormone(FSH) quantititive	1	All Parameters	Follicle stimulating hormone(FSH) quantititive immunoassay kit(chemiluminescent immunosassay) YY/T 1193-2011		2023-02-14
		2	Appearance	Follicle stimulating hormone(FSH) quantititive immunoassay kit(chemiluminescent immunosassay) YY/T 1193-2011 4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	immunoassay kit(chemiluminescent immunosassay)	3	traceability	Follicle stimulating hormone(FSH) quantititive immunoassay kit(chemiluminescent immunosassay) YY/T 1193-2011 4.2		2023-02-14
		4	Degree of accuracy	Follicle stimulating hormone(FSH) quantititive immunoassay kit(chemiluminescent immunosassay) YY/T 1193-2011 4.3		2023-02-14
		5	Minimum detection limit	Follicle stimulating hormone(FSH) quantititive immunoassay kit(chemiluminescent immunosassay) YY/T 1193-2011 4.4		2023-02-14
		6	Specificity	Follicle stimulating hormone(FSH) quantititive immunoassay kit(chemiluminescent immunosassay) YY/T 1193-2011 4.5		2023-02-14
		7	linear	Follicle stimulating hormone(FSH) quantititive immunoassay kit(chemiluminescent immunosassay) YY/T 1193-2011 4.6		2023-02-14
		8	Repeatability	Follicle stimulating hormone(FSH) quantititive immunoassay kit(chemiluminescent immunosassay) YY/T 1193-2011 4.7		2023-02-14
		9	Difference between batch	Follicle stimulating hormone(FSH) quantititive immunoassay kit(chemiluminescent immunosassay) YY/T 1193-2011 4.8		2023-02-14
		10	Stabilization	Follicle stimulating hormone(FSH) quantititive immunoassay kit(chemiluminescent immunosassay) YY/T 1193-2011 4.9		2023-02-14
14	Procalcitonin testing kit	1	All Parameters	Procalcitonin testing kit YY/T 1588-2018		2023-02-14
		2	Appearance	Procalcitonin testing kit YY/T 1588-2018 3.1		2023-02-14
		3	traceability	Procalcitonin testing kit YY/T 1588-2018 3.2		2023-02-14
		4	Detection limit	Procalcitonin testing kit YY/T 1588-2018 3.3		2023-02-14
		5	Degree of accuracy	Procalcitonin testing kit YY/T 1588-2018 3.4		2023-02-14
		6	linear	Procalcitonin testing kit YY/T 1588-2018 3.5		2023-02-14
		7	Repeatability	Procalcitonin testing kit YY/T 1588-2018 3.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Difference between batch	Procalcitonin testing kit YY/T 1588-2018 3.7		2023-02-14
		9	Stabilization	Procalcitonin testing kit YY/T 1588-2018 3.8		2023-02-14
15	C-reactive protein testing kit	1	All Parameters	C-reactive protein testing kit YY/T 1513 -2017		2023-02-14
		2	Appearance	C-reactive protein testing kit YY/T 1513 -2017 4.1		2023-02-14
		3	traceability	C-reactive protein testing kit YY/T 1513 -2017 4.2		2023-02-14
		4	Blank absorbance of reagent	C-reactive protein testing kit YY/T 1513 -2017 4.3		2023-02-14
		5	Analytical sensitivity	C-reactive protein testing kit YY/T 1513 -2017 4.4		2023-02-14
		6	Detection limit	C-reactive protein testing kit YY/T 1513 -2017 4.5		2023-02-14
		7	Degree of accuracy	C-reactive protein testing kit YY/T 1513 -2017 4.6	GB9706.1 , GB9706.9	2023-02-14
		8	linear	C-reactive protein testing kit YY/T 1513 -2017 4.7		2023-02-14
		9	Repeatability	C-reactive protein testing kit YY/T 1513 -2017 4.8		2023-02-14
		10	Difference between batch	C-reactive protein testing kit YY/T 1513 -2017 4.9		2023-02-14
		11	Stabilization	C-reactive protein testing kit YY/T 1513 -2017 4.10	GB9706.1 , GB9706.9	2023-02-14
		12	The general	C-reactive protein testing kit YY/T 1513 -2017 4.10.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Validity stability	C-reactive protein testing kit YY/T 1513 -2017 4.10.2		2023-02-14
		14	Thermal stability test	C-reactive protein testing kit YY/T 1513 -2017 4.10.3		2023-02-14
16	Chloride assay kit(Enzymic method)	1	All Parameters	Chloride assay kit(Enzymic method) YY/T 1196 -2013		2023-02-14
		2	Appearance	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.1		2023-02-14
		3	The load	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.2		2023-02-14
		4	The reagent blank	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.3		2023-02-14
		5	Blank absorbance of reagent	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.3.1		2023-02-14
		6	Change rate of absorbance of blank reagent	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.3.2		2023-02-14
		7	Linear range	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.4		2023-02-14
		8	Degree of accuracy	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.5		2023-02-14
		9	Analytical sensitivity	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.6		2023-02-14
		10	Degree of precision	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.7		2023-02-14
		11	Within-run precision	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.7.1		2023-02-14
		12	Difference between batch	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.7.2		2023-02-14
		13	Stabilization	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.8		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	End-of-term stability	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.8.1		2023-02-14
		15	Accelerated stability	Chloride assay kit(Enzymic method) YY/T 1196 -2013 3.8.2		2023-02-14
17	Alanine aminotransferase diagnostic kit (IFCC method)	1	All Parameters	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013		2023-02-14
		2	Appearance	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.1		2023-02-14
		3	The load	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.2		2023-02-14
		4	The reagent blank	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.3		2023-02-14
		5	Blank absorbance of reagent	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.3.1		2023-02-14
		6	Change rate of absorbance of blank reagent	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.3.2		2023-02-14
		7	The linear range	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.4		2023-02-14
		8	Degree of accuracy	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.5		2023-02-14
		9	Analytical sensitivity	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.6		2023-02-14
		10	Rate method	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.6.1		2023-02-14
		11	The finish method	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.6.2		2023-02-14
		12	Degree of precision	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Within-run precision	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.7.1		2023-02-14
		14	Batch precision	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.7.2		2023-02-14
		15	Stabilization	Alanine aminotransferase diagnostic kit (IFCC method) YY/T 1197-2013 4.8		2023-02-14
18	Aspartate aminotransferase diagnostic kit (IFECC method)	1	All Parameters	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013		2023-02-14
		2	Appearance	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013 4.1		2023-02-14
		3	The load	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013 4.2		2023-02-14
		4	The reagent blank	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013 4.3		2023-02-14
		5	Blank absorbance of reagent	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013 4.3.1		2023-02-14
		6	Change rate of absorbance of blank reagent	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013 4.3.2		2023-02-14
		7	The linear range	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013 4.4		2023-02-14
		8	Degree of accuracy	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013 4.5		2023-02-14
		9	Analytical sensitivity	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013 4.6		2023-02-14
		10	Degree of precision	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013 4.7		2023-02-14
		11	Within-run precision	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013 4.7.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Batch precision	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013 4.7.2		2023-02-14
		13	Stabilization	Aspartate aminotransferase diagnostic kit (IFECC method) YY/T 1198-2013 4.8		2023-02-14
19	Triglycerides assay kit(Oxidase method)	1	All Parameters	Triglycerides assay kit(Oxidase method) YY/T 1199-2013		2023-02-14
		2	Appearance	Triglycerides assay kit(Oxidase method) YY/T 1199-2013 4.1		2023-02-14
		3	The load	Triglycerides assay kit(Oxidase method) YY/T 1199-2013 4.2		2023-02-14
		4	The reagent blank	Triglycerides assay kit(Oxidase method) YY/T 1199-2013 4.3		2023-02-14
		5	The linear range	Triglycerides assay kit(Oxidase method) YY/T 1199-2013 4.4		2023-02-14
		6	Degree of accuracy	Triglycerides assay kit(Oxidase method) YY/T 1199-2013 4.5		2023-02-14
		7	Analytical sensitivity	Triglycerides assay kit(Oxidase method) YY/T 1199-2013 4.6		2023-02-14
		8	Degree of precision	Triglycerides assay kit(Oxidase method) YY/T 1199-2013 4.7		2023-02-14
		9	Within-run precision	Triglycerides assay kit(Oxidase method) YY/T 1199-2013 4.7.1		2023-02-14
		10	Batch precision	Triglycerides assay kit(Oxidase method) YY/T 1199-2013 4.7.2		2023-02-14
		11	Stabilization	Triglycerides assay kit(Oxidase method) YY/T 1199-2013 4.8		2023-02-14
20	Glucose assay kit(Enzymic method)	1	All Parameters	Glucose assay kit(Enzymic method) YY/T 1200-2013		2023-02-14
		2	Appearance	Glucose assay kit(Enzymic method) YY/T 1200-2013 4.1		2023-02-14
		3	The load	Glucose assay kit(Enzymic method) YY/T 1200-2013 4.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Blank absorbance of reagent	Glucose assay kit(Enzymic method) YY/T 1200-2013 4.3		2023-02-14
		5	The linear range	Glucose assay kit(Enzymic method) YY/T 1200-2013 4.4		2023-02-14
		6	Degree of accuracy	Glucose assay kit(Enzymic method) YY/T 1200-2013 4.5		2023-02-14
		7	Analytical sensitivity	Glucose assay kit(Enzymic method) YY/T 1200-2013 4.6		2023-02-14
		8	Degree of precision	Glucose assay kit(Enzymic method) YY/T 1200-2013 4.7		2023-02-14
		9	Within-run precision	Glucose assay kit(Enzymic method) YY/T 1200-2013 4.7.1		2023-02-14
		10	Batch precision	Glucose assay kit(Enzymic method) YY/T 1200-2013 4.7.2		2023-02-14
		11	Stabilization	Glucose assay kit(Enzymic method) YY/T 1200-2013 4.8		2023-02-14
21	Urea assay kit(Enzyme coupling kinetic method)	1	All Parameters	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013		2023-02-14
		2	Appearance	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013 4.1		2023-02-14
		3	The load	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013 4.2		2023-02-14
		4	The reagent blank	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013 4.3		2023-02-14
		5	Blank absorbance of reagent	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013 4.3.1		2023-02-14
		6	Change rate of absorbance of blank reagent	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013 4.3.2		2023-02-14
		7	Linear range	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013 4.4		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Degree of accuracy	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013 4.5		2023-02-14
		9	Analytical sensitivity	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013 4.6		2023-02-14
		10	Degree of precision	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013 4.7		2023-02-14
		11	Within-run precision	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013 4.7.1		2023-02-14
		12	Batch precision	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013 4.7.2		2023-02-14
		13	Stabilization	Urea assay kit(Enzyme coupling kinetic method) YY/T 1201-2013 4.8		2023-02-14
22	Kalium assay kit （Enzymic method)	1	All Parameters	Kalium assay kit （Enzymic method) YY/T 1202-2013		2023-02-14
		2	Appearance	Kalium assay kit （Enzymic method) YY/T 1202-2013 4.1		2023-02-14
		3	The load	Kalium assay kit （Enzymic method) YY/T 1202-2013 4.2		2023-02-14
		4	The reagent blank	Kalium assay kit （Enzymic method) YY/T 1202-2013 4.3		2023-02-14
		5	Blank absorbance of reagent	Kalium assay kit （Enzymic method) YY/T 1202-2013 4.3.1		2023-02-14
		6	Change rate of absorbance of blank reagent	Kalium assay kit （Enzymic method) YY/T 1202-2013 4.3.2		2023-02-14
		7	The linear range	Kalium assay kit （Enzymic method) YY/T 1202-2013 4.4		2023-02-14
		8	Accuracy	Kalium assay kit （Enzymic method) YY/T 1202-2013 4.5		2023-02-14
		9	Analytical sensitivity	Kalium assay kit （Enzymic method) YY/T 1202-2013 4.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Accuracy	Kalium assay kit （Enzymic method) YY/T 1202-2013 4.7		2023-02-14
		11	Within-run precision	Kalium assay kit （Enzymic method) YY/T 1202-2013 4.7.1		2023-02-14
		12	Batch precision	Kalium assay kit （Enzymic method) YY/T 1202-2013 4.7.2		2023-02-14
		13	Stabilization	Kalium assay kit （Enzymic method) YY/T 1202-2013 4.8		2023-02-14
23	Sodium assay kit (Enzymic method)	1	All Parameters	Sodium assay kit (Enzymic method) YY/T 1203-2013		2023-02-14
		2	Appearance	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.1		2023-02-14
		3	The load	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.2		2023-02-14
		4	The reagent blank	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.3		2023-02-14
		5	Blank absorbance of reagent	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.3.1		2023-02-14
		6	Change rate of absorbance of blank reagent	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.3.2		2023-02-14
		7	The linear range	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.4		2023-02-14
		8	Accuracy	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.5		2023-02-14
		9	Analytical sensitivity	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.6		2023-02-14
		10	Precision	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.7		2023-02-14
		11	Within-run precision	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.7.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Difference between batch	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.7.2		2023-02-14
		13	Stabilization	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.8		2023-02-14
		14	End-of-term stability	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.8.1		2023-02-14
		15	Accelerated stability	Sodium assay kit (Enzymic method) YY/T 1203-2013 3.8.2		2023-02-14
24	Total bile acids assay kit (Enzyme cycle method)	1	All Parameters	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-2013		2023-02-14
		2	Appearance	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-2013 4.1		2023-02-14
		3	The load	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-2013 4.2		2023-02-14
		4	The reagent blank	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-2013 4.3		2023-02-14
		5	Blank absorbance of reagent	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-2013 4.3.1		2023-02-14
		6	Change rate of absorbance of blank reagent	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-2013 4.3.2		2023-02-14
		7	The linear range	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-2013 4.4		2023-02-14
		8	Accuracy	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-2013 4.5		2023-02-14
		9	Analytical sensitivity	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-2013 4.6		2023-02-14
		10	Precision	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-2013 4.7		2023-02-14
		11	Within-run	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			precision	2013 4.7.1		
		12	Batch precision	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-2013 4.7.2		2023-02-14
		13	Stabilization	Total bile acids assay kit (Enzyme cycle method) YY/T 1204-2013 4.8		2023-02-14
25	Total bilirubin test kit (Vanadate oxidation method)	1	All Parameters	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013		2023-02-14
		2	Appearance	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013 3.1		2023-02-14
		3	The load	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013 3.2		2023-02-14
		4	Blank absorbance of reagent	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013 3.3		2023-02-14
		5	The linear range	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013 3.4		2023-02-14
		6	Accuracy	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013 3.5		2023-02-14
		7	Analytical sensitivity	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013 3.6		2023-02-14
		8	Precision	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013 3.7		2023-02-14
		9	Within-run precision	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013 3.7.1		2023-02-14
		10	Difference between batch	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013 3.7.2		2023-02-14
		11	Stabilization	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013 3.8		2023-02-14
		12	End-of-term stability	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013 3.8.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Accelerated stability	Total bilirubin test kit (Vanadate oxidation method) YY/T 1205-2013 3.8.2		2023-02-14
26	Total cholesterol kit (COD-PAP method)	1	All Parameters	Total cholesterol kit (COD-PAP method) YY/T 1206-2013		2023-02-14
		2	Appearance	Total cholesterol kit (COD-PAP method) YY/T 1206-2013 3.1		2023-02-14
		3	The load	Total cholesterol kit (COD-PAP method) YY/T 1206-2013 3.2		2023-02-14
		4	Blank absorbance of reagent	Total cholesterol kit (COD-PAP method) YY/T 1206-2013 3.3		2023-02-14
		5	The linear range	Total cholesterol kit (COD-PAP method) YY/T 1206-2013 3.4		2023-02-14
		6	Accuracy	Total cholesterol kit (COD-PAP method) YY/T 1206-2013 3.5		2023-02-14
		7	Analytical sensitivity	Total cholesterol kit (COD-PAP method) YY/T 1206-2013 3.6		2023-02-14
		8	Precision	Total cholesterol kit (COD-PAP method) YY/T 1206-2013 3.7		2023-02-14
		9	Batch precision	Total cholesterol kit (COD-PAP method) YY/T 1206-2013 3.7.1		2023-02-14
		10	Difference between batch	Total cholesterol kit (COD-PAP method) YY/T 1206-2013 3.7.2		2023-02-14
		11	Stabilization	Total cholesterol kit (COD-PAP method) YY/T 1206-2013 3.8		2023-02-14
		12	End-of-term stability	Total cholesterol kit (COD-PAP method) YY/T 1206-2013 3.8.1		2023-02-14
		13	Accelerated stability	Total cholesterol kit (COD-PAP method) YY/T 1206-2013 3.8.2		2023-02-14
27	Uric acid assay kit (Uricase-PAP method)	1	All Parameters	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013		2023-02-14
		2	Appearance	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013 3.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	The load	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013 3.2		2023-02-14
		4	Blank absorbance of reagent	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013 3.3		2023-02-14
		5	The linear range	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013 3.4		2023-02-14
		6	Accuracy	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013 3.5		2023-02-14
		7	Analytical sensitivity	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013 3.6		2023-02-14
		8	Precision	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013 3.7		2023-02-14
		9	Within-run precision	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013 3.7.1		2023-02-14
		10	Difference between batch	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013 3.7.2		2023-02-14
		11	Stabilization	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013 3.8		2023-02-14
		12	End-of-term stability	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013 3.8.1		2023-02-14
		13	Accelerated stability	Uric acid assay kit (Uricase-PAP method) YY/T 1207-2013 3.8.2		2023-02-14
28	"Prolactin Detection Kit (Chemiluminescence Immunoassay) "	1	All Parameters	Prolactin quantitative labelling immunoassay kit YY/T 1516-2017		2023-02-14
		2	Appearance	Prolactin quantitative labelling immunoassay kit YY/T 1516-2017 4.1		2023-02-14
		3	Blank limit	Prolactin quantitative labelling immunoassay kit YY/T 1516-2017 4.2		2023-02-14
		4	Linearity	Prolactin quantitative labelling immunoassay kit YY/T 1516-2017 4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Accuracy	Prolactin quantitative labelling immunoassay kit YY/T 1516-2017 4.4		2023-02-14
		6	Within-run precision	Prolactin quantitative labelling immunoassay kit YY/T 1516-2017 4.5.1		2023-02-14
		7	Within-batch precision	Prolactin quantitative labelling immunoassay kit YY/T 1516-2017 4.5.2		2023-02-14
		8	Specificity	Prolactin quantitative labelling immunoassay kit YY/T 1516-2017 4.6		2023-02-14
		9	Stability at the end of life	Prolactin quantitative labelling immunoassay kit YY/T 1516-2017 4.7.1		2023-02-14
		10	Thermal stability	Prolactin quantitative labelling immunoassay kit YY/T 1516-2017 4.7.2		2023-02-14
		11	Stability after reconstituting freeze-dried reagent	Prolactin quantitative labelling immunoassay kit YY/T 1516-2017 4.7.3		2023-02-14
29	Albumin test reagent kit	1	All Parameters	Albumin test reagent kit YY/T 1228-2014		2023-02-14
		2	Appearance	Albumin test reagent kit YY/T 1228-2014 3.1		2023-02-14
		3	The load	Albumin test reagent kit YY/T 1228-2014 3.2		2023-02-14
		4	Blank absorbance of reagent	Albumin test reagent kit YY/T 1228-2014 3.3		2023-02-14
		5	Analytical sensitivity	Albumin test reagent kit YY/T 1228-2014 3.4		2023-02-14
		6	The linear range	Albumin test reagent kit YY/T 1228-2014 3.5		2023-02-14
		7	Precision	Albumin test reagent kit YY/T 1228-2014 3.6		2023-02-14
		8	Repeatability	Albumin test reagent kit YY/T 1228-2014 3.6.1		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Difference between batch	Albumin test reagent kit YY/T 1228-2014 3.6.2		2023-02-14
		10	Accuracy	Albumin test reagent kit YY/T 1228-2014 3.7		2023-02-14
		11	Stabilization	Albumin test reagent kit YY/T 1228-2014 3.8		2023-02-14
30	Calcium test reagent kit	1	All Parameters	Calcium test reagent kit YY/T 1229-2014		2023-02-14
		2	Appearance	Calcium test reagent kit YY/T 1229-2014 3.1		2023-02-14
		3	The load	Calcium test reagent kit YY/T 1229-2014 3.2		2023-02-14
		4	Blank absorbance of reagent	Calcium test reagent kit YY/T 1229-2014 3.3		2023-02-14
		5	Analytical sensitivity	Calcium test reagent kit YY/T 1229-2014 3.4		2023-02-14
		6	The linear range	Calcium test reagent kit YY/T 1229-2014 3.5		2023-02-14
		7	Precision	Calcium test reagent kit YY/T 1229-2014 3.6		2023-02-14
		8	Repeatability	Calcium test reagent kit YY/T 1229-2014 3.6.1		2023-02-14
		9	Difference between batch	Calcium test reagent kit YY/T 1229-2014 3.6.2		2023-02-14
		10	Accuracy	Calcium test reagent kit YY/T 1229-2014 3.7		2023-02-14
		11	Stabilization	Calcium test reagent kit YY/T 1229-2014 3.8		2023-02-14
31	Cystatin C test reagent kit	1	All Parameters	Cystatin C test reagent kit YY/T 1230-2014		2023-02-14
		2	Appearance	Cystatin C test reagent kit YY/T 1230-2014 3.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	The load	Cystatin C test reagent kit YY/T 1230-2014 3.2		2023-02-14
		4	Blank absorbance of reagent	Cystatin C test reagent kit YY/T 1230-2014 3.3		2023-02-14
		5	Analytical sensitivity	Cystatin C test reagent kit YY/T 1230-2014 3.4		2023-02-14
		6	The linear range	Cystatin C test reagent kit YY/T 1230-2014 3.5		2023-02-14
		7	Precision	Cystatin C test reagent kit YY/T 1230-2014 3.6		2023-02-14
		8	Repeatability	Cystatin C test reagent kit YY/T 1230-2014 3.6.1		2023-02-14
		9	Difference between batch	Cystatin C test reagent kit YY/T 1230-2014 3.6.2		2023-02-14
		10	Accuracy	Cystatin C test reagent kit YY/T 1230-2014 3.7		2023-02-14
		11	Stabilization	Cystatin C test reagent kit YY/T 1230-2014 3.8		2023-02-14
32	Creatinine test reagent kit(Method of sarcosine oxidase)	1	All Parameters	Creatinine test reagent kit(Method of sarcosine oxidase) YY/T 1231-2014		2023-02-14
		2	Appearance	Creatinine test reagent kit(Method of sarcosine oxidase) YY/T 1231-2014 3.1		2023-02-14
		3	The load	Creatinine test reagent kit(Method of sarcosine oxidase) YY/T 1231-2014 3.2		2023-02-14
		4	Blank absorbance of reagent	Creatinine test reagent kit(Method of sarcosine oxidase) YY/T 1231-2014 3.3		2023-02-14
		5	Analytical sensitivity	Creatinine test reagent kit(Method of sarcosine oxidase) YY/T 1231-2014 3.4		2023-02-14
		6	The linear range	Creatinine test reagent kit(Method of sarcosine oxidase) YY/T 1231-2014 3.5		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Precision	Creatinine test reagent kit(Method of sarcosine oxidase) YY/T 1231-2014 3.6		2023-02-14
		8	Repeatability	Creatinine test reagent kit(Method of sarcosine oxidase) YY/T 1231-2014 3.6.1		2023-02-14
		9	Difference between batch	Creatinine test reagent kit(Method of sarcosine oxidase) YY/T 1231-2014 3.6.2		2023-02-14
		10	Accuracy	Creatinine test reagent kit(Method of sarcosine oxidase) YY/T 1231-2014 3.7		2023-02-14
		11	Stabilization	Creatinine test reagent kit(Method of sarcosine oxidase) YY/T 1231-2014 3.8		2023-02-14
33	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA)	1	All Parameters	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014		2023-02-14
		2	Appearance	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.1		2023-02-14
		3	The load	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.2		2023-02-14
		4	The reagent blank	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.3		2023-02-14
		5	Blank absorbance of reagent	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.3.1		2023-02-14
		6	Change rate of absorbance of blank reagent	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.3.2		2023-02-14
		7	Analytical sensitivity	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.4		2023-02-14
		8	The linear range	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.5		2023-02-14
		9	Precision	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Repeatability	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.6.1		2023-02-14
		11	Difference between bottles in batch	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.6.2		2023-02-14
		12	Difference between batch	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.6.3		2023-02-14
		13	Accuracy	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.7		2023-02-14
		14	Stabilization	γ-Glutamyl transpeptadase test reagent kit(Method of GPNA) YY/T 1232-2014 3.8		2023-02-14
34	Alkaline phosphatase test reagent kit(Method of NPP-AMP)	1	All Parameters	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014		2023-02-14
		2	Appearance	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.1		2023-02-14
		3	The load	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.2		2023-02-14
		4	The reagent blank	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.3		2023-02-14
		5	Blank absorbance of reagent	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.3.1		2023-02-14
		6	Change rate of absorbance of blank reagent	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.3.2		2023-02-14
		7	Analytical sensitivity	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.4		2023-02-14
		8	The linear range	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.5		2023-02-14
		9	Precision	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.6		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Repeatability	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.6.1		2023-02-14
		11	Difference between bottles in batch	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.6.2		2023-02-14
		12	Difference between batch	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.6.3		2023-02-14
		13	Accuracy	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.7		2023-02-14
		14	Stabilization	Alkaline phosphatase test reagent kit(Method of NPP-AMP) YY/T 1234-2014 3.8		2023-02-14
35	D-Dimer reagent (kit)	1	All Parameters	D-Dimer reagent (kit) YY/T 1240-2014		2023-02-14
		2	Appearance	D-Dimer reagent (kit) YY/T 1240-2014 4.1		2023-02-14
		3	Negative prediction rate	D-Dimer reagent (kit) YY/T 1240-2014		2023-02-14
		4	The test interval	D-Dimer reagent (kit) YY/T 1240-2014 4.3		2023-02-14
		5	Precision	D-Dimer reagent (kit) YY/T 1240-2014 4.4		2023-02-14
		6	Repeatability	D-Dimer reagent (kit) YY/T 1240-2014 4.4.1		2023-02-14
		7	Difference between batch	D-Dimer reagent (kit) YY/T 1240-2014 4.4.2		2023-02-14
		8	Stabilization	D-Dimer reagent (kit) YY/T 1240-2014 4.5		2023-02-14
		9	The report way	D-Dimer reagent (kit) YY/T 1240-2014 4.6		2023-02-14
36	L-Lactate dehydrogenase test reagent	1	All Parameters	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	(kit)	2	Appearance	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.1		2023-02-14
		3	The load	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.2		2023-02-14
		4	The reagent blank	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.3		2023-02-14
		5	Blank absorbance of reagent	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.3.1		2023-02-14
		6	Change rate of absorbance of blank reagent	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.3.2		2023-02-14
		7	Analytical sensitivity	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.4		2023-02-14
		8	The linear range	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.5		2023-02-14
		9	Precision	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.6		2023-02-14
		10	Repeatability	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.6.1		2023-02-14
		11	Difference between bottles in batch	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.6.2		2023-02-14
		12	Difference between batch	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.6.3		2023-02-14
		13	Accuracy	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.7		2023-02-14
		14	Stabilization	L-Lactate dehydrogenase test reagent (kit) YY/T 1241-2014 4.8		2023-02-14
37	α-Hydroxybutyrate dehydrogenase	1	All Parameters	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014		2023-02-14
		2	Appearance	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	test reagent(kit)	3	The load	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.2		2023-02-14
		4	The reagent blank	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.3		2023-02-14
		5	Blank absorbance of reagent	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.3.1		2023-02-14
		6	Change rate of absorbance of blank reagent	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.3.2		2023-02-14
		7	Analytical sensitivity	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.4		2023-02-14
		8	The linear range	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.5		2023-02-14
		9	Precision	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.6		2023-02-14
		10	Repeatability	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.6.1		2023-02-14
		11	Difference between bottles in batch	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.6.2		2023-02-14
		12	Difference between batch	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.6.3		2023-02-14
		13	Accuracy	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.7		2023-02-14
		14	Stabilization	α-Hydroxybutyrate dehydrogenase test reagent(kit) YY/T 1242-2014 4.8		2023-02-14
38	Creatine kinase test reagent (kit)	1	All Parameters	Creatine kinase test reagent (kit) YY/T 1243-2014		2023-02-14
		2	Appearance	Creatine kinase test reagent (kit) YY/T 1243-2014 4.1		2023-02-14
		3	The load	Creatine kinase test reagent (kit) YY/T 1243-2014 4.2		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	The reagent blank	Creatine kinase test reagent (kit) YY/T 1243-2014 4.3		2023-02-14
		5	Blank absorbance of reagent	Creatine kinase test reagent (kit) YY/T 1243-2014 4.3.1		2023-02-14
		6	Change rate of absorbance of blank reagent	Creatine kinase test reagent (kit) YY/T 1243-2014 4.3.2		2023-02-14
		7	Analytical sensitivity	Creatine kinase test reagent (kit) YY/T 1243-2014 4.4		2023-02-14
		8	The linear range	Creatine kinase test reagent (kit) YY/T 1243-2014 4.5		2023-02-14
		9	Precision	Creatine kinase test reagent (kit) YY/T 1243-2014 4.6		2023-02-14
		10	Repeatability	Creatine kinase test reagent (kit) YY/T 1243-2014 4.6.1		2023-02-14
		11	Difference between bottles in batch	Creatine kinase test reagent (kit) YY/T 1243-2014 4.6.2		2023-02-14
		12	Difference between batch	Creatine kinase test reagent (kit) YY/T 1243-2014 4.6.3		2023-02-14
		13	Accuracy	Creatine kinase test reagent (kit) YY/T 1243-2014 4.7		2023-02-14
		14	Stabilization	Creatine kinase test reagent (kit) YY/T 1243-2014 4.8		2023-02-14
39	Low density lipoprotein(LDL) cholesterol assay kit	1	All Parameters	Low density lipoprotein(LDL) cholesterol assay kit YY/T 1253-2015		2023-02-14
		2	Appearance	Low density lipoprotein(LDL) cholesterol assay kit YY/T 1253-2015 3.1		2023-02-14
		3	The load	Low density lipoprotein(LDL) cholesterol assay kit YY/T 1253-2015 3.2		2023-02-14
		4	Blank absorbance of reagent	Low density lipoprotein(LDL) cholesterol assay kit YY/T 1253-2015 3.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Analytical sensitivity	Low density lipoprotein(LDL) cholesterol assay kit YY/T 1253-2015 3.4		2023-02-14
		6	linear	Low density lipoprotein(LDL) cholesterol assay kit YY/T 1253-2015 3.5		2023-02-14
		7	Precision	Low density lipoprotein(LDL) cholesterol assay kit YY/T 1253-2015 3.6		2023-02-14
		8	Repeatability	Low density lipoprotein(LDL) cholesterol assay kit YY/T 1253-2015 3.6.1		2023-02-14
		9	Difference between batch	Low density lipoprotein(LDL) cholesterol assay kit YY/T 1253-2015 3.6.2		2023-02-14
		10	Accuracy	Low density lipoprotein(LDL) cholesterol assay kit YY/T 1253-2015 3.7		2023-02-14
		11	Stabilization	Low density lipoprotein(LDL) cholesterol assay kit YY/T 1253-2015 3.8		2023-02-14
40	High density lipoprotein(LDL) cholesterol assay kit	1	All Parameters	High density lipoprotein(LDL) cholesterol assay kit YY/T 1254-2015		2023-02-14
		2	Appearance	High density lipoprotein(LDL) cholesterol assay kit YY/T 1254-2015 3.1		2023-02-14
		3	The load	High density lipoprotein(LDL) cholesterol assay kit YY/T 1254-2015 3.2		2023-02-14
		4	Blank absorbance of reagent	High density lipoprotein(LDL) cholesterol assay kit YY/T 1254-2015 3.3		2023-02-14
		5	Analytical sensitivity	High density lipoprotein(LDL) cholesterol assay kit YY/T 1254-2015 3.4		2023-02-14
		6	linear	High density lipoprotein(LDL) cholesterol assay kit YY/T 1254-2015 3.5		2023-02-14
		7	Precision	High density lipoprotein(LDL) cholesterol assay kit YY/T 1254-2015 3.6		2023-02-14
		8	Repeatability	High density lipoprotein(LDL) cholesterol assay kit YY/T 1254-2015 3.6.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Difference between batch	High density lipoprotein(LDL) cholesterol assay kit YY/T 1254-2015 3.6.2		2023-02-14
		10	Accuracy	High density lipoprotein(LDL) cholesterol assay kit YY/T 1254-2015 3.7		2023-02-14
		11	Stabilization	High density lipoprotein(LDL) cholesterol assay kit YY/T 1254-2015 3.8		2023-02-14
41	Homocysteine assay kit(enzymatic cycling method)	1	All Parameters	Homocysteine assay kit(enzymatic cycling method) YY/T 1258-2015		2023-02-14
		2	Appearance	Homocysteine assay kit(enzymatic cycling method) YY/T 1258-2015 3.1		2023-02-14
		3	The load	Homocysteine assay kit(enzymatic cycling method) YY/T 1258-2015 3.2		2023-02-14
		4	The reagent blank	Homocysteine assay kit(enzymatic cycling method) YY/T 1258-2015 3.3		2023-02-14
		5	Analytical sensitivity	Homocysteine assay kit(enzymatic cycling method) YY/T 1258-2015 3.4		2023-02-14
		6	linear	Homocysteine assay kit(enzymatic cycling method) YY/T 1258-2015 3.5		2023-02-14
		7	Precision	Homocysteine assay kit(enzymatic cycling method) YY/T 1258-2015 3.6		2023-02-14
		8	Repeatability	Homocysteine assay kit(enzymatic cycling method) YY/T 1258-2015 3.6.1		2023-02-14
		9	Difference between batch	Homocysteine assay kit(enzymatic cycling method) YY/T 1258-2015 3.6.2		2023-02-14
		10	Accuracy	Homocysteine assay kit(enzymatic cycling method) YY/T 1258-2015 3.7		2023-02-14
		11	Stabilization	Homocysteine assay kit(enzymatic cycling method) YY/T 1258-2015 3.8		2023-02-14
	General technical	1	All Parameters	General technical requirements of quality control materials for in vitro diagnostic reagents YY/T 1652-2019		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	requirements of quality control materials for in vitro diagnostic reagents	2	Appearance	General technical requirements of quality control materials for in vitro diagnostic reagents YY/T 1652-2019 3.1		2023-02-14
		3	Loading quantity	General technical requirements of quality control materials for in vitro diagnostic reagents YY/T 1652-2019 3.2		2023-02-14
		4	Intended result	General technical requirements of quality control materials for in vitro diagnostic reagents YY/T 1652-2019 3.3		2023-02-14
		5	homogeneity	General technical requirements of quality control materials for in vitro diagnostic reagents YY/T 1652-2019 3.4		2023-02-14
		6	stability	General technical requirements of quality control materials for in vitro diagnostic reagents YY/T 1652-2019 3.5		2023-02-14
43	Quality control material for clinical chemistry analyzer	1	All Parameters	Quality control material for clinical chemistry analyzer YY/T 1662-2019		2023-02-14
		2	character	Quality control material for clinical chemistry analyzer YY/T 1662-2019 4.1		2023-02-14
		3	The load	Quality control material for clinical chemistry analyzer YY/T 1662-2019 4.2		2023-02-14
		4	Acceptable range/value	Quality control material for clinical chemistry analyzer YY/T 1662-2019 4.3		2023-02-14
		5	Bottle to bottle uniformity	Quality control material for clinical chemistry analyzer YY/T 1662-2019 4.4		2023-02-14
		6	Stabilization	Quality control material for clinical chemistry analyzer YY/T 1662-2019 4.5		2023-02-14
		7	" Stability after initialdissolution "	Quality control material for clinical chemistry analyzer YY/T 1662-2019 4.5.1		2023-02-14
		8	Resolution stability	Quality control material for clinical chemistry analyzer YY/T 1662-2019 4.5.2		2023-02-14
		9	Validity stability	Quality control material for clinical chemistry analyzer YY/T 1662-2019 4.5.3		2023-02-14
44	Immunoturbidimetry reagent	1	All Parameters	Immunoturbidimetry reagent (kit) YY/T 1255-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	(kit)	2	Appearance	Immunoturbidimetry reagent (kit) YY/T 1255-2015 4.1		2023-02-14
		3	The load	Immunoturbidimetry reagent (kit) YY/T 1255-2015 4.2		2023-02-14
		4	Blank limit	Immunoturbidimetry reagent (kit) YY/T 1255-2015 4.3		2023-02-14
		5	linear	Immunoturbidimetry reagent (kit) YY/T 1255-2015 4.4		2023-02-14
		6	Repeatability	Immunoturbidimetry reagent (kit) YY/T 1255-2015 4.5		2023-02-14
		7	Difference between batch	Immunoturbidimetry reagent (kit) YY/T 1255-2015 4.6		2023-02-14
		8	Trace to the source	Immunoturbidimetry reagent (kit) YY/T 1255-2015 4.7		2023-02-14
		9	Accuracy	Immunoturbidimetry reagent (kit) YY/T 1255-2015 4.8		2023-02-14
		10	Stabilization	Immunoturbidimetry reagent (kit) YY/T 1255-2015 4.9		2023-02-14
45	Triiodothyronine Detection Kit (Chemiluminescence Immunoassay)	1	All Parameters	Totle T3 quantitative labelling immunoassay kit YY/T 1222-2014		2023-02-14
		2	Appearance and physical inspection	Totle T3 quantitative labelling immunoassay kit YY/T 1222-2014 4.1		2023-02-14
		3	Linearity	Totle T3 quantitative labelling immunoassay kit YY/T 1222-2014 4.2		2023-02-14
		4	Lowest limit of detection	Totle T3 quantitative labelling immunoassay kit YY/T 1222-2014 4.3		2023-02-14
		5	Accuracy	Totle T3 quantitative labelling immunoassay kit YY/T 1222-2014 4.4		2023-02-14
		6	Within-analysis precision	Totle T3 quantitative labelling immunoassay kit YY/T 1222-2014 4.5.1		2023-02-14
		7	Within-batch	Totle T3 quantitative labelling immunoassay kit YY/T 1222-2014		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			precision	4.5.2		
		8	Control measured value	Totle T3 quantitative labelling immunoassay kit YY/T 1222-2014 4.6		2023-02-14
		9	Specificity	Totle T3 quantitative labelling immunoassay kit YY/T 1222-2014 4.7		2023-02-14
		10	Stability at the end of life	Totle T3 quantitative labelling immunoassay kit YY/T 1222-2014 4.8.1		2023-02-14
		11	Thermal stability	Totle T3 quantitative labelling immunoassay kit YY/T 1222-2014 4.8.2		2023-02-14
		12	Stability after reconstituting freeze-dried reagent	Totle T3 quantitative labelling immunoassay kit YY/T 1222-2014 4.8.3		2023-02-14
46	Estradiol Detection Kit (Chemiluminescence Immunoassay)	1	All Parameters	Estradiol testing kit(Chemiluminescent immunoassay) YY/T 1589-2018		2023-02-14
		2	Appearance and physical inspection	Estradiol testing kit(Chemiluminescent immunoassay) YY/T 1589-2018 3.1		2023-02-14
		3	Linearity	Estradiol testing kit(Chemiluminescent immunoassay) YY/T 1589-2018 3.2		2023-02-14
		4	Limit of detection	Estradiol testing kit(Chemiluminescent immunoassay) YY/T 1589-2018 3.3		2023-02-14
		5	Accuracy	Estradiol testing kit(Chemiluminescent immunoassay) YY/T 1589-2018 3.4		2023-02-14
		6	Repeatability	Estradiol testing kit(Chemiluminescent immunoassay) YY/T 1589-2018 3.5		2023-02-14
		7	Between-batch difference	Estradiol testing kit(Chemiluminescent immunoassay) YY/T 1589-2018 3.6		2023-02-14
		8	Stability	Estradiol testing kit(Chemiluminescent immunoassay) YY/T 1589-2018 3.7		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Traceability	Estradiol testing kit(Chemiluminescent immunoassay) YY/T 1589-2018 3.8		2023-02-14
47	Thyroxine Detection Kit (Chemiluminescence Immunoassay)	1	All Parameters	Totle T4 quantitative labelling immunoassay kit YY/T 1223-2014		2023-02-14
		2	Appearance and physical inspection	Totle T4 quantitative labelling immunoassay kit YY/T 1223-2014 4.1		2023-02-14
		3	Linearity	Totle T4 quantitative labelling immunoassay kit YY/T 1223-2014 4.2		2023-02-14
		4	Lowest limit of detection	Totle T4 quantitative labelling immunoassay kit YY/T 1223-2014 4.3		2023-02-14
		5	Accuracy	Totle T4 quantitative labelling immunoassay kit YY/T 1223-2014 4.4		2023-02-14
		6	Within-analysis precision	Totle T4 quantitative labelling immunoassay kit YY/T 1223-2014 4.5.1		2023-02-14
		7	Between-analysis precision	Totle T4 quantitative labelling immunoassay kit YY/T 1223-2014 4.5.2		2023-02-14
		8	Control measured value	Totle T4 quantitative labelling immunoassay kit YY/T 1223-2014 4.6		2023-02-14
		9	Specificity	Totle T4 quantitative labelling immunoassay kit YY/T 1223-2014 4.7		2023-02-14
		10	Stability at the end of life	Totle T4 quantitative labelling immunoassay kit YY/T 1223-2014 4.8.1		2023-02-14
		11	Thermal stability	Totle T4 quantitative labelling immunoassay kit YY/T 1223-2014 4.8.2		2023-02-14
		12	Stability after reconstituting freeze-dried reagent	Totle T4 quantitative labelling immunoassay kit YY/T 1223-2014 4.8.3		2023-02-14
	Thyroid Stimulating Hormone	1	All Parameters	Thyroid-stimulating quantitative labelling immunoassay kit YY/T 1218-2013		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	Detection Kit (Chemiluminescence Immunoassay)	2	Appearance and physical inspection	Thyroid-stimulating quantitative labelling immunoassay kit YY/T 1218-2013 4.1		2023-02-14
		3	Lowest limit of detection	Thyroid-stimulating quantitative labelling immunoassay kit YY/T 1218-2013 4.2		2023-02-14
		4	Accuracy	Thyroid-stimulating quantitative labelling immunoassay kit YY/T 1218-2013 4.3		2023-02-14
		5	Dosage-reaction curve linearity	Thyroid-stimulating quantitative labelling immunoassay kit YY/T 1218-2013 4.4		2023-02-14
		6	Within-analysis precision	Thyroid-stimulating quantitative labelling immunoassay kit YY/T 1218-2013 4.5.1		2023-02-14
		7	Between-analysis precision	Thyroid-stimulating quantitative labelling immunoassay kit YY/T 1218-2013 4.5.2		2023-02-14
		8	Within-batch precision	Thyroid-stimulating quantitative labelling immunoassay kit YY/T 1218-2013 4.5.3		2023-02-14
		9	Control measured value	Thyroid-stimulating quantitative labelling immunoassay kit YY/T 1218-2013 4.6		2023-02-14
		10	Specificity	Thyroid-stimulating quantitative labelling immunoassay kit YY/T 1218-2013 4.7		2023-02-14
		11	Stability at the end of life	Thyroid-stimulating quantitative labelling immunoassay kit YY/T 1218-2013 4.8.1		2023-02-14
		12	Thermal stability	Thyroid-stimulating quantitative labelling immunoassay kit YY/T 1218-2013 4.8.2		2023-02-14
49	Antibodies to Thyroglobulin Detection Kit (Chemiluminescence Immunoassay)	1	All Parameters	Anti-quantitative labelling immunoassay kit YY/T 1594-2018		2023-02-14
		2	Appearance	Anti-quantitative labelling immunoassay kit YY/T 1594-2018 4.1		2023-02-14
		3	Blank limit	Anti-quantitative labelling immunoassay kit YY/T 1594-2018 4.2		2023-02-14
		4	Linearity	Anti-quantitative labelling immunoassay kit YY/T 1594-2018 4.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Accuracy	Anti-quantitative labelling immunoassay kit YY/T 1594-2018 4.4		2023-02-14
		6	Within-run precision	Anti-quantitative labelling immunoassay kit YY/T 1594-2018 4.5.1		2023-02-14
		7	Within-batch precision	Anti-quantitative labelling immunoassay kit YY/T 1594-2018 4.5.2		2023-02-14
		8	Specificity	Anti-quantitative labelling immunoassay kit YY/T 1594-2018 4.6		2023-02-14
		9	Stability within life	Anti-quantitative labelling immunoassay kit YY/T 1594-2018 4.7.1		2023-02-14
		10	Thermal stability	Anti-quantitative labelling immunoassay kit YY/T 1594-2018 4.7.2		2023-02-14
50	Antibodies to Thyroid Peroxidase Detection Kit (Chemiluminescence Immunoassay)	1	All Parameters	Antibodies to thyroid peroxidase quantitative test reagent(chemiluminescent immunoassay) YY/T 1458-2016		2023-02-14
		2	Appearance	Antibodies to thyroid peroxidase quantitative test reagent(chemiluminescent immunoassay) YY/T 1458-2016 3.1		2023-02-14
		3	Traceability	Antibodies to thyroid peroxidase quantitative test reagent(chemiluminescent immunoassay) YY/T 1458-2016 3.2		2023-02-14
		4	Accuracy	Antibodies to thyroid peroxidase quantitative test reagent(chemiluminescent immunoassay) YY/T 1458-2016 3.3		2023-02-14
		5	Limit of detection	Antibodies to thyroid peroxidase quantitative test reagent(chemiluminescent immunoassay) YY/T 1458-2016 3.4		2023-02-14
		6	Linearity	Antibodies to thyroid peroxidase quantitative test reagent(chemiluminescent immunoassay) YY/T 1458-2016 3.5		2023-02-14
		7	Repeatability	Antibodies to thyroid peroxidase quantitative test reagent(chemiluminescent immunoassay) YY/T 1458-2016 3.6		2023-02-14
		8	Between-batch difference	Antibodies to thyroid peroxidase quantitative test reagent(chemiluminescent immunoassay) YY/T 1458-2016 3.7		2023-02-14
		9	Stability within life	Antibodies to thyroid peroxidase quantitative test reagent(chemiluminescent immunoassay) YY/T 1458-2016 3.8.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Thermal stability	Antibodies to thyroid peroxidase quantitative test reagent(chemiluminescent immunoassay) YY/T 1458-2016 3.8.3		2023-02-14
51	Luteinizing Hormone Detection Kit (Chemiluminescence Immunoassay)	1	All Parameters	Luteinizing hormone quantitative labelling immunoassay kit YY/T 1217-2013		2023-02-14
		2	Appearance and physical inspection	Luteinizing hormone quantitative labelling immunoassay kit YY/T 1217-2013 4.1		2023-02-14
		3	Lowest limit of detection	Luteinizing hormone quantitative labelling immunoassay kit YY/T 1217-2013 4.2		2023-02-14
		4	Accuracy	Luteinizing hormone quantitative labelling immunoassay kit YY/T 1217-2013 4.3		2023-02-14
		5	Dosage-reaction curve linearity	Luteinizing hormone quantitative labelling immunoassay kit YY/T 1217-2013 4.4		2023-02-14
		6	Within-analysis precision	Luteinizing hormone quantitative labelling immunoassay kit YY/T 1217-2013 4.5.1		2023-02-14
		7	Between-analysis precision	Luteinizing hormone quantitative labelling immunoassay kit YY/T 1217-2013 4.5.2		2023-02-14
		8	Within-batch precision	Luteinizing hormone quantitative labelling immunoassay kit YY/T 1217-2013 4.5.3		2023-02-14
		9	Control measured value	Luteinizing hormone quantitative labelling immunoassay kit YY/T 1217-2013 4.6		2023-02-14
		10	Specificity	Luteinizing hormone quantitative labelling immunoassay kit YY/T 1217-2013 4.7		2023-02-14
		11	Stability at the end of life	Luteinizing hormone quantitative labelling immunoassay kit YY/T 1217-2013 4.8.1		2023-02-14
		12	Thermal stability	Luteinizing hormone quantitative labelling immunoassay kit YY/T 1217-2013 4.8.2		2023-02-14
52	Beta-Human Chorionic Gonadotropin Detection Kit	1	All Parameters	Human chorionic gonadotropin(HCG) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1192-2011		2023-02-14
		2	Appearance	Human chorionic gonadotropin(HCG) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1192-2011		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	(Chemiluminescence Immunoassay)			4.1		
		3	Traceability	Human chorionic gonadotropin(HCG) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1192-2011 4.2		2023-02-14
		4	Accuracy	Human chorionic gonadotropin(HCG) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1192-2011 4.3		2023-02-14
		5	Lowest limit of detection	Human chorionic gonadotropin(HCG) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1192-2011 4.4		2023-02-14
		6	Specificity	Human chorionic gonadotropin(HCG) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1192-2011 4.5		2023-02-14
		7	Linearity	Human chorionic gonadotropin(HCG) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1192-2011 4.6		2023-02-14
		8	Repeatability	Human chorionic gonadotropin(HCG) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1192-2011 4.7		2023-02-14
		9	Between-batch difference	Human chorionic gonadotropin(HCG) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1192-2011 4.8		2023-02-14
		10	Stability	Human chorionic gonadotropin(HCG) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1192-2011 4.9		2023-02-14
53	"Cardiac Troponin I Detection Kit (Chemilumines	1	All Parameters	Cardiac troponin-I(cTnI) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1233-2014		2023-02-14
		2	Appearance	Cardiac troponin-I(cTnI) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1233-2014		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	cence Immunoassay) "			4.1		
		3	Traceability	Cardiac troponin-I(cTnI) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1233-2014 4.2		2023-02-14
		4	Accuracy	Cardiac troponin-I(cTnI) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1233-2014 4.3		2023-02-14
		5	Blank limit	Cardiac troponin-I(cTnI) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1233-2014 4.4		2023-02-14
		6	Linear interval	Cardiac troponin-I(cTnI) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1233-2014 4.5		2023-02-14
		7	Repeatability	Cardiac troponin-I(cTnI) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1233-2014 4.6		2023-02-14
		8	Between-batch difference	Cardiac troponin-I(cTnI) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1233-2014 4.7		2023-02-14
		9	Analytical specificity	Cardiac troponin-I(cTnI) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1233-2014 4.8		2023-02-14
		10	Stability	Cardiac troponin-I(cTnI) quantitative detective reagent(kit)(chemiluminescent immunoassay) YY/T 1233-2014 4.9		2023-02-14
54	"Insulin Detection Kit (Chemilumines	1	All Parameters	Insulin quantitative labelling immunoassay kit YY/T 1250-2014		2023-02-14
		2	Appearance and physical inspection	Insulin quantitative labelling immunoassay kit YY/T 1250-2014 4.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	cence Immunoassay) "	3	Linearity	Insulin quantitative labelling immunoassay kit YY/T 1250-2014 4.2		2023-02-14
		4	Lowest limit of detection	Insulin quantitative labelling immunoassay kit YY/T 1250-2014 4.3		2023-02-14
		5	Accuracy	Insulin quantitative labelling immunoassay kit YY/T 1250-2014 4.4		2023-02-14
		6	Within-analysis precision	Insulin quantitative labelling immunoassay kit YY/T 1250-2014 4.5.1		2023-02-14
		7	Within-batch precision	Insulin quantitative labelling immunoassay kit YY/T 1250-2014 4.5.2		2023-02-14
		8	Control measured value	Insulin quantitative labelling immunoassay kit YY/T 1250-2014 4.6		2023-02-14
		9	Specificity	Insulin quantitative labelling immunoassay kit YY/T 1250-2014 4.7		2023-02-14
		10	Stability at the end of life	Insulin quantitative labelling immunoassay kit YY/T 1250-2014 4.8.1		2023-02-14
		11	Thermal stability	Insulin quantitative labelling immunoassay kit YY/T 1250-2014 4.8.2		2023-02-14
		12	Stability after reconstituting freeze-dried reagent	Insulin quantitative labelling immunoassay kit YY/T 1250-2014 4.8.3		2023-02-14
55	Luteinizing hormone(LH) test strip (Colloidal gold immunochromatographic assay)	1	All Parameters	Luteinizing hormone(LH) test strip (Colloidal gold immunochromatographic assay) GB/T 18990-2008		2023-02-14
		2	appearance	Luteinizing hormone(LH) test strip (Colloidal gold immunochromatographic assay) GB/T 18990-2008 4.1.1		2023-02-14
		3	strip width	Luteinizing hormone(LH) test strip (Colloidal gold immunochromatographic assay) GB/T 18990-2008 4.1.2		2023-02-14
		4	liquid movement speed	Luteinizing hormone(LH) test strip (Colloidal gold immunochromatographic assay) GB/T 18990-2008 4.1.3		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	cut-off	Luteinizing hormone(LH) test strip (Colloidal gold immunochromatographic assay) GB/T 18990-2008 4.2		2023-02-14
		6	specificity	Luteinizing hormone(LH) test strip (Colloidal gold immunochromatographic assay) GB/T 18990-2008 4.3		2023-02-14
		7	Repeatability	Luteinizing hormone(LH) test strip (Colloidal gold immunochromatographic assay) GB/T 18990-2008 4.4		2023-02-14
		8	stability	Luteinizing hormone(LH) test strip (Colloidal gold immunochromatographic assay) GB/T 18990-2008 4.5		2023-02-14
		9	Inter coefficients of variation	Luteinizing hormone(LH) test strip (Colloidal gold immunochromatographic assay) GB/T 18990-2008 4.6		2023-02-14
56	General technical requirements for chemical reagent strips for urinalysis	1	All Parameters	General technical requirements for chemical reagent strips for urinalysis YY/T 0478-2011		2023-02-14
		2	appearance	General technical requirements for chemical reagent strips for urinalysis YY/T 0478-2011 4.1		2023-02-14
		3	Accuracy	General technical requirements for chemical reagent strips for urinalysis YY/T 0478-2011 4.2		2023-02-14
		4	Repeatability	General technical requirements for chemical reagent strips for urinalysis YY/T 0478-2011 4.3		2023-02-14
		5	analytical specificity	General technical requirements for chemical reagent strips for urinalysis YY/T 0478-2011 4.4		2023-02-14
		6	specificity	General technical requirements for chemical reagent strips for urinalysis YY/T 0478-2011 4.5		2023-02-14
		7	Inter coefficients of variation	General technical requirements for chemical reagent strips for urinalysis YY/T 0478-2011 4.6		2023-02-14
		8	stability	General technical requirements for chemical reagent strips for urinalysis YY/T 0478-2011 4.7		2023-02-14
Direct contact with drugs packaging materials and containers						
Direct contact with drugs packaging materials and containers						

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
1	Infusion Bottles Made of Soda Lime Glass	1	Partial Parameters	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015	Except for "As"	2023-02-14
		2	Appearance	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015		2023-02-14
		4	Joint Line	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015		2023-02-14
		5	Tick Mark、Word、Sign	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015		2023-02-14
		6	121℃ Water Durability of Pellets	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015		2023-02-14
		7	Water Durability on Internal Surface	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015		2023-02-14
		8	Thermal Stability	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015		2023-02-14
		9	Thermal Shock Durability	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015		2023-02-14
		10	Internal Pressure Durability	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015		2023-02-14
		11	Internal Stress	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015		2023-02-14
		12	Lixiviate Amount of As、Sb、Pb、Cd	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015	Except for "As"	2023-02-14
		13	Deviation of Vertical Axis	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015		2023-02-14
		14	Reticle Volume	Infusion Bottles Made of Soda Lime Glass YBB00032005-2015		2023-02-14
2	Infusion	1	Partial Parameters	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-	Except for	2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	Bottles Made of Low Borosilicate Glass			2015	"As"	
		2	Appearance	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14
		4	B2O3 Content	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14
		5	Joint Line	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14
		6	Tick Mark、Word、Sign	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14
		7	121℃ Water Durability of Pellets	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14
		8	Water Durability on Internal Surface	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14
		9	Thermal Stability	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14
		10	Thermal Shock Durability	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14
		11	Internal Pressure Durability	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14
		12	Internal Stress	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14
		13	Lixiviate Amount of As、Sb、Pb、Cd	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015	Except for "As"	2023-02-14
		14	Deviation of Vertical Axis	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Reticle Volume	Infusion Bottles Made of Low Borosilicate Glass YBB00012004-2015		2023-02-14
3	Infusion Bottles Made of Middle Borosilicate Glass	1	Partial Parameters	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015	Except for "As"	2023-02-14
		2	Appearance	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
		4	B2O3 Content	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
		5	Joint Line	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
		6	Tick Mark、Word、Sign	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
		7	121℃ Water Durability of Pellets	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
		8	98℃ Water Durability of Pellets	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
		9	Water Durability on Internal Surface	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
		10	Thermal Stability	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
		11	Thermal Shock Durability	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
		12	Internal Pressure Durability	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
		13	Internal Stress	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Lixiviate Amount of As、Sb、Pb、Cd	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015	Except for "As"	2023-02-14
		15	Deviation of Vertical Axis	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
		16	Reticle Volume	Infusion Bottles Made of Middle Borosilicate Glass YBB00022005-2-2015		2023-02-14
4	Ampoules Made of Low Borosilicate Glass Tubing	1	Partial Parameters	Ampoules Made of Low Borosilicate Glass Tubing YBB00332002-2015	Except for "As"	2023-02-14
		2	Appearance	Ampoules Made of Low Borosilicate Glass Tubing YBB00332002-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Ampoules Made of Low Borosilicate Glass Tubing YBB00332002-2015		2023-02-14
		4	B2O3 Content	Ampoules Made of Low Borosilicate Glass Tubing YBB00332002-2015		2023-02-14
		5	121℃ Water Durability of Pellets	Ampoules Made of Low Borosilicate Glass Tubing YBB00332002-2015		2023-02-14
		6	Water Durability on Internal Surface	Ampoules Made of Low Borosilicate Glass Tubing YBB00332002-2015		2023-02-14
		7	Internal Stress	Ampoules Made of Low Borosilicate Glass Tubing YBB00332002-2015		2023-02-14
		8	Circle Run-out	Ampoules Made of Low Borosilicate Glass Tubing YBB00332002-2015		2023-02-14
		9	Breaking Strength	Ampoules Made of Low Borosilicate Glass Tubing YBB00332002-2015		2023-02-14
		10	Lixiviate Amount of As、Sb、Pb、Cd	Ampoules Made of Low Borosilicate Glass Tubing YBB00332002-2015	Except for "As"	2023-02-14
5	Ampoules Made of Middle	1	Partial Parameters	Ampoules Made of Middle Borosilicate Glass Tubing YBB00322005-2-2015	Except for "As"	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	Borosilicate Glass Tubing	2	Appearance	Ampoules Made of Middle Borosilicate Glass Tubing YBB00322005-2-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Ampoules Made of Middle Borosilicate Glass Tubing YBB00322005-2-2015		2023-02-14
		4	B2O3 Content	Ampoules Made of Middle Borosilicate Glass Tubing YBB00322005-2-2015		2023-02-14
		5	121℃ Water Durability of Pellets	Ampoules Made of Middle Borosilicate Glass Tubing YBB00322005-2-2015		2023-02-14
		6	98℃ Water Durability of Pellets	Ampoules Made of Middle Borosilicate Glass Tubing YBB00322005-2-2015		2023-02-14
		7	Water Durability on Internal Surface	Ampoules Made of Middle Borosilicate Glass Tubing YBB00322005-2-2015		2023-02-14
		8	Internal Stress	Ampoules Made of Middle Borosilicate Glass Tubing YBB00322005-2-2015		2023-02-14
		9	Circle Run-out	Ampoules Made of Middle Borosilicate Glass Tubing YBB00322005-2-2015		2023-02-14
		10	Breaking Strength	Ampoules Made of Middle Borosilicate Glass Tubing YBB00322005-2-2015		2023-02-14
		11	Lixiviate Amount of As、Sb、Pb、Cd	Ampoules Made of Middle Borosilicate Glass Tubing YBB00322005-2-2015	Except for "As"	2023-02-14
6	Injection Vials Made of Soda Lime Glass Tubing	1	Partial Parameters	Injection Vials Made of Soda Lime Glass Tubing YBB00332003-2015	Except for "As"	2023-02-14
		2	Appearance	Injection Vials Made of Soda Lime Glass Tubing YBB00332003-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Injection Vials Made of Soda Lime Glass Tubing YBB00332003-2015		2023-02-14
		4	121℃ Water Durability of Pellets	Injection Vials Made of Soda Lime Glass Tubing YBB00332003-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Water Durability on Internal Surface	Injection Vials Made of Soda Lime Glass Tubing YBB00332003-2015		2023-02-14
		6	Internal Stress	Injection Vials Made of Soda Lime Glass Tubing YBB00332003-2015		2023-02-14
		7	Lixiviate Amount of As、Sb、Pb、Cd	Injection Vials Made of Soda Lime Glass Tubing YBB00332003-2015	Except for "As"	2023-02-14
		8	Deviation of Vertical Axis	Injection Vials Made of Soda Lime Glass Tubing YBB00332003-2015		2023-02-14
7	Injection Vials Made of Low Borosilicate Glass Tubing	1	Partial Parameters	Injection Vials Made of Low Borosilicate Glass Tubing YBB00302002-2015	Except for "As"	2023-02-14
		2	Appearance	Injection Vials Made of Low Borosilicate Glass Tubing YBB00302002-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Injection Vials Made of Low Borosilicate Glass Tubing YBB00302002-2015		2023-02-14
		4	B2O3 Content	Injection Vials Made of Low Borosilicate Glass Tubing YBB00302002-2015		2023-02-14
		5	121℃ Water Durability of Pellets	Injection Vials Made of Low Borosilicate Glass Tubing YBB00302002-2015		2023-02-14
		6	Water Durability on Internal Surface	Injection Vials Made of Low Borosilicate Glass Tubing YBB00302002-2015		2023-02-14
		7	Internal Stress	Injection Vials Made of Low Borosilicate Glass Tubing YBB00302002-2015		2023-02-14
		8	Lixiviate Amount of As、Sb、Pb、Cd	Injection Vials Made of Low Borosilicate Glass Tubing YBB00302002-2015	Except for "As"	2023-02-14
		9	Deviation of Vertical Axis	Injection Vials Made of Low Borosilicate Glass Tubing YBB00302002-2015		2023-02-14
8	Injection Vials Made of Middle	1	Partial Parameters	Injection Vials Made of Middle Borosilicate Glass Tubing YBB00292005-2-2015	Except for "As"	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	Borosilicate Glass Tubing	2	Appearance	Injection Vials Made of Middle Borosilicate Glass Tubing YBB00292005-2-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Injection Vials Made of Middle Borosilicate Glass Tubing YBB00292005-2-2015		2023-02-14
		4	B2O3 Content	Injection Vials Made of Middle Borosilicate Glass Tubing YBB00292005-2-2015		2023-02-14
		5	121℃ Water Durability of Pellets	Injection Vials Made of Middle Borosilicate Glass Tubing YBB00292005-2-2015		2023-02-14
		6	98℃ Water Durability of Pellets	Injection Vials Made of Middle Borosilicate Glass Tubing YBB00292005-2-2015		2023-02-14
		7	Water Durability on Internal Surface	Injection Vials Made of Middle Borosilicate Glass Tubing YBB00292005-2-2015		2023-02-14
		8	Internal Stress	Injection Vials Made of Middle Borosilicate Glass Tubing YBB00292005-2-2015		2023-02-14
		9	Heat Durability	Injection Vials Made of Middle Borosilicate Glass Tubing YBB00292005-2-2015		2023-02-14
		10	Freeze Durability	Injection Vials Made of Middle Borosilicate Glass Tubing YBB00292005-2-2015		2023-02-14
		11	Lixiviate Amount of As、Sb、Pb、Cd	Injection Vials Made of Middle Borosilicate Glass Tubing YBB00292005-2-2015	Except for "As"	2023-02-14
		12	Deviation of Vertical Axis	Injection Vials Made of Middle Borosilicate Glass Tubing YBB00292005-2-2015		2023-02-14
9	Injection Vials Made of High Borosilicate Glass Tubing	1	Partial Parameters	Injection Vials Made of High Borosilicate Glass Tubing YBB00292005-1-2015	Except for "As"	2023-02-14
		2	Appearance	Injection Vials Made of High Borosilicate Glass Tubing YBB00292005-1-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Injection Vials Made of High Borosilicate Glass Tubing YBB00292005-1-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	B2O3 Content	Injection Vials Made of High Borosilicate Glass Tubing YBB00292005-1-2015		2023-02-14
		5	121℃ Water Durability of Pellets	Injection Vials Made of High Borosilicate Glass Tubing YBB00292005-1-2015		2023-02-14
		6	98℃ Water Durability of Pellets	Injection Vials Made of High Borosilicate Glass Tubing YBB00292005-1-2015		2023-02-14
		7	Water Durability on Internal Surface	Injection Vials Made of High Borosilicate Glass Tubing YBB00292005-1-2015		2023-02-14
		8	Internal Stress	Injection Vials Made of High Borosilicate Glass Tubing YBB00292005-1-2015		2023-02-14
		9	Heat Durability	Injection Vials Made of High Borosilicate Glass Tubing YBB00292005-1-2015		2023-02-14
		10	Freeze Durability	Injection Vials Made of High Borosilicate Glass Tubing YBB00292005-1-2015		2023-02-14
		11	Lixiviate Amount of As、Sb、Pb、Cd	Injection Vials Made of High Borosilicate Glass Tubing YBB00292005-1-2015	Except for "As"	2023-02-14
		12	Deviation of Vertical Axis	Injection Vials Made of High Borosilicate Glass Tubing YBB00292005-1-2015		2023-02-14
10	Injecion Vials Made of Moulded Soda Lime Glass	1	Partial Parameters	Injecion Vials Made of Moulded Soda Lime Glass YBB00312002-2015	Except for "As"	2023-02-14
		2	Appearance	Injecion Vials Made of Moulded Soda Lime Glass YBB00312002-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Injecion Vials Made of Moulded Soda Lime Glass YBB00312002-2015		2023-02-14
		4	Joint Line	Injecion Vials Made of Moulded Soda Lime Glass YBB00312002-2015		2023-02-14
		5	121℃ Water Durability of Pellets	Injecion Vials Made of Moulded Soda Lime Glass YBB00312002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Water Durability on Internal Surface	Injecion Vials Made of Moulded Soda Lime Glass YBB00312002-2015		2023-02-14
		7	Thermal Shock Durability	Injecion Vials Made of Moulded Soda Lime Glass YBB00312002-2015		2023-02-14
		8	Internal Pressure Durability	Injecion Vials Made of Moulded Soda Lime Glass YBB00312002-2015		2023-02-14
		9	Internal Stress	Injecion Vials Made of Moulded Soda Lime Glass YBB00312002-2015		2023-02-14
		10	Lixiviate Amount of As、Sb、Pb、Cd	Injecion Vials Made of Moulded Soda Lime Glass YBB00312002-2015	Except for "As"	2023-02-14
		11	Deviation of Vertical Axis	Injecion Vials Made of Moulded Soda Lime Glass YBB00312002-2015		2023-02-14
11	Injection Vials Made of Moulded Low Borosilicate Glass	1	Partial Parameters	Injection Vials Made of Moulded Low Borosilicate Glass YBB00322003-2015	Except for "As"	2023-02-14
		2	Appearance	Injection Vials Made of Moulded Low Borosilicate Glass YBB00322003-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Injection Vials Made of Moulded Low Borosilicate Glass YBB00322003-2015		2023-02-14
		4	B2O3 Content	Injection Vials Made of Moulded Low Borosilicate Glass YBB00322003-2015		2023-02-14
		5	Joint Line	Injection Vials Made of Moulded Low Borosilicate Glass YBB00322003-2015		2023-02-14
		6	121℃ Water Durability of Pellets	Injection Vials Made of Moulded Low Borosilicate Glass YBB00322003-2015		2023-02-14
		7	Water Durability on Internal Surface	Injection Vials Made of Moulded Low Borosilicate Glass YBB00322003-2015		2023-02-14
		8	Thermal Shock Durability	Injection Vials Made of Moulded Low Borosilicate Glass YBB00322003-2015		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Internal Pressure Durability	Injection Vials Made of Moulded Low Borosilicate Glass YBB00322003-2015		2023-02-14
		10	Internal Stress	Injection Vials Made of Moulded Low Borosilicate Glass YBB00322003-2015		2023-02-14
		11	Lixiviate Amount of As、Sb、Pb、Cd	Injection Vials Made of Moulded Low Borosilicate Glass YBB00322003-2015	Except for "As"	2023-02-14
		12	Deviation of Vertical Axis	Injection Vials Made of Moulded Low Borosilicate Glass YBB00322003-2015		2023-02-14
12	Injection Vials Made of Moulded Middle Borosilicate Glass	1	Partial Parameters	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015	Except for "As"	2023-02-14
		2	Appearance	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015		2023-02-14
		4	B2O3 Content	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015		2023-02-14
		5	Joint Line	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015		2023-02-14
		6	121℃ Water Durability of Pellets	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015		2023-02-14
		7	98℃ Water Durability of Pellets	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015		2023-02-14
		8	Water Durability on Internal Surface	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015		2023-02-14
		9	Thermal Shock Durability	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015		2023-02-14
		10	Internal Pressure Durability	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Internal Stress	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015		2023-02-14
		12	Lixiviate Amount of As、Sb、Pb、Cd	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015	Except for "As"	2023-02-14
		13	Deviation of Vertical Axis	Injection Vials Made of Moulded Middle Borosilicate Glass YBB00062005-2-2015		2023-02-14
13	Oral Liquid Bottles Made of Soda Lime Glass Tubing	1	Partial Parameters	Oral Liquid Bottles Made of Soda Lime Glass Tubing YBB00032004-2015	Except for "As"	2023-02-14
		2	Appearance	Oral Liquid Bottles Made of Soda Lime Glass Tubing YBB00032004-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Oral Liquid Bottles Made of Soda Lime Glass Tubing YBB00032004-2015		2023-02-14
		4	121℃ Water Durability of Pellets	Oral Liquid Bottles Made of Soda Lime Glass Tubing YBB00032004-2015		2023-02-14
		5	Water Durability on Internal Surface	Oral Liquid Bottles Made of Soda Lime Glass Tubing YBB00032004-2015		2023-02-14
		6	Internal Stress	Oral Liquid Bottles Made of Soda Lime Glass Tubing YBB00032004-2015		2023-02-14
		7	Lixiviate Amount of As、Sb、Pb、Cd	Oral Liquid Bottles Made of Soda Lime Glass Tubing YBB00032004-2015	Except for "As"	2023-02-14
		8	Deviation of Vertical Axis	Oral Liquid Bottles Made of Soda Lime Glass Tubing YBB00032004-2015		2023-02-14
14	Oral Liquid Bottles Made of Low Borosilicate Glass Tubing	1	Partial Parameters	Oral Liquid Bottles Made of Low Borosilicate Glass Tubing YBB00282002-2015	Except for "As"	2023-02-14
		2	Appearance	Oral Liquid Bottles Made of Low Borosilicate Glass Tubing YBB00282002-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Oral Liquid Bottles Made of Low Borosilicate Glass Tubing YBB00282002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	B2O3 Content	Oral Liquid Bottles Made of Low Borosilicate Glass Tubing YBB00282002-2015		2023-02-14
		5	121℃ Water Durability of Pellets	Oral Liquid Bottles Made of Low Borosilicate Glass Tubing YBB00282002-2015		2023-02-14
		6	Water Durability on Internal Surface	Oral Liquid Bottles Made of Low Borosilicate Glass Tubing YBB00282002-2015		2023-02-14
		7	Internal Stress	Oral Liquid Bottles Made of Low Borosilicate Glass Tubing YBB00282002-2015		2023-02-14
		8	Lixiviate Amount of As、Sb、Pb、Cd	Oral Liquid Bottles Made of Low Borosilicate Glass Tubing YBB00282002-2015	Except for "As"	2023-02-14
		9	Deviation of Vertical Axis	Oral Liquid Bottles Made of Low Borosilicate Glass Tubing YBB00282002-2015		2023-02-14
15	Oral Liquid Bottles Made of Borosilicate Glass Tubing	1	Partial Parameters	Oral Liquid Bottles Made of Borosilicate Glass Tubing YBB00022004-2015	Except for "As"	2023-02-14
		2	Appearance	Oral Liquid Bottles Made of Borosilicate Glass Tubing YBB00022004-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Oral Liquid Bottles Made of Borosilicate Glass Tubing YBB00022004-2015		2023-02-14
		4	B2O3 Content	Oral Liquid Bottles Made of Borosilicate Glass Tubing YBB00022004-2015		2023-02-14
		5	121℃ Water Durability of Pellets	Oral Liquid Bottles Made of Borosilicate Glass Tubing YBB00022004-2015		2023-02-14
		6	Water Durability on Internal Surface	Oral Liquid Bottles Made of Borosilicate Glass Tubing YBB00022004-2015		2023-02-14
		7	Internal Stress	Oral Liquid Bottles Made of Borosilicate Glass Tubing YBB00022004-2015		2023-02-14
		8	Lixiviate Amount of As、Sb、Pb、Cd	Oral Liquid Bottles Made of Borosilicate Glass Tubing YBB00022004-2015	Except for "As"	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Deviation of Vertical Axis	Oral Liquid Bottles Made of Borosilicate Glass Tubing YBB00022004-2015		2023-02-14
16	Medicinal Bottles Made of Moulded Soda Lime Glass	1	Partial Parameters	Medicinal Bottles Made of Moulded Soda Lime Glass YBB00272002-2015	Except for "As"	2023-02-14
		2	Appearance	Medicinal Bottles Made of Moulded Soda Lime Glass YBB00272002-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Medicinal Bottles Made of Moulded Soda Lime Glass YBB00272002-2015		2023-02-14
		4	Joint Line	Medicinal Bottles Made of Moulded Soda Lime Glass YBB00272002-2015		2023-02-14
		5	121℃ Water Durability of Pellets	Medicinal Bottles Made of Moulded Soda Lime Glass YBB00272002-2015		2023-02-14
		6	Water Durability on Internal Surface	Medicinal Bottles Made of Moulded Soda Lime Glass YBB00272002-2015		2023-02-14
		7	Thermal Shock Durability	Medicinal Bottles Made of Moulded Soda Lime Glass YBB00272002-2015		2023-02-14
		8	Internal Stress	Medicinal Bottles Made of Moulded Soda Lime Glass YBB00272002-2015		2023-02-14
		9	Lixiviate Amount of As、Sb、Pb、Cd	Medicinal Bottles Made of Moulded Soda Lime Glass YBB00272002-2015	Except for "As"	2023-02-14
		10	Deviation of Vertical Axis	Medicinal Bottles Made of Moulded Soda Lime Glass YBB00272002-2015		2023-02-14
		11	Brimful Capacity	Medicinal Bottles Made of Moulded Soda Lime Glass YBB00272002-2015		2023-02-14
17	Medicinal Bottles Made of Moulded Low	1	Partial Parameters	Medicinal Bottles Made of Moulded Low Borosilicate Glass YBB00302003-2015	Except for "As"	2023-02-14
		2	Appearance	Medicinal Bottles Made of Moulded Low Borosilicate Glass YBB00302003-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	Borosilicate Glass	3	Coefficient of Linear Thermal Expansion	Medicinal Bottles Made of Moulded Low Borosilicate Glass YBB00302003-2015		2023-02-14
		4	B2O3 Content	Medicinal Bottles Made of Moulded Low Borosilicate Glass YBB00302003-2015		2023-02-14
		5	Joint Line	Medicinal Bottles Made of Moulded Low Borosilicate Glass YBB00302003-2015		2023-02-14
		6	121℃ Water Durability of Pellets	Medicinal Bottles Made of Moulded Low Borosilicate Glass YBB00302003-2015		2023-02-14
		7	Water Durability on Internal Surface	Medicinal Bottles Made of Moulded Low Borosilicate Glass YBB00302003-2015		2023-02-14
		8	Thermal Shock Durability	Medicinal Bottles Made of Moulded Low Borosilicate Glass YBB00302003-2015		2023-02-14
		9	Internal Stress	Medicinal Bottles Made of Moulded Low Borosilicate Glass YBB00302003-2015		2023-02-14
		10	Lixiviate Amount of As、Sb、Pb、Cd	Medicinal Bottles Made of Moulded Low Borosilicate Glass YBB00302003-2015	Except for "As"	2023-02-14
		11	Deviation of Vertical Axis	Medicinal Bottles Made of Moulded Low Borosilicate Glass YBB00302003-2015		2023-02-14
		12	Brimful Capacity	Medicinal Bottles Made of Moulded Low Borosilicate Glass YBB00302003-2015		2023-02-14
18	Medicinal Botttles Made of Moulded Borosilicate Glass	1	Part Parameters	Medicinal Botttles Made of Moulded Borosilicate Glass YBB00052004-2015	Except for "As"	2023-02-14
		2	Appearance	Medicinal Botttles Made of Moulded Borosilicate Glass YBB00052004-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Medicinal Botttles Made of Moulded Borosilicate Glass YBB00052004-2015		2023-02-14
		4	B2O3 Content	Medicinal Botttles Made of Moulded Borosilicate Glass YBB00052004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Joint Line	Medicinal Botttles Made of Moulded Borosilicate Glass YBB00052004-2015		2023-02-14
		6	121℃Water Durability of Pellets	Medicinal Botttles Made of Moulded Borosilicate Glass YBB00052004-2015		2023-02-14
		7	Water Durability on Internal Surface	Medicinal Botttles Made of Moulded Borosilicate Glass YBB00052004-2015		2023-02-14
		8	Thermal Shock Durability	Medicinal Botttles Made of Moulded Borosilicate Glass YBB00052004-2015		2023-02-14
		9	Internal Stress	Medicinal Botttles Made of Moulded Borosilicate Glass YBB00052004-2015		2023-02-14
		10	Lixiviate Amount of As、Sb、Pb、Cd	Medicinal Botttles Made of Moulded Borosilicate Glass YBB00052004-2015	Except for "As"	2023-02-14
		11	Deviation of Vertical Axis	Medicinal Botttles Made of Moulded Borosilicate Glass YBB00052004-2015		2023-02-14
		12	Brimful Capacity	Medicinal Botttles Made of Moulded Borosilicate Glass YBB00052004-2015		2023-02-14
19	Medicinal Bottles Made of Soda Lime Glass Tubing	1	Part Parameters	Medicinal Bottles Made of Soda Lime Glass Tubing YBB00362003-2015	Except for "As"	2023-02-14
		2	Appearance	Medicinal Bottles Made of Soda Lime Glass Tubing YBB00362003-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Medicinal Bottles Made of Soda Lime Glass Tubing YBB00362003-2015		2023-02-14
		4	121℃Water Durability of Pellets	Medicinal Bottles Made of Soda Lime Glass Tubing YBB00362003-2015		2023-02-14
		5	Water Durability on Internal Surface	Medicinal Bottles Made of Soda Lime Glass Tubing YBB00362003-2015		2023-02-14
		6	Thermal Shock Durability	Medicinal Bottles Made of Soda Lime Glass Tubing YBB00362003-2015		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Internal Stress	Medicinal Bottles Made of Soda Lime Glass Tubing YBB00362003-2015		2023-02-14
		8	Lixiviate Amount of As、Sb、Pb、Cd	Medicinal Bottles Made of Soda Lime Glass Tubing YBB00362003-2015	Except for "As"	2023-02-14
		9	Deviation of Vertical Axis	Medicinal Bottles Made of Soda Lime Glass Tubing YBB00362003-2015		2023-02-14
20	Medicinal Bottles Made of Low Borosilicate Glass Tubing	1	Part Parameters	Medicinal Bottles Made of Low Borosilicate Glass Tubing YBB00352003-2015	Except for "As"	2023-02-14
		2	Appearance	Medicinal Bottles Made of Low Borosilicate Glass Tubing YBB00352003-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Medicinal Bottles Made of Low Borosilicate Glass Tubing YBB00352003-2015		2023-02-14
		4	B2O3 Content	Medicinal Bottles Made of Low Borosilicate Glass Tubing YBB00352003-2015		2023-02-14
		5	121℃Water Durability of Pellets	Medicinal Bottles Made of Low Borosilicate Glass Tubing YBB00352003-2015		2023-02-14
		6	Water Durability on Internal Surface	Medicinal Bottles Made of Low Borosilicate Glass Tubing YBB00352003-2015		2023-02-14
		7	Thermal Shock Durability	Medicinal Bottles Made of Low Borosilicate Glass Tubing YBB00352003-2015		2023-02-14
		8	Internal Stress	Medicinal Bottles Made of Low Borosilicate Glass Tubing YBB00352003-2015		2023-02-14
		9	Lixiviate Amount of As、Sb、Pb、Cd	Medicinal Bottles Made of Low Borosilicate Glass Tubing YBB00352003-2015	Except for "As"	2023-02-14
		10	Deviation of Vertical Axis	Medicinal Bottles Made of Low Borosilicate Glass Tubing YBB00352003-2015		2023-02-14
21	Medicinal Botttles Made of Borosilicate	1	Part Parameters	Medicinal Botttles Made of Borosilicate Glass Tubing YBB00042004-2015	Except for "As"	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	Glass Tubing	2	Appearance	Medicinal Botttles Made of Borosilicate Glass Tubing YBB00042004-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Medicinal Botttles Made of Borosilicate Glass Tubing YBB00042004-2015		2023-02-14
		4	B2O3 Content	Medicinal Botttles Made of Borosilicate Glass Tubing YBB00042004-2015		2023-02-14
		5	121℃Water Durability of Pellets	Medicinal Botttles Made of Borosilicate Glass Tubing YBB00042004-2015		2023-02-14
		6	Water Durability on Internal Surface	Medicinal Botttles Made of Borosilicate Glass Tubing YBB00042004-2015		2023-02-14
		7	Thermal Shock Durability	Medicinal Botttles Made of Borosilicate Glass Tubing YBB00042004-2015		2023-02-14
		8	Internal Stress	Medicinal Botttles Made of Borosilicate Glass Tubing YBB00042004-2015		2023-02-14
		9	Lixiviate Amount of As、Sb、Pb、Cd	Medicinal Botttles Made of Borosilicate Glass Tubing YBB00042004-2015	Except for "As"	2023-02-14
		10	Deviation of Vertical Axis	Medicinal Botttles Made of Borosilicate Glass Tubing YBB00042004-2015		2023-02-14
22	Pharamaceutical Tube Made of Soda Lime Glass	1	Part Parameters	Pharamaceutical Tube Made of Soda Lime Glass YBB00282003-2015	Except for "As"	2023-02-14
		2	Crack	Pharamaceutical Tube Made of Soda Lime Glass YBB00282003-2015		2023-02-14
		3	Air Line	Pharamaceutical Tube Made of Soda Lime Glass YBB00282003-2015		2023-02-14
		4	Calculus	Pharamaceutical Tube Made of Soda Lime Glass YBB00282003-2015		2023-02-14
		5	Knot	Pharamaceutical Tube Made of Soda Lime Glass YBB00282003-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Accurate and Pointed、Fillet in Pipe End	Pharamaceutical Tube Made of Soda Lime Glass YBB00282003-2015		2023-02-14
		7	Coefficient of Linear Thermal Expansion	Pharamaceutical Tube Made of Soda Lime Glass YBB00282003-2015		2023-02-14
		8	Deviation of Outer Diameter	Pharamaceutical Tube Made of Soda Lime Glass YBB00282003-2015		2023-02-14
		9	Deviation of Wall Thickness、Skewness of Wall Thicknes	Pharamaceutical Tube Made of Soda Lime Glass YBB00282003-2015		2023-02-14
		10	Straightness	Pharamaceutical Tube Made of Soda Lime Glass YBB00282003-2015		2023-02-14
		11	121℃Water Durability of Pellets	Pharamaceutical Tube Made of Soda Lime Glass YBB00282003-2015		2023-02-14
		12	Lixiviate Amount of As、Sb、Pb、Cd	Pharamaceutical Tube Made of Soda Lime Glass YBB00282003-2015	Except for "As"	2023-02-14
23	Pharamaceutical Tube Made of Low Borosilicate Glass	1	Part Parameters	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015	Except for "As"	2023-02-14
		2	Crack	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015		2023-02-14
		3	Air Line	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015		2023-02-14
		4	Calculus	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015		2023-02-14
		5	Knot	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015		2023-02-14
		6	Accurate and Pointed、Fillet in	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Pipe End			
		7	Coefficient of Linear Thermal Expansion	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015		2023-02-14
		8	B2O3 Content	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015		2023-02-14
		9	Deviation of Outer Diameter	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015		2023-02-14
		10	Deviation of Wall Thickness、Skewness of Wall Thicknes	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015		2023-02-14
		11	Straightnes	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015		2023-02-14
		12	121℃Water Durability of Pellets	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015		2023-02-14
		13	Lixiviate Amount of As、Sb、Pb、Cd	Pharamaceutical Tube Made of Low Borosilicate Glass YBB00272003-2015	Except for "As"	2023-02-14
24	Pharamaceutical Tube Made of Middle Borosilicate Glass	1	Part Parameters	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015	Except for "As"	2023-02-14
		2	Crack	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015		2023-02-14
		3	Air Line	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015		2023-02-14
		4	Calculus	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015		2023-02-14
		5	Knot	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Accurate and Pointed、Fillet in Pipe End	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015		2023-02-14
		7	Coefficient of Linear Thermal Expansion	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015		2023-02-14
		8	B2O3 Content	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015		2023-02-14
		9	Deviation of Outer Diameter	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015		2023-02-14
		10	Deviation of Wall Thickness、Skewness of Wall Thicknes	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015		2023-02-14
		11	Straightness	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015		2023-02-14
		12	121℃Water Durability of Pellets	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015		2023-02-14
		13	98℃Water Durability of Pellets	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015		2023-02-14
		14	Lixiviate Amount of As、Sb、Pb、Cd	Pharamaceutical Tube Made of Middle Borosilicate Glass YBB00012005-2-2015	Except for "As"	2023-02-14
25	Pharamaceutical Tube Made of High Borosilicate Glass	1	Part Parameters	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015	Except for "As"	2023-02-14
		2	Crack	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015		2023-02-14
		3	Air Line	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015		2023-02-14
		4	Calculus	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Knot	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015		2023-02-14
		6	Accurate and Pointed、Fillet in Pipe End	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015		2023-02-14
		7	Coefficient of Linear Thermal Expansion	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015		2023-02-14
		8	B2O3 Content	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015		2023-02-14
		9	Deviation of Outer Diameter	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015		2023-02-14
		10	Deviation of Wall Thickness、Skewness of Wall Thicknes	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015		2023-02-14
		11	Straightness	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015		2023-02-14
		12	121℃Water Durability of Pellets	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015		2023-02-14
		13	98℃Water Durability of Pellets	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015		2023-02-14
		14	Lixiviate Amount of As、Sb、Pb、Cd	Pharamaceutical Tube Made of High Borosilicate Glass YBB00012005-1-2015	Except for "As"	2023-02-14
26	Ceramic Bottles for Oral Solid Preparation	1	Part Parameters	Ceramic Bottles for Oral Solid Preparation YBB00162005-2015	Except for "Water Absorption "	2023-02-14
		2	Appearance	Ceramic Bottles for Oral Solid Preparation YBB00162005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Lixiviate Amount of As、Sb、Pb、Cd	Ceramic Bottles for Oral Solid Preparation YBB00162005-2015		2023-02-14
		4	Microbial Limit	Ceramic Bottles for Oral Solid Preparation YBB00162005-2015		2023-02-14
27	Aluminium Foil for Medicine	1	All Parameters	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		2	Appearance	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		3	Pinhole Degree	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		4	Water Vapor Transit Dose	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		5	Sealing Strength in Bond Coat	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		6	Bond of Maskant	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		7	Heat Resistance of Maskant	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		8	Discrepancy of Adhesive Coating Weight	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		9	Uncoiled Property	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		10	Sealing Strength of Fractur	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		11	Fluorescent Material	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		12	Volatile Matter	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		13	Readily Oxidizable Substance	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Heavy Metal	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		15	Microbial Limit	Aluminium Foil for Medicine YBB00152002-2015		2023-02-14
		16	Abnormal toxicity	Aluminum Foils for Medicine YBB00152002-2015		2023-02-14
28	Aluminium Tube for Ointment	1	Part Parameters	Aluminium Tube for Ointment YBB00162002-2015	Except for Under Continuity	2023-02-14
		2	Appearance	Aluminium Tube for Ointment YBB00162002-2015		2023-02-14
		3	Flexibility and Adhesion in Coating	Aluminium Tube for Ointment YBB00162002-2015		2023-02-14
		4	Pipe Cooperated with Cap	Aluminium Tube for Ointment YBB00162002-2015		2023-02-14
		5	Tail Coat Uniformity	Aluminium Tube for Ointment YBB00162002-2015		2023-02-14
		6	Closure	Aluminium Tube for Ointment YBB00162002-2015		2023-02-14
		7	Undercoat Chemical Stability	Aluminium Tube for Ointment YBB00162002-2015		2023-02-14
		8	Tenacity	Aluminium Tube for Ointment YBB00162002-2015		2023-02-14
		9	Microbial Limit	Aluminium Tube for Ointment YBB00162002-2015		2023-02-14
		10	Sterility	Aluminium Tube for Ointment YBB00162002-2015		2023-02-14
		11	Abnormal toxicity	Aluminium Tube for Ointment YBB00162002-2015		2023-02-14
		12	Primary skin irritation test	Aluminium Tube for Ointment YBB00162002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
29	Aluminium Caps for Injection Bottles	1	All Parameters	Aluminium Caps for Injection Bottles YBB00082005-2015		2023-02-14
		2	Appearance	Aluminium Caps for Injection Bottles YBB00082005-2015		2023-02-14
		3	Aluminum Material Mechanical Property	Aluminium Caps for Injection Bottles YBB00082005-2015		2023-02-14
		4	Flange	Aluminium Caps for Injection Bottles YBB00082005-2015		2023-02-14
		5	Opening Force	Aluminium Caps for Injection Bottles YBB00082005-2015		2023-02-14
		6	Sterilization Resistant	Aluminium Caps for Injection Bottles YBB00082005-2015		2023-02-14
		7	Cooperation	Aluminium Caps for Injection Bottles YBB00082005-2015		2023-02-14
		8	Coating Firmness	Aluminium Caps for Injection Bottles YBB00082005-2015		2023-02-14
30	Aluminium Caps for Infusion Bottles	1	All Parameters	Aluminium Caps for Infusion Bottles YBB00092005-2015		2023-02-14
		2	Appearance	Aluminium Caps for Infusion Bottles YBB00092005-2015		2023-02-14
		3	Aluminum Material Mechanical Property	Aluminium Caps for Infusion Bottles YBB00092005-2015		2023-02-14
		4	Flange	Aluminium Caps for Infusion Bottles YBB00092005-2015		2023-02-14
		5	Opening Force	Aluminium Caps for Infusion Bottles YBB00092005-2015		2023-02-14
		6	Sterilization Resistant	Aluminium Caps for Infusion Bottles YBB00092005-2015		2023-02-14
		7	Cooperation	Aluminium Caps for Infusion Bottles YBB00092005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Coating Firmness	Aluminium Caps for Infusion Bottles YBB00092005-2015		2023-02-14
31	Aluminium Tearing Caps for Oral Liquid Preparation Bottles	1	All Parameters	Aluminium Tearing Caps for Oral Liquid Preparation Bottles YBB00382003-2015		2023-02-14
		2	Appearance	Aluminium Tearing Caps for Oral Liquid Preparation Bottles YBB00382003-2015		2023-02-14
		3	Aluminum Material Mechanical Property	Aluminium Tearing Caps for Oral Liquid Preparation Bottles YBB00382003-2015		2023-02-14
		4	Flange	Aluminium Tearing Caps for Oral Liquid Preparation Bottles YBB00382003-2015		2023-02-14
		5	Tear Force	Aluminium Tearing Caps for Oral Liquid Preparation Bottles YBB00382003-2015		2023-02-14
		6	Cooperation	Aluminium Tearing Caps for Oral Liquid Preparation Bottles YBB00382003-2015		2023-02-14
		7	Coating Firmness	Aluminium Tearing Caps for Oral Liquid Preparation Bottles YBB00382003-2015		2023-02-14
32	LDPE Infusion Bottles	1	Part Parameters	LDPE Infusion Bottles YBB00012002-2015	Except for "Additive"	2023-02-14
		2	Appearance	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		3	Infrared Spectrum	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		4	Density	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		5	Thermal Adaptability	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		6	Anti-to Drop	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		7	Transparency	LDPE Infusion Bottles YBB00012002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Insoluble Particle	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		9	Puncture Force	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		10	Impermeability in Puncture Part	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		11	Hanging Force	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		12	Water Vapor Transit Dose	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		13	Luminousness	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		14	Residue on Ignition	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		15	Cu	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		16	Cd	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		17	Cr	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		18	Pb	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		19	Sn	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		20	Ba	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		21	Clarity	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		22	Colour	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		23	Amount of PH	LDPE Infusion Bottles YBB00012002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		24	Absorbance	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		25	Readily Oxidizable Substance	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		26	Nonvolatile Matter	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		27	Heavy Metal	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		28	Ammonium Ion	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		29	Barium Ion	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		30	Cuprum Ion	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		31	Cadmium Ion	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		32	Plumbum Ion	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		33	Stannum Ion	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		34	Chromium Ion	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		35	Aluminum Ion	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		36	Bacterial Endotoxin	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		37	Cellular Toxicity	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		38	Intracutaneous Reactivity	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		39	Sensitization on Skin	LDPE Infusion Bottles YBB00012002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		40	Acute Systemic Toxic	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
		41	Hemolysis	LDPE Infusion Bottles YBB00012002-2015		2023-02-14
33	PP Infusion Bottles	1	All Parameters	PP Infusion Bottles YBB00022002-2015		2023-02-14
		2	Appearance	PP Infusion Bottles YBB00022002-2015		2023-02-14
		3	Infrared Spectrum	PP Infusion Bottles YBB00022002-2015		2023-02-14
		4	Density	PP Infusion Bottles YBB00022002-2015		2023-02-14
		5	Thermal Adaptability	PP Infusion Bottles YBB00022002-2015		2023-02-14
		6	Anti-to Drop	PP Infusion Bottles YBB00022002-2015		2023-02-14
		7	Transparency	PP Infusion Bottles YBB00022002-2015		2023-02-14
		8	Insoluble Particle	PP Infusion Bottles YBB00022002-2015		2023-02-14
		9	Puncture Force	PP Infusion Bottles YBB00022002-2015		2023-02-14
		10	Impermeability in Puncture Part	PP Infusion Bottles YBB00022002-2015		2023-02-14
		11	Hanging Force	PP Infusion Bottles YBB00022002-2015		2023-02-14
		12	Water Vapor Transit Dose	PP Infusion Bottles YBB00022002-2015		2023-02-14
		13	Luminousness	PP Infusion Bottles YBB00022002-2015		2023-02-14
		14	Residue on Ignition	PP Infusion Bottles YBB00022002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Cu	PP Infusion Bottles YBB00022002-2015		2023-02-14
		16	Cd	PP Infusion Bottles YBB00022002-2015		2023-02-14
		17	Cr	PP Infusion Bottles YBB00022002-2015		2023-02-14
		18	Pb	PP Infusion Bottles YBB00022002-2015		2023-02-14
		19	Sn	PP Infusion Bottles YBB00022002-2015		2023-02-14
		20	Ba	PP Infusion Bottles YBB00022002-2015		2023-02-14
		21	Clarity	PP Infusion Bottles YBB00022002-2015		2023-02-14
		22	Colour	PP Infusion Bottles YBB00022002-2015		2023-02-14
		23	Amount of PH	PP Infusion Bottles YBB00022002-2015		2023-02-14
		24	Absorbance	PP Infusion Bottles YBB00022002-2015		2023-02-14
		25	Readily Oxidizable Substance	PP Infusion Bottles YBB00022002-2015		2023-02-14
		26	Nonvolatile Matter	PP Infusion Bottles YBB00022002-2015		2023-02-14
		27	Heavy Metal	PP Infusion Bottles YBB00022002-2015		2023-02-14
		28	Ammonium Ion	PP Infusion Bottles YBB00022002-2015		2023-02-14
		29	Barium Ion	PP Infusion Bottles YBB00022002-2015		2023-02-14
		30	Cuprum Ion	PP Infusion Bottles YBB00022002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		31	Cadmium Ion	PP Infusion Bottles YBB00022002-2015		2023-02-14
		32	Plumbum Ion	PP Infusion Bottles YBB00022002-2015		2023-02-14
		33	Stannum Ion	PP Infusion Bottles YBB00022002-2015		2023-02-14
		34	Chromium Ion	PP Infusion Bottles YBB00022002-2015		2023-02-14
		35	Aluminum Ion	PP Infusion Bottles YBB00022002-2015		2023-02-14
		36	Bacterial Endotoxin	PP Infusion Bottles YBB00022002-2015		2023-02-14
		37	Cellular Toxicity	PP Infusion Bottles YBB00022002-2015		2023-02-14
		38	Intracutaneous Reactivity	PP Infusion Bottles YBB00022002-2015		2023-02-14
		39	Sensitization on Skin	PP Infusion Bottles YBB00022002-2015		2023-02-14
		40	Acute Systemic Toxic	PP Infusion Bottles YBB00022002-2015		2023-02-14
		41	Hemolysis	PP Infusion Bottles YBB00022002-2015		2023-02-14
34	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull）	1	All Parameters	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		2	Outer Cap:Appearance	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		3	Outer Cap:Pull-tab Opening Force	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		4	Out Cap:Sealing in Pull-tab Shear Mark	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Outer Cap:Readily Oxidizable Substance	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		6	Outer Cap:Nonvolatile Matter	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		7	Outer Cap:Heavy Metal	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		8	Inner Cap:Appearance	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		9	Inner Cap:Infrared Spectrum	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		10	Inner Cap:Density	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		11	Inner Cap:Insoluble Particle	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		12	Inner Cap:Residue on Ignition	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		13	Inner Cap:Cu	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		14	Inner Cap:Cd	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		15	Inner Cap:Cr	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		16	Inner Cap:Pb	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		17	Inner Cap:Sn	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	Inner Cap:Ba	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		19	Inner Cap:Clarity and Colour	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		20	Inner Cap:Amount of PH	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		21	Inner Cap:Absorbance	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		22	Inner Cap:Readily Oxidizable Substance	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		23	Inner Cap:Nonvolatile Matter	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		24	Inner Cap:Heavy Metal	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		25	Inner Cap:Ammonium Ion	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		26	Inner Cap:Barium Ion	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		27	Inner Cap:Cuprum Io	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		28	Inner Cap:Cadmium Ion	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		29	Inner Cap:Plumbum Ion	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		30	Inner Cap:Stannum Ion	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		31	Inner Cap:Chromium Ion	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		32	Inner Cap:Aluminum Ion	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		33	Inner Cap:Cellular Toxicity	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		34	Inner Cap:Hemolysis	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		35	Combinational Cap:Appearance	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		36	Combinational Cap:Thermal Adaptability	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		37	Combinational Cap:Puncture Force	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		38	Combinational Cap:Puncture Exfoliation	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		39	Combinational Cap:Dynamic Retentivity of Puncture Outfit	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		40	Combinational Cap:Static Retentivity of Puncture Outfit	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		41	Combinational Cap:Sealing on Inject Medicine	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Point			
		42	Combinational Cap:Bacterial Endotoxin	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		43	Intracutaneous Reactivity	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		44	Sensitization on Skin	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
		45	Acute Systemic Toxic	Combinational Closures of PP for Plastic Infusion Containers （with ring-pull） YBB00242004-2015		2023-02-14
35	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion	1	All Parameters	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		2	Appearance	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		3	Identify	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		4	Thermal Adaptability	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		5	Anti-to Drop	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		6	Transparency	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		7	Insoluble Particle	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		8	Puncture Outfit Retentivity and Impermeability on Insertion Point	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Sealing on Inject Medicine Point	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		10	Suspension Force	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		11	Water Vapor Transit Dose	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		12	Oxygen Transit Dose	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		13	Nitrogen Transit Dose	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		14	Tensile Strength	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		15	Heating Strength	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		16	Luminousness	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		17	Residue on Ignition	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		18	Cu	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		19	Cd	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		20	Cr	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		21	Pb	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		22	Sn	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		23	Ba	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		24	Clarity	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		25	Colour	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		26	Amount of PH	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		27	Absorbance	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		28	Readily Oxidizable Substance	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		29	Nonvolatile Matter	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		30	Heavy Metal	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		31	Ammonium Ion	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		32	Barium Ion	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		33	Cuprum Ion	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		34	Cadmium Ion	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		35	Plumbum Ion	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		36	Stannum Ion	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		37	Chromium Io	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		38	Plumbum Ion	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		39	Bacterial Endotoxin	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		40	Cellular Toxicity	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		41	puncture force	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		42	Intracutaneous Reactivity	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		43	Sensitization on Skin	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		44	Acute Systemic Toxic	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
		45	Hemolysis	General Requirement for Multi-layer Co-extrusion Film and Bag for Infusion YBB00342002-2015		2023-02-14
36	3-layer Co-extrusion Film (I) and Bag for Infusion	1	All Parameters	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		2	Appearance	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		3	Microscopic Features	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		4	Infrared Spectrum	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		5	Thermal Adaptability	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		6	Anti-to Drop	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		7	Transparency	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		8	Insoluble Particle	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Puncture Force	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		10	Puncture Outfit Retentivity and Impermeability on Insertion Point	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		11	Sealing on Inject Medicine Point	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		12	Hanging Force	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		13	Water Vapor Transit Dose	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		14	Oxygen Transit Dose	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		15	Nitrogen Transit Dose	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		16	Tensile Strength	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		17	Heating Strength	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		18	Luminousness	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		19	Residue on Ignition	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		20	Cu	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		21	Cd	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		22	Cr	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Pb	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		24	Sn	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		25	Ba	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		26	Clarity	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		27	Colour	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		28	Amount of PH	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		29	Absorbance	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		30	Readily Oxidizable Substance	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		31	Nonvolatile Matter	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		32	Heavy Metal	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		33	Ammonium Ion	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		34	Barium Ion	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		35	Cuprum Ion	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		36	Cadmium Ion	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		37	Plumbum Ion	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		38	Stannum Ion	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		39	Chromium Ion	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		40	Plumbum Ion	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		41	Froth Test	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		42	Bacterial Endotoxin	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		43	Cellular Toxicity	3-layer Co-extrusion Film (I) and Bag for Infusion YBB00102005-2015		2023-02-14
		44	Intracutaneous Reactivity	3-layer Co-extrusion Film（I） and Bag for Infusion YBB00102005-2015		2023-02-14
		45	Sensitization on Skin	3-layer Co-extrusion Film（I） and Bag for Infusion YBB00102005-2015		2023-02-14
		46	Acute Systemic Toxic	3-layer Co-extrusion Film（I） and Bag for Infusion YBB00102005-2015		2023-02-14
		47	Hemolysis	3-layer Co-extrusion Film（I） and Bag for Infusion YBB00102005-2015		2023-02-14
37	5-layer Co-extrusion Film (I) and Bag for Infusion	1	All Parameters	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		2	Appearance	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		3	Microscopic Features	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		4	Infrared Spectrum	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		5	Thermal Adaptability	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Anti-to Drop	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		7	Transparency	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		8	Insoluble Particle	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		9	Puncture Force	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		10	Puncture Outfit Retentivity and Impermeability on Insertion Point	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		11	Sealing on Inject Medicine Point	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		12	Hanging Force	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		13	Water Vapor Transit Dose	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		14	Oxygen Transit Dose	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		15	Nitrogen Transit Dose	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		16	Tensile Strength	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		17	Heating Strength	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		18	Luminousness	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		19	Residue on Ignition	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		20	Cu	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		21	Cd	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		22	Cr	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		23	Pb	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		24	Sn	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		25	Ba	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		26	Clarity	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		27	Colour	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		28	Amount of PH	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		29	Absorbance	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		30	Readily Oxidizable Substance	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		31	Nonvolatile Matter	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		32	Heavy Metal	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		33	Ammonium Ion	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		34	Barium Ion	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		35	Cuprum Ion	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		36	Cadmium Ion	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		37	Plumbum Ion	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		38	Stannum Ion	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		39	Chromium Ion	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		40	Aluminum Ion	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		41	Froth Test	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		42	Bacterial Endotoxin	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		43	Cellular Toxicity Test	5-layer Co-extrusion Film (I) and Bag for Infusion YBB00112005-2015		2023-02-14
		44	Intracutaneous Reactivity	3-layer Co-extrusion Film（I） and Bag for Infusion YBB00112005-2015		2023-02-14
		45	Sensitization on Skin	3-layer Co-extrusion Film（I） and Bag for Infusion YBB00112005-2015		2023-02-14
		46	Acute Systemic Toxic	3-layer Co-extrusion Film（I） and Bag for Infusion YBB00112005-2015		2023-02-14
		47	Hemolysis	3-layer Co-extrusion Film（I） and Bag for Infusion YBB00112005-2015		2023-02-14
38	LDPE Bottles for Eye Drops	1	All Parameters	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		2	Appearance	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Infrared Spectrum	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		4	Density	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		5	Sealing	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		6	Amount of Drip Out	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		7	Visible Foreign Matter	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		8	Clarity	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		9	Variation of ph Values	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		10	Absorbance	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		11	Readily Oxidizable Substance	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		12	Nonvolatile Matter	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		13	Heavy Metal	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		14	Residue on Ignition	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		15	Nonvolatile Matter of N-Hexane	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		16	Decoloration Test	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		17	Microbial Limit	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		18	Sterility	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	Abnormal toxicity	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
		20	Ophthalmic Irritancy test	LDPE Bottles for Eye Drops YBB00062002-2015		2023-02-14
39	PP Bottles for Eye Drops	1	All Parameters	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		2	Appearance	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		3	Infrared Spectrum	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		4	Density	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		5	Sealing	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		6	Amount of Drip Out	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		7	Visible Foreign Matter	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		8	Clarity	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		9	Variation of ph Values	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		10	Absorbance	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		11	Readily Oxidizable Substance	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		12	Nonvolatile Matter	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		13	Heavy Metal	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		14	Residue on Ignition	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Nonvolatile Matter of N-Hexane	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		16	Decoloration Test	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		17	Microbial Limit	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		18	Sterility	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		19	Abnormal toxicity	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
		20	Ophthalmic Irritancy test	PP Bottles for Eye Drops YBB00072002-2015		2023-02-14
40	PP Bottles for Oral Liquid Preparation	1	All Parameters	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		2	Appearance	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		3	Infrared Spectrum	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		4	Density	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		5	Sealing	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		6	Anti-to Drop	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		7	Water Vapor Transit Dose	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		8	Residue on Ignition	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		9	Clarity	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		10	Variation of ph Values	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Absorbance	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		12	Readily Oxidizable Substance	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		13	Nonvolatile Matter	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		14	Heavy Metal	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		15	Decoloration Test	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		16	Microbial Limit	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
		17	Abnormal toxicity	PP Bottles for Oral Liquid Preparation YBB00082002-2015		2023-02-14
41	HDPE Bottles for Oral Liquid Preparation	1	All Parameters	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		2	Appearance	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		3	Infrared Spectrum	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		4	Density	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		5	Sealing	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		6	Anti-to Drop	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		7	Water Vapor Transit Dose	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		8	Residue on Ignition	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		9	Clarity	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Variation of ph Values	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		11	Absorbance	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		12	Readily Oxidizable Substance	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		13	Nonvolatile Matter	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		14	Heavy Metal	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		15	Decoloration Test	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		16	Microbial Limit	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
		17	Abnormal toxicity	HDPE Bottles for Oral Liquid Preparation YBB00092002-2015		2023-02-14
42	PET Bottles for Oral Liquid Preparation	1	Part Parameters	PET Bottles for Oral Liquid Preparation YBB00102002-2015	Except for Acetaldehyde	2023-02-14
		2	Appearance	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		3	Infrared Spectrum	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		4	Density	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		5	Sealing	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		6	Anti-to Drop	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		7	Water Vapor Transit Dose	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Residue on Ignition	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		9	Clarity	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		10	Variation of ph Values	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		11	Absorbance	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		12	Readily Oxidizable Substance	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		13	Nonvolatile Matter	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		14	Heavy Metal	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		15	Decoloration Test	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		16	Microbial Limit	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
		17	Abnormal toxicity	PET Bottles for Oral Liquid Preparation YBB00102002-2015		2023-02-14
43	HDPE Bottles for Topical Liquid Preparation	1	All Parameters	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		2	Appearance	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		3	Infrared Spectrum	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		4	Density	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		5	Sealing	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Anti-to Drop	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		7	Water Vapor Transit Dose	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		8	Ethyl Alcohol Transit Dose	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		9	Oil Pierced Capacity	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		10	Residue on Ignition	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		11	Clarity	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		12	Absorbance of Water Provided Test	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		13	Absorbance of Ethyl Alcohol Provided Test	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		14	Variation of ph Values	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		15	Readily Oxidizable Substance	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		16	Nonvolatile Matter	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		17	Heavy Metal	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		18	Decoloration Test	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		19	Microbial Limit	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		20	Sterility	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		21	Abnormal toxicity	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
		22	Derma irritancy	HDPE Bottles for Topical Liquid Preparation YBB00392003-2015		2023-02-14
44	PP Bottles for Oral Solid Preparation	1	All Parameters	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14
		2	Appearance	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14
		3	Infrared Spectrum	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14
		4	Density	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14
		5	Sealing	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14
		6	Vibration Test	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14
		7	Water Vapor Transit Dose	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14
		8	Residue on Ignition	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14
		9	Readily Oxidizable Substance	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14
		10	Nonvolatile Matter	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14
		11	Heavy Metal	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14
		12	Microbial Limit	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14
		13	Abnormal toxicity	PP Bottles for Oral Solid Preparation YBB00112002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
45	HDPE Bottles for Oral Solid Preparation	1	All Parameters	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
		2	Appearance	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
		3	Infrared Spectrum	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
		4	Density	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
		5	Sealing	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
		6	Vibration Test	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
		7	Water Vapor Transit Dose	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
		8	Residue on Ignition	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
		9	Readily Oxidizable Substance	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
		10	Nonvolatile Matter	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
		11	Heavy Metal	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
		12	Microbial Limit	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
		13	Abnormal toxicity	HDPE Bottles for Oral Solid Preparation YBB00122002-2015		2023-02-14
46	PP Bottles for Oral Solid Preparation	1	Part Parameters	PP Bottles for Oral Solid Preparation YBB00262002-2015	Except for Acetaldehyde	2023-02-14
		2	Appearance	PP Bottles for Oral Solid Preparation YBB00262002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Infrared Spectrum	PP Bottles for Oral Solid Preparation YBB00262002-2015		2023-02-14
		4	Density	PP Bottles for Oral Solid Preparation YBB00262002-2015		2023-02-14
		5	Sealing	PP Bottles for Oral Solid Preparation YBB00262002-2015		2023-02-14
		6	Vibration Test	PP Bottles for Oral Solid Preparation YBB00262002-2015		2023-02-14
		7	Water Vapor Transit Dose	PP Bottles for Oral Solid Preparation YBB00262002-2015		2023-02-14
		8	Residue on Ignition	PP Bottles for Oral Solid Preparation YBB00262002-2015		2023-02-14
		9	Readily Oxidizable Substance	PP Bottles for Oral Solid Preparation YBB00262002-2015		2023-02-14
		10	Nonvolatile Matter	PP Bottles for Oral Solid Preparation YBB00262002-2015		2023-02-14
		11	Heavy Metal	PP Bottles for Oral Solid Preparation YBB00262002-2015		2023-02-14
		12	Microbial Limit	PP Bottles for Oral Solid Preparation YBB00262002-2015		2023-02-14
		13	Abnormal toxicity	PET Bottles for Oral Solid Preparation YBB00262002-2015		2023-02-14
47	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation	1	Part Parameters	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015	Except for As	2023-02-14
		2	Appearance	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		3	Infrared Spectrum	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		4	Density	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		5	Residue on Ignition	Moistureproof Combinational Closures of LDPE for Oral Solid		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Preparation YBB00172004-2015		
		6	Silica Gel	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		7	Molecular Sieve	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		8	Silica Gel:Molecular Sieve(4:6)Mixture	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		9	Desiccant Saturation Hygroscopicity	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		10	Desiccant Short-term Hygroscopicity	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		11	Anti-to Drop	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		12	Pb	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		13	Fluorescence Inspection	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		14	Decoloration Test	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		15	Readily Oxidizable Substance	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		16	Nonvolatile Matter	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		17	Heavy Metal	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		18	Microbial Limit	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	oaperboard moisture content	Moistureproof Combinational Closures of LDPE for Oral Solid Preparation YBB00172004-2015		2023-02-14
		20	Abnormal toxicity	Moistureproof Combinational Closures of LDPE for Oral Soild prepatation YBB00172004-2015		2023-02-14
48	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging	1	All Parameters	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		2	Appearance	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		3	Infrared Spectrum	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		4	Water Vapor Transit Dose	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		5	Oxygen Transit Dose	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		6	Peeled Strength of Inner Layer with Second Inner Layer	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		7	Sealing Strength of Compound Pocket	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		8	Solvent Residual Quantity	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		9	Pressure Durability Property of Bag	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		10	Drop Property of Bag	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		11	Readily Oxidizable Substance	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		12	Nonvolatile Matter	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Heavy Metal	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		14	Microbial Limit	General Requirement for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
		15	Abnormal toxicity	General Requirement for Laminated Films and Pouchers for Pharmaceutical Packaging YBB00132002-2015		2023-02-14
49	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging	1	All Parameters	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		2	Appearance	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		3	Infrared Spectrum	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		4	Water Vapor Transit Dose	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		5	Oxygen Transit Dose	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		6	Peeled Strength of PE Layer with Al Layer	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		7	Sealing Strength	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		8	Solvent Residual Quantity	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		9	Pressure Durability Property of Bag	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		10	Drop Property of Bag	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		11	Readily Oxidizable Substance	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Nonvolatile Matter	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		13	Heavy Metal	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		14	Microbial Limit	Laminated Films and Pouches （PET/AL/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
		15	Abnormal toxicity	Laminated Films and Pouchers（PET/Al/PE） for Pharmaceutical Packaging YBB00172002-2015		2023-02-14
50	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging	1	All Prameters	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		2	Appearance	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		3	Infrared Spectrum	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		4	Water Vapor Transit Dose	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		5	Oxygen Transit Dose	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		6	Peeled Strength of PET Layer with LDPE Layer	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		7	Sealing Strength	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		8	Solvent Residual Quantity	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		9	Pressure Durability Property of Bag	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		10	Drop Property of Bag	Laminated Films and Pouches （PET/LDPE） for		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Pharmaceutical Packaging YBB00182002-2015		
		11	Readily Oxidizable Substance	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		12	Nonvolatile Matter	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		13	Heavy Metal	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		14	Microbial Limit	Laminated Films and Pouches （PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
		15	Abnormal toxicity	Laminated Films and Pouchers（PET/LDPE） for Pharmaceutical Packaging YBB00182002-2015		2023-02-14
51	Laminated Films and Pouches （BOPP/LDPE） for Pharmaceutical Packaging	1	All Parameters	Laminated Films and Pouches （BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		2	Appearance	Laminated Films and Pouches （BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		3	Infrared Spectrum	Laminated Films and Pouches （BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		4	Water Vapor Transit Dose	Laminated Films and Pouches （BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		5	Oxygen Transit Dose	Laminated Films and Pouches （BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		6	Peeled Strength of BOPP Layer with LDPE Layer	Laminated Films and Pouches （BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		7	Sealing Strength	Laminated Films and Pouches （BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		8	Solvent Residual Quantity	Laminated Films and Pouches （BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Pressure Durability Property of Bag	Laminated Films and Pouches（BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		10	Drop Property of Bag	Laminated Films and Pouches（BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		11	Readily Oxidizable Substance	Laminated Films and Pouches（BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		12	Nonvolatile Matter	Laminated Films and Pouches（BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		13	Heavy Metal	Laminated Films and Pouches（BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		14	Microbial Limit	Laminated Films and Pouches（BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
		15	Abnormal toxicity	Laminated Films and Pouchers（BOPP/LDPE） for Pharmaceutical Packaging YBB00192002-2015		2023-02-14
52	Laminated Film and Pouches(BOPP /VMCPP)for Pharmaceutical Packaging	1	All Parameters	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		2	Appearance	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		3	Infrared Spectrum	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		4	Water Vapor Transit Dose	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		5	Oxygen Transit Dose	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		6	Peeled Strength of BOPP Layer with VMCPP Layer	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		7	Sealing Strength	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Solvent Residual Quantity	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		9	Pressure Durability Property of Bag	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		10	Drop Property of Bag	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		11	Readily Oxidizable Substance	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		12	Nonvolatile Matter	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		13	Heavy Metal	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		14	Microbial Limit	Laminated Film and Pouches(BOPP/VMCPP)for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
		15	Abnormal toxicity	Laminated Films and Pouchers（BOPP/VMCPP） for Pharmaceutical Packaging YBB00192004-2015		2023-02-14
53	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging	1	All Parameters	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		2	Appearance	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		3	Infrared Spectrum	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		4	Water Vapor Transit Dose	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		5	Oxygen Transit Dose	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		6	Peeled Strength of AL Layer with PE Layer	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Sealing Strength	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		8	Solvent Residual Quantity	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		9	Pressure Durability Property of Bag	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		10	Drop Property of Bag	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		11	Readily Oxidizable Substance	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		12	Nonvolatile Matter	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		13	Heavy Metal	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		14	Microbial Limit	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
		15	Abnormal toxicity	Laminated Film and Pouches(PT/Al/PE)for Pharmaceutical Packaging YBB00202004-2015		2023-02-14
54	PVC Sheet for Solid Preparation	1	All Parameters	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		2	Appearance	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		3	Infrared Spectrum	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		4	Density	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		5	Water Vapor Transit Dose	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		6	Oxygen Transit Dose	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Tensile Strength	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		8	Shock Durability	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		9	Calefaction Flex Rate	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		10	Sealing Strength	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		11	Chloroethylene Monocase	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		12	Clarity	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		13	Readily Oxidizable Substance	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		14	Nonvolatile Matter	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		15	Heavy Metal	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		16	Ba	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		17	Microbial Limit	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
		18	Abnormal toxicity	PVC Sheet for Solid Preparation YBB00212005-2015		2023-02-14
55	PVC/LDPE Composite Sheet for Solid Preparation	1	All Parameters	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		2	Appearance	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		3	Infrared Spectrum	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		4	Water Vapor Transit	PVC/LDPE Composite Sheet for Solid Preparation		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Dose	YBB00232005-2015		
		5	Oxygen Transit Dose	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		6	Tensile Strength	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		7	Shock Durability	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		8	Calefaction Flex Rate	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		9	Sealing Strength	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		10	Solvent Residual Quantity	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		11	Chloroethylene Monocase	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		12	Clarity	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		13	Readily Oxidizable Substance	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		14	Nonvolatile Matter	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		15	Heavy Metal	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		16	Microbial Limit	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
		17	Abnormal toxicity	PVC/LDPE Composite Sheet for Solid Preparation YBB00232005-2015		2023-02-14
56	PVC/PVDC Composite	1	All Parameters	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	Sheet for Solid Preparation	2	Appearance	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		3	Infrared Spectrum	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		4	Colour Reaction	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		5	Coating Weight of PVDC	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		6	Water Vapor Transit Dose	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		7	Oxygen Transit Dose	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		8	Tensile Strength	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		9	Shock Durability	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		10	Calefaction Flex Rate	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		11	Sealing Strength	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		12	Solvent Residual Quantity	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		13	Chloroethylene Monocase	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		14	Vinylidene Chloride Monocase	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		15	Clarity	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		16	Readily Oxidizable Substance	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	Nonvolatile Matter	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		18	Heavy Metal	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		19	Microbial Limit	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
		20	Abnormal toxicity	PVC/PVDC Composite Sheet for Solid Preparation YBB00222005-2015		2023-02-14
57	Al/PE Cold-formed Foil for Solid Preparation	1	All Parameters	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		2	Appearance	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		3	Identify	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		4	Water Vapor Transit Dose	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		5	Oxygen Transit Dose	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		6	Peeled Strength	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		7	Sealing Strength	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		8	Bond of Maskant	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		9	Heat Resistance of Maskant	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		10	Height of Raised Top	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		11	Solvent Residual Quantity	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Readily Oxidizable Substance	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		13	Nonvolatile Matter	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		14	Heavy Metal	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		15	Microbial Limit	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
		16	Abnormal toxicity	Al/PE Cold-formed Foil for Solid Preparation YBB00182004-2015		2023-02-14
58	PVC/PE/PVDC Composite Sheet for Solid Preparation	1	All Parameters	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		2	Appearance	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		3	Infrared Spectrum	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		4	Colour Reaction	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		5	Coating Weight of PVDC	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		6	Water Vapor Transit Dose	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		7	Oxygen Transit Dose	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		8	Tensile Strength	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		9	Shock Durability	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		10	Calefaction Flex Rate	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Heating Strength	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		12	Solvent Residual Quantity	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		13	Chloroethylene Monocase	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		14	Vinylidene Chloride Monocase	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		15	Clarity	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		16	Readily Oxidizable Substance	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		17	Nonvolatile Matte	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		18	Heavy Metal	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		19	Microbial Limit	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
		20	Abnormal toxicity	PVC/PE/PVDC Composite Sheet for Solid Preparation YBB00202005-2015		2023-02-14
59	PA/Al/PVC Cold-formed Foil for Solid Preparation	1	All Parameters	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14
		2	Appearance	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14
		3	Infrared Spectrum	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14
		4	Water Vapor Transit Dose	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14
		5	Oxygen Transit Dose	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Peeled Strength	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14
		7	Sealing Strength	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14
		8	Chloroethylene Monocase	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14
		9	Readily Oxidizable Substance	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14
		10	Nonvolatile Matte	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14
		11	Heavy Metal	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14
		12	Microbial Limit	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14
		13	Abnormal toxicity	PA/Al/PVC Cold-formed Foil for Solid Preparation YBB00242002-2015		2023-02-14
60	Aluminium-plastics Combination Caps for Antibiotics Bottles	1	All Parameters	Aluminium-plastics Combination Caps for Antibiotics Bottles YBB00372003-2015		2023-02-14
		2	Appearance	Aluminium-plastics Combination Caps for Antibiotics Bottles YBB00372003-2015		2023-02-14
		3	Aluminum Material Mechanical Property	Aluminium-plastics Combination Caps for Antibiotics Bottles YBB00372003-2015		2023-02-14
		4	Flange	Aluminium-plastics Combination Caps for Antibiotics Bottles YBB00372003-2015		2023-02-14
		5	Remove Strength of Plastomer	Aluminium-plastics Combination Caps for Antibiotics Bottles YBB00372003-2015		2023-02-14
		6	Tear Force of Teared Slice（ZD or OD with Al	Aluminium-plastics Combination Caps for Antibiotics Bottles YBB00372003-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Teared Slice）			
		7	Mass in Opened Part	Aluminium-plastics Combination Caps for Antibiotics Bottles YBB00372003-2015		2023-02-14
		8	Cooperation	Aluminium-plastics Combination Caps for Antibiotics Bottles YBB00372003-2015		2023-02-14
		9	Sterilization Resistant	Aluminium-plastics Combination Caps for Antibiotics Bottles YBB00372003-2015		2023-02-14
		10	Coating Firmness	Aluminium-plastics Combination Caps for Antibiotics Bottles YBB00372003-2015		2023-02-14
61	Aluminium-plastics Combination Caps for Infusion Bottles	1	All Parameters	Aluminium-plastics Combination Caps for Infusion Bottles YBB00402003-2015		2023-02-14
		2	Appearance	Aluminium-plastics Combination Caps for Infusion Bottles YBB00402003-2015		2023-02-14
		3	Aluminum Material Mechanical Property	Aluminium-plastics Combination Caps for Infusion Bottles YBB00402003-2015		2023-02-14
		4	Flange	Aluminium-plastics Combination Caps for Infusion Bottles YBB00402003-2015		2023-02-14
		5	Remove Strength of Plastomer	Aluminium-plastics Combination Caps for Infusion Bottles YBB00402003-2015		2023-02-14
		6	Tear Force of Teared Slice（ZD Teared Slice）	Aluminium-plastics Combination Caps for Infusion Bottles YBB00402003-2015		2023-02-14
		7	Mass in Opened Part	Aluminium-plastics Combination Caps for Infusion Bottles YBB00402003-2015		2023-02-14
		8	Cooperation	Aluminium-plastics Combination Caps for Infusion Bottles YBB00402003-2015		2023-02-14
		9	Sterilization Resistant	Aluminium-plastics Combination Caps for Infusion Bottles YBB00402003-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Coating Firmness	Aluminium-plastics Combination Caps for Infusion Bottles YBB00402003-2015		2023-02-14
62	General Requirement for Aluminium-plastics Foil Laminated Closure Liners for Pharmaceutical Packaging	1	Part Parameters	General Requirement for Aluminium-plastics Foil Laminated Closure Liners for Pharmaceutical Packaging YBB00212004-2015	Except for "As"	2023-02-14
		2	Appearance	General Requirement for Aluminium-plastics Foil Laminated Closure Liners for Pharmaceutical Packaging YBB00212004-2015		2023-02-14
		3		General Requirement for Aluminium-plastics Foil Laminated Closure Liners for Pharmaceutical Packaging YBB00212004-2015		2023-02-14
		4	Hyperthermia Separation Property	General Requirement for Aluminium-plastics Foil Laminated Closure Liners for Pharmaceutical Packaging YBB00212004-2015		2023-02-14
		5	Paperboard Fluorescence	General Requirement for Aluminium-plastics Foil Laminated Closure Liners for Pharmaceutical Packaging YBB00212004-2015		2023-02-14
		6	Pb	General Requirement for Aluminium-plastics Foil Laminated Closure Liners for Pharmaceutical Packaging YBB00212004-2015		2023-02-14
		7	Microbial Limit	General Requirement for Aluminium-plastics Foil Laminated Closure Liners for Pharmaceutical Packaging YBB00212004-2015		2023-02-14
63	Foil Laminated Closure Liners(PET/Al/PP)for Pharmaceutical Packaging	1	Part Parameters	Foil Laminated Closure Liners(PET/Al/PP)for Pharmaceutical Packaging YBB00132005-2015	Except for "As"	2023-02-14
		2	Appearance	Foil Laminated Closure Liners(PET/Al/PP)for Pharmaceutical Packaging YBB00132005-2015		2023-02-14
		3	Sealing Strength	Foil Laminated Closure Liners(PET/Al/PP)for Pharmaceutical Packaging YBB00132005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Hyperthermia Separation Property	Foil Laminated Closure Liners(PET/Al/PP)for Pharmaceutical Packaging YBB00132005-2015		2023-02-14
		5	Paperboard Fluorescence	Foil Laminated Closure Liners(PET/Al/PP)for Pharmaceutical Packaging YBB00132005-2015		2023-02-14
		6	Pb	Foil Laminated Closure Liners(PET/Al/PP)for Pharmaceutical Packaging YBB00132005-2015		2023-02-14
		7	Microbial Limit	Foil Laminated Closure Liners(PET/Al/PP)for Pharmaceutical Packaging YBB00132005-2015		2023-02-14
64	Foil Laminated Closure Liners(PET/Al/PET)for Pharmaceutical Packaging	1	Part Parameters	Foil Laminated Closure Liners(PET/Al/PET)for Pharmaceutical Packaging YBB00142005-2015	Except for "As"	2023-02-14
		2	Appearance	Foil Laminated Closure Liners(PET/Al/PET)for Pharmaceutical Packaging YBB00142005-2015		2023-02-14
		3	Sealing Strength	Foil Laminated Closure Liners(PET/Al/PET)for Pharmaceutical Packaging YBB00142005-2015		2023-02-14
		4	Hyperthermia Separation Property	Foil Laminated Closure Liners(PET/Al/PET)for Pharmaceutical Packaging YBB00142005-2015		2023-02-14
		5	Paperboard Fluorescence	Foil Laminated Closure Liners(PET/Al/PET)for Pharmaceutical Packaging YBB00142005-2015		2023-02-14
		6	Pb	Foil Laminated Closure Liners(PET/Al/PET)for Pharmaceutical Packaging YBB00142005-2015		2023-02-14
		7	Microbial Limit	Foil Laminated Closure Liners(PET/Al/PET)for Pharmaceutical Packaging YBB00142005-2015		2023-02-14
65	Foil Laminated Closure Liners(PET/Al/PE)for Pharmaceutical Packaging	1	Part Parameters	Foil Laminated Closure Liners(PET/Al/PE)for Pharmaceutical Packaging YBB00152005-2015	Except for "As"	2023-02-14
		2	Appearance	Foil Laminated Closure Liners(PET/Al/PE)for Pharmaceutical Packaging YBB00152005-2015		2023-02-14
		3	Sealing Strength	Foil Laminated Closure Liners(PET/Al/PE)for Pharmaceutical Packaging YBB00152005-2015		2023-02-14
		4	Hyperthermia Separation Property	Foil Laminated Closure Liners(PET/Al/PE)for Pharmaceutical Packaging YBB00152005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Paperboard Fluorescence	Foil Laminated Closure Liners(PET/Al/PE)for Pharmaceutical Packaging YBB00152005-2015		2023-02-14
		6	Pb	Foil Laminated Closure Liners(PET/Al/PE)for Pharmaceutical Packaging YBB00152005-2015		2023-02-14
		7	Microbial Limit	Foil Laminated Closure Liners(PET/Al/PE)for Pharmaceutical Packaging YBB00152005-2015		2023-02-14
66	Composite Tube(PE/Al/PE)for Ointment	1	All Parameters	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		2	Appearance	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		3	Infrared Spectrum	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		4	Pressure Durability Strength	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		5	Peeled Strength of Inner Layer with Second Inner Layer	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		6	Tensile Strength	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		7	Heating Strength in External Pipe	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		8	Heating Strength in Tail Pipe	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		9	Sealing	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		10	Water Vapor Transit Dose	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		11	Oxygen Transit Dose	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		12	Ethyl Alcohol Transit Dose	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Oil Pierced Capacity	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		14	Exposed Al in Welding Line	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		15	Absorbance	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		16	Readily Oxidizable Substance	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		17	Nonvolatile Matter	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		18	Heavy Metal	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		19	Microbial Limit	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		20	Sterility	Composite Tube(PE/Al/PE)for Ointment YBB00252005-2015		2023-02-14
		21	Abnormal toxicity	Composite Tube PE/Al/PE for Ointment YBB00252005-2015		2023-02-14
		22	Derma irritancy	Composite Tube PE/Al/PE for Ointment YBB00252005-2015		2023-02-14
67	LDPE Films and Pouches for Pharmaceutical Packaging	1	All Parameters	LDPE Films and Pouches for Pharmaceutical Packaging YBB00072005-2015		2023-02-14
		2	Appearance	LDPE Films and Pouches for Pharmaceutical Packaging YBB00072005-2015		2023-02-14
		3	Infrared Spectrum	LDPE Films and Pouches for Pharmaceutical Packaging YBB00072005-2015		2023-02-14
		4	Density	LDPE Films and Pouches for Pharmaceutical Packaging YBB00072005-2015		2023-02-14
		5	Tensile Strength	LDPE Films and Pouches for Pharmaceutical Packaging YBB00072005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Breakage Elongation	LDPE Films and Pouches for Pharmaceutical Packaging YBB00072005-2015		2023-02-14
		7	Heating Strength	LDPE Films and Pouches for Pharmaceutical Packaging YBB00072005-2015		2023-02-14
		8	Residue on Ignition	LDPE Films and Pouches for Pharmaceutical Packaging YBB00072005-2015		2023-02-14
		9	Readily Oxidizable Substance	LDPE Films and Pouches for Pharmaceutical Packaging YBB00072005-2015		2023-02-14
		10	Nonvolatile Matter	LDPE Films and Pouches for Pharmaceutical Packaging YBB00072005-2015		2023-02-14
		11	Heavy Metal	LDPE Films and Pouches for Pharmaceutical Packaging YBB00072005-2015		2023-02-14
		12	Microbial Limit	LDPE Films and Pouches for Pharmaceutical Packaging YBB00072005-2015		2023-02-14
		13	Abnormal toxicity	LDPE Films and Pouchers for Pharmaceutical Packaging YBB00072005-2015		2023-02-14
68	Halogenated Butyl Rubber Stopper for Injection	1	All Parameters	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		2	Appearance	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		3	Identify(1)	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		4	Identify(2)	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		5	Puncture Exfoliation	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		6	Puncture Force	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		7	Sealing and Retentivity of	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Puncture Outfit			
		8	Ash	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		9	Volatile Sulfide	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		10	Insoluble Particle	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		11	Clarity and Colour	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		12	Variation of ph Values	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		13	Absorbance	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		14	Readily Oxidizable Substance	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		15	Nonvolatile Matter	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		16	Heavy Metal	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		17	Ammonium Ion	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		18	Zinc Ion	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		19	Electric Conductivity	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
		20	Pyrogen	Halogenated Butyl Rubber Stopper for Injiection YBB00042005-2015		2023-02-14
		21	Acute Systemic Toxic	Halogenated Butyl Rubber Stopper for Injiection YBB00042005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	Hemolysis	Halogenated Butyl Rubber Stopper for Injection YBB00042005-2015		2023-02-14
69	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder	1	All Parameters	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		2	Appearance	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		3	Identify(1)	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		4	Identify(2)	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		5	Puncture Exfoliation	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		6	Sealing of Rubber Plug and Container	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		7	Self-Sealing Performance	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		8	Ash	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		9	Volatile Sulfide	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		10	Insoluble Particle	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		11	Clarity and Colour	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		12	Variation of ph Values	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		13	Absorbance	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		14	Readily Oxidizable Substance	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Nonvolatile Matter	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		16	Heavy Metal	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		17	Ammonium Ion	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		18	Electric Conductivity	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		19	puncture force	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		20	zinc ions	Halogenated Butyl Rubber Stopper for Injectable Sterile Powder YBB00052005-2015		2023-02-14
		21	Pyrogen	Halogenated Butyl Rubber Stopper for Injiection Sterile Powder YBB00052005-2015		2023-02-14
		22	Acute Systemic Toxic	Halogenated Butyl Rubber Stopper for Injiection Sterile Powder YBB00052005-2015		2023-02-14
		23	Hemolysis	Halogenated Butyl Rubber Stopper for Injiection Sterile Powder YBB00052005-2015		2023-02-14
70	Pharmaceutical Synthetic Polyisoprene Liners	1	All Parameters	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		2	Appearance	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		3	Identify	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		4	Puncture Exfoliation	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		5	Puncture Force	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		6	Sealing and Retentivity of	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Puncture Outfit			
		7	Ash	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		8	Volatile Sulfide	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		9	Clarity and Colour	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		10	Variation of ph Values	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		11	Absorbance	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		12	Readily Oxidizable Substance	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		13	Nonvolatile Matter	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		14	Heavy Metal	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		15	Ammonium Ion	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		16	Zinc Ion	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		17	Electric Conductivity	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		18	Pyrogen	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		19	Acute Systemic Toxic	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14
		20	Hemolysis	Pharmaceutical Synthetic Polyisoprene Liners YBB00232004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
71	Silicone Elastomer Closures and Liners for Oral preparation	1	All Parameters	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		2	Appearance	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		3	Infrared Spectrum	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		4	Density	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		5	Benzene-Containing Compound	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		6	Nonvolatile Matter of N-Hexane	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		7	Volatile Matter	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		8	Peroxide	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		9	Mineral Oil	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		10	Clarity and Colour	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		11	Variation of ph Values	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		12	Absorbance	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		13	Readily Oxidizable Substance	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		14	Nonvolatile Matter	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
		15	Heavy Metal	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Acute Systemic Toxic	Silicone Elastomer Closures and Liners for Oral preparation YBB00222004-2015		2023-02-14
72	Assemblages for Prefilled Syringes (with Stainless Steel Needles)	1	All Parameters	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		2	Appearance	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		3	Glass Syringe	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		4	Rubber Pistons	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		5	Entry Needle of Stainless Steel	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		6	Protective Cap of Needle	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		7	Connection Force of Needle and Needle File	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		8	Withdrawal Force of Protective Cap of Needle	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		9	Cooperation of Pistons with Putter	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		10	Pistons Lubricity	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		11	Smooth Property of Pistons	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		12	Container Sealing	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		13	Residual Quantity of Entry Needle	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Accuracy of Graded Capacity	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		15	Amount of Silicone Oil	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		16	Insoluble Particle	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		17	Residual Quantity of Oxirane	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		18	Bacterial Endotoxin	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		19	Sterility	Assemblages for Prefilled Syringes (with Stainless Steel Needles) YBB00112004-2015		2023-02-14
		20	Acute Systemic Toxic	Assemblages for prefilled syringes （with Stainless Steel Needles） YBB00112004-2015		2023-02-14
73	Borosilicate Glass Barrels for Prefilled Syringes	1	Part Parameters	Borosilicate Glass Barrels for Prefilled Syringes YBB00062004-2015	Except for "As"	2023-02-14
		2	Appearance	Borosilicate Glass Barrels for Prefilled Syringes YBB00062004-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Borosilicate Glass Barrels for Prefilled Syringes YBB00062004-2015		2023-02-14
		4	B2O3 Content	Borosilicate Glass Barrels for Prefilled Syringes YBB00062004-2015		2023-02-14
		5	121℃Water Durability of Pellets	Borosilicate Glass Barrels for Prefilled Syringes YBB00062004-2015		2023-02-14
		6	Water Durability on Internal Surface	Borosilicate Glass Barrels for Prefilled Syringes YBB00062004-2015		2023-02-14
		7	Internal Stress	Borosilicate Glass Barrels for Prefilled Syringes YBB00062004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Lixiviate Amount of As、Sb、Pb、Cd	Borosilicate Glass Barrels for Prefilled Syringes YBB00062004-2015	Except for "As"	2023-02-14
74	Stainless Steel Needles for Prefilled Syringes	1	All Parameters	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		2	Appearance	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		3	Rigidity	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		4	Tenacity	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		5	Corrosion Resistance	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		6	Foreign Matter on Internal Surface of Needle	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		7	Unobstructed Capactiy of Pinhole	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		8	Puncture Force of Needle Tip	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		9	Connection Force of Needle and Needle File	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		10	Withdrawal Force of Protective Cap of Needle	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		11	PH Value	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		12	Cadmium Ion	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Heavy Metal	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		14	Cellular Toxicity	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		15	Acute Systemic Toxic	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		16	Hemolysis	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		17	Intracutaneous Reactivity	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
		18	Sensitization	Stainless Steel Needles for Prefilled Syringes YBB00092004-2015		2023-02-14
75	Chlorobutyl Rubber Plungers for Prefilled Syringes	1	All Parameters	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		2	Appearance	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		3	Identify(1)	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		4	Identify(2)	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		5	Cooperation of Pistons with Putter	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		6	Pistons Lubricity	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		7	Smooth Property of Pistons	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		8	Container Sealing	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		9	Ash	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Volatile Sulfide	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		11	Clarity and Colour	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		12	Variation of ph Values	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		13	Absorbance	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		14	Readily Oxidizable Substance	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		15	Nonvolatile Matter	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		16	Heavy Metal	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		17	Ammonium Ion	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		18	Zinc Ion	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		19	Electric Conductivity	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		20	insoluble particles	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		21	Pyrogen	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		22	Acute Systemic Toxic	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
		23	Hemolysis	Chlorobutyl Rubber Plungers for Prefilled Syringes YBB00072004-2015		2023-02-14
	Bromobutyl Rubber	1	All Parameters	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	Plungers for Prefilled Syringes	2	Appearance	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		3	Identify(1)	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		4	Identify(2)	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		5	Cooperation of Pistons with Putter	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		6	Pistons Lubricity	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		7	Smooth Property of Pistons	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		8	Container Sealing	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		9	Ash	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		10	Volatile Sulfide	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		11	Insoluble Particle	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		12	Insoluble Particle	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		13	Variation of ph Values	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		14	Absorbance	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		15	Readily Oxidizable Substance	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		16	Nonvolatile Matter	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	Heavy Metal	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		18	Ammonium Ion	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		19	Zinc Ion	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		20	Electric Conductivity	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		21	Acute Systemic Toxic	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		22	Pyrogen	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
		23	Hemolysis	Bromobutyl Rubber Plungers for Prefilled Syringes YBB00082004-2015		2023-02-14
77	Polyisoprene Rubber Caps for Prefilled Syringe Needles	1	All Parameters	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		2	Appearance	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		3	Identify	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		4	Ash	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		5	Volatile Sulfide	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		6	Insoluble Particle	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		7	Variation of ph Values	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		8	Absorbance	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Readily Oxidizable Substance	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		10	Nonvolatile Matter	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		11	Heavy Metal	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		12	Ammonium Ion	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		13	Zinc Ion	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		14	Electric Conductivity	Polyisoprene Rubber Caps for Prefilled Syringe Needles YBB00102004-2015		2023-02-14
		15	Pyrogen	Polyisoprene Rubber Caps for Prefilled Syringes Needles YBB00102004-2015		2023-02-14
		16	Acute Systemic Toxic	Polyisoprene Rubber Caps for Prefilled Syringes Needles YBB00102004-2015		2023-02-14
		17	Hemolysis	Polyisoprene Rubber Caps for Prefilled Syringes Needles YBB00102004-2015		2023-02-14
78	Borosilicate Glass Beads for Pen-injectors	1	Part Parameters	Borosilicate Glass Beads for Pen-injectors YBB00122004-2015	Except for "As"	2023-02-14
		2	Appearance	Borosilicate Glass Beads for Pen-injectors YBB00122004-2015		2023-02-14
		3	Specification and Dimension	Borosilicate Glass Beads for Pen-injectors YBB00122004-2015		2023-02-14
		4	Coefficient of Linear Thermal Expansion	Borosilicate Glass Beads for Pen-injectors YBB00122004-2015		2023-02-14
		5	B2O3 Content	Borosilicate Glass Beads for Pen-injectors YBB00122004-2015		2023-02-14
		6	121℃Water	Borosilicate Glass Beads for Pen-injectors YBB00122004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Durability of Pellets			
		7	Heat Resistance	Borosilicate Glass Beads for Pen-injectors YBB00122004-2015		2023-02-14
		8	Lixiviate Amount of As、Sb、Pb、Cd	Borosilicate Glass Beads for Pen-injectors YBB00122004-2015	Except for "As"	2023-02-14
79	Borosilicate Glass Barrels for Pen-injectors	1	Part Parameters	Borosilicate Glass Barrels for Pen-injectors YBB00132004-2015	Except for "As"	2023-02-14
		2	Appearance	Borosilicate Glass Barrels for Pen-injectors YBB00132004-2015		2023-02-14
		3	Coefficient of Linear Thermal Expansion	Borosilicate Glass Barrels for Pen-injectors YBB00132004-2015		2023-02-14
		4	B2O3 Content	Borosilicate Glass Barrels for Pen-injectors YBB00132004-2015		2023-02-14
		5	Sealing Surface	Borosilicate Glass Barrels for Pen-injectors YBB00132004-2015		2023-02-14
		6	121℃Water Durability of Pellets	Borosilicate Glass Barrels for Pen-injectors YBB00132004-2015		2023-02-14
		7	Water Durability on Internal Surface	Borosilicate Glass Barrels for Pen-injectors YBB00132004-2015		2023-02-14
		8	Internal Stress	Borosilicate Glass Barrels for Pen-injectors YBB00132004-2015		2023-02-14
		9	Heat Resistance	Borosilicate Glass Barrels for Pen-injectors YBB00132004-2015		2023-02-14
		10	Lixiviate Amount of As、Sb、Pb、Cd	Borosilicate Glass Barrels for Pen-injectors YBB00132004-2015	Except for "As"	2023-02-14
80	Aluminium Caps for Pen-injectors	1	All Parameters	Aluminium Caps for Pen-injectors YBB00142004-2015		2023-02-14
		2	Appearance	Aluminium Caps for Pen-injectors YBB00142004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Cooperation	Aluminium Caps for Pen-injectors YBB00142004-2015		2023-02-14
		4	Sterilization Resistant	Aluminium Caps for Pen-injectors YBB00142004-2015		2023-02-14
		5	Coating Firmness	Aluminium Caps for Pen-injectors YBB00142004-2015		2023-02-14
		6	Adhesive Force of Rubber Mat	Aluminium Caps for Pen-injectors YBB00142004-2015		2023-02-14
81	Chlorobutyl Rubber Plungers and Liners for Pen-injectors	1	All Parameters	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		2	Appearance	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		3	Identify(1)	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		4	Identify(2)	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		5	Puncture Exfoliation	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		6	Leakage Test	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		7	Smooth Property of Pistons Test	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		8	Ash	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		9	Volatile Sulfide	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		10	Insoluble Particle	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		11	Clarity and Colour	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Variation of ph Values	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		13	Absorbance	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		14	Readily Oxidizable Substance	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		15	Nonvolatile Matter	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		16	Heavy Metal	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		17	Ammonium Ion	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		18	Zinc Ion	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		19	Electric Conductivity	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		20	Pyrogen	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		21	Acute Systemic Toxic	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
		22	Hemolysis	Chlorobutyl Rubber Plungers and Liners for Pen-injectors YBB00152004-2015		2023-02-14
82	Bromobutyl Rubber Plungers and Liners for Pen-injectors	1	All Parameters	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		2	Appearance	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		3	Identify(1)	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		4	Identify(2)	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Puncture Exfoliation	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		6	Leakage Test	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		7	Smooth Property of Pistons Test	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		8	Ash	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		9	Volatile Sulfide	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		10	Insoluble Particle	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		11	Clarity and Colour	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		12	Variation of ph Values	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		13	Absorbance	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		14	Readily Oxidizable Substance	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		15	Nonvolatile Matter	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		16	Heavy Metal	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		17	Ammonium Ion	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		18	Zinc Ion	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		19	Electric Conductivity	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		20	Pyrogen	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		21	Acute Systemic Toxic	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
		22	Hemolysis	Bromobutyl Rubber Plungers and Liners for Pen-injectors YBB00162004-2015		2023-02-14
83	Direct Contact with Drugs Packaging Materials and Containers	1	Infrared Spectrum of Packaging Materials	Test for Infrared Spectrum of Packaging Materials YBB00262004-2015	Except for Method II	2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4002		2023-02-14
		2	Insoluble Particulate Matter of Packaging Materials	Test for Insoluble Particulate Matter of Packaging Materials YBB00272004-2015		2023-02-14
		3	Thermal Ratio	Test for Thermal Ratio YBB00292004-2015		2023-02-14
		4	Volatile Sulfides	Determination of Volatile Sulfides YBB00302004-2015		2023-02-14
		5	Residual Solvent of Packaging Materials	Test for Residual Solvent of Packaging Materials YBB00312004-2015		2023-02-14
		6	Penetration Force of Injection Closures	Test for Penetration Force of Injection Closures YBB00322004-2015		2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4015		2023-02-14
		7	Fragmentation of Injection Closures	Test for Fragmentation of Injection Closures YBB00332004-2015		2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4016		2023-02-14
		8	Test and Classification for Hydrolytic	YBB00362004-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Resistance of Glass Grains at 98℃			
		9	Test for Release of Arsenic Antimony Lead and Cadmium	YBB00372004-2015	Except for "As"	2023-02-14
		10	Straightness	Test for Straightness YBB00392004-2015		2023-02-14
		11	Limits of Arsenic Antimony Lead and Cadmium Release from Medicinal Glass	Limits of Arsenic Antimony Lead and Cadmium Release from Medicinal Glass YBB00172005-2015	Except for "As"	2023-02-14
		12	Limits of Lead and Cadmium Release from Medicinal Ceramic Containers	Limits of Lead and Cadmium Release from Medicinal Ceramic Containers YBB00182005-2015		2023-02-14
		13	Lead and Cadmium Release from Medicinal Ceramic Containers	Test for Lead and Cadmium Release from Medicinal Ceramic Containers YBB00192005-2015		2023-02-14
		14	Residue of Ethylene Oxide	Test for Residue of Ethylene Oxide YBB00242005-2015		2023-02-14
		15	Ash for Rubber	Determination of Ash for Rubber YBB00262005-2015		2023-02-14
		16	Cytotoxicity	Test for Cytotoxicity YBB00012003-2015		2023-02-14
		17	Gas Transmission	Test for Gas Transmission YBB00082003-2015		2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4007		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	Water Transmission	Test for Water Transmission YBB00092003-2015	Except for Method II	2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4010		2023-02-14
		19	Peel Strength	Test for Peel Strength YBB00102003-2015		2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4004		2023-02-14
		20	Tensile Properties	Test for Tensile Properties YBB00112003-2015		2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4005		2023-02-14
		21	Welding Strength	Test for Welding Strength YBB00122003-2015		2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4008		2023-02-14
		22	Density	Test for Density YBB00132003-2015		2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4012		2023-02-14
		23	Determination of Vinyl Chloride Monomer	Determination of Vinyl Chloride Monomer YBB00142003-2015		2023-02-14
		24	Determination of Ethylene Dichloride	Determination of Ethylene Dichloride YBB00152003-2015		2023-02-14
		25	Stress	Test for Stress YBB00162003-2015		2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4003		2023-02-14
		26	Internal Pressure Resistance	Test for Internal Pressure Resistance YBB00172003-2015		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		27	Thermal Shock and Thermal Shock Endurance	Test for Thermal Shock and Thermal Shock Endurance YBB00182003-2015		2023-02-14
		28	Vertical Axis Deviation of Bottles	Test for Vertical Axis Deviation of Bottles YBB00192003-2015		2023-02-14
		29	Coefficient of Mean Linear Thermal Expansion	Test for Coefficient of Mean Linear Thermal Expansion YBB00202003-2015		2023-02-14
		30	Coefficient of Li near Thermal Expansion	Test for Coefficient of Li near Thermal Expansion YBB00212003-2015		2023-02-14
		31	Boron Oxide	Determination of Boron Oxide YBB00232003-2015		2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4009		2023-02-14
		32	Hydrolytic Resistance of Interior Surfaces at 121 ℃	Test and Classification for Hydrolytic Resistance of Interior Surfaces at 121 ℃ YBB00242003-2015		2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4006		2023-02-14
		33	Hydrolytic Resistance of Glass Grains at 121℃	Test and Classification for Hydrolytic Resistance of Glass Grains at 121℃ YBB00252003-2015		2023-02-14
				General Principles of the Chinese Pharmacopoeia 2020 Edition Volume IV 4001		2023-02-14
		34	Composition,Classification & Parameters of Medicinal Glass	Composition,Classification & Parameters of Medicinal Glass YBB00342003-2015		2023-02-14
Clean Room						
Clean Room						

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
1	Clean room (area)	1	cleanliness	Architectural technical code for hospital clean operating department GB50333-2013 13.3.11		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 E.4		2023-02-14
				Test method for airborne particles in clean room（zone）of the pharmaceutical industry GB/T 16292-2010 5 test rules		2023-02-14
				Test method for clean room to produce pharmaceutical parking materials YBB00412004-2015 Test method6		2023-02-14
				Architectural and technical code for biosafety laboratories GB50346-2011 10.2.7		2023-02-14
				Drug production quality management standard (revised in 2010) Drug production quality management standard (revised in 2010) chapter three		2023-02-14
		2	airborne microbe	Architectural technical code for hospital clean operating department GB50333-2013 13.3.18		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 E.8		2023-02-14
				Test method for airborne microbe in clean room（zone）of the pharmaceutical industry GB/T 16293-2010 5 test rules		2023-02-14
				Test method for clean room to produce pharmaceutical parking materials YBB00412004-2015 Test method 7		2023-02-14
				Drug production quality management standard (revised in 2010) Drug production quality management standard (revised in 2010) chapter three		2023-02-14
		3	settling microbe	Architectural technical code for hospital clean operating department GB50333-2013 13.3.18		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 E.8		2023-02-14
				Test method for settling microbe in clean room（zone）of the pharmaceutical industry GB/T 16294-2010 5 test rules		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Drug production quality management standard (revised in 2010) Drug production quality management standard (revised in 2010) chapter three		2023-02-14
				YBB00412004-2015 Test method 8		2023-02-14
		4	temperature	Architectural technical code for hospital clean operating department GB50333-2013 13.3.12		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 E.5		2023-02-14
				Test method for clean room to produce pharmaceutical parking materials YBB00412004-2015 Test method 1		2023-02-14
		5	humidity	Architectural technical code for hospital clean operating department GB50333-2013 13.3.12		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 E.5		2023-02-14
				Test method for clean room to produce pharmaceutical parking materials YBB00412004-2015 Test method 1		2023-02-14
		6	noise	Architectural technical code for hospital clean operating department GB50333-2013 13.3.13		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 E.6		2023-02-14
				Architectural and technical code for biosafety laboratories GB50346-2011 10.2.8		2023-02-14
				Class biological safety cabinets YY0569-2011 6.3.3		2023-02-14
		7	Intensity of illumination	Architectural technical code for hospital clean operating department GB50333-2013 13.3.14		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 E.7		2023-02-14
				Test method for clean room to produce pharmaceutical parking		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				materials YBB00412004-2015 Test method 9		
				Architectural and technical code for biosafety laboratories GB50346-2011 10.2.9		2023-02-14
				Class biological safety cabinets YY0569-2011 6.3.4		2023-02-14
		8	Wind speed	Architectural technical code for hospital clean operating department GB50333-2013 13.3.6,13.3.7,13.3.15		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 E.1		2023-02-14
				Test method for clean room to produce pharmaceutical parking materials YBB00412004-2015 Test method 2、3		2023-02-14
				Architectural and technical code for biosafety laboratories GB50346-2011 10.2.4/10.2.6/10.2.11/10.2.14		2023-02-14
		9	air volume	Architectural technical code for hospital clean operating department GB50333-2013 13.3.6,13.3.7		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 E.1		2023-02-14
				Test method for clean room to produce pharmaceutical parking materials YBB00412004-2015 Test method 2、3		2023-02-14
				Architectural and technical code for biosafety laboratories GB50346-2011 10.2.4/10.2.6/10.2.11/10.2.14		2023-02-14
		10	air changes	Architectural technical code for hospital clean operating department GB50333-2013 13.3.6,13.3.7,13.3.15		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 E.1		2023-02-14
				Test method for clean room to produce pharmaceutical parking materials YBB00412004-2015 Test method 2、3		2023-02-14
				Architectural and technical code for biosafety laboratories GB50346-2011 10.2.4/10.2.6/10.2.11/10.2.14		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Differential pressure	Architectural technical code for hospital clean operating department GB50333-2013 13.3.10		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 E.2		2023-02-14
				Test method for clean room to produce pharmaceutical parking materials YBB00412004-2015 Test method 5		2023-02-14
				Architectural and technical code for biosafety laboratories GB50346-2011 10.2.12		2023-02-14
		12	High efficiency filter leak detection	Architectural technical code for hospital clean operating department GB50333-2013 13.3.8		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 D		2023-02-14
				Architectural and technical code for biosafety laboratories GB50346-2011 10.2.10		2023-02-14
				Class biological safety cabinets YY0569-2011 6.3.2		2023-02-14
		13	Formaldehyde concentration	Architectural technical code for hospital clean operating department GB50333-2013 13.3.16		2023-02-14
				Code for construction and acceptance of cleanroom GB50591-2010 Appendix E.13		2023-02-14
		14	Total number of bacteria on worker's hand surface	Hygienic standard for disposable sanitary product GB 15979-2002 5.3		2023-02-14
		15	Total number of bacterial colony in air	Hygienic standard for disposable sanitary product GB 15979-2002 5.1		2023-02-14
		16	Total number of bacterial colonies on the surface of working table	Hygienic standard for disposable sanitary product GB 15979-2002 5.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	Air Flow Pattern	Test for Clean Rooms（Areas）Producing Pharmaceutical Packaging Materials YBB00412004-2015 4		2023-02-14
				Class Ⅱ biological safety cabinets YY 0569-2011 5.4.9		2023-02-14
				Code for construction and acceptance of cleanroom GB 50591-2010 Appendix E. 12		2023-02-14
Electromagnetic compatibility						
Electromagnetic compatibility						
1	Medical equipment	1	Marking on the outside of Equipment or Equipment parts	Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests IEC 60601-1-2：2007 5.1	Accrediation only for specific clients	2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 5.1		2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 5.1		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 IEC 60601-1-2：2004 6.1.201		2023-02-14
		2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT	Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 5.1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			parts			
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 IEC 60601-1-2：2004 6.8.2.201		2023-02-14
				5.2.1 5.2.1	Accrediation only for specific clients	2023-02-14
		3	Instructions for use	Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 5.2.1		2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 5.2.1		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 5.2.1		2023-02-14
		4	Technical description	Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests IEC 60601-1-2：2007 5.2.1	Accrediation only for specific clients	2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 5.2.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 5.2.2		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 IEC 60601-1-2：2004 6.8.3.201		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 5.2.2		2023-02-14
		5	Protection of radio services	Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 7.1		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests IEC 60601-1-2：2007 6.1.1	Except for: Insertion loss、Click、Loop antenna method、Disturbance power；Accrediation only for specific clients	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 7.1	Except for: Insertion loss、Click、Loop antenna method、Disturbance power.	2023-02-14
				36.201.1	Except for: Insertion loss、Click、Loop antenna method、Disturbance power.	2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 6.1.1	Except for: Insertion loss、Click、Loop antenna method、Disturbance power	2023-02-14
		6	Harmonic distortion	Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 7.2.1		
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 IEC 60601-1-2：2004 36.201.3.1		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests IEC 60601-1-2：2007 6.1.3.1	Accrediation only for specific clients	2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 7.2.1		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 6.1.3.1		2023-02-14
		7	Voltage fluctuations and flicker	Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests IEC 60601-1-2：2007 6.1.3.2	Accrediation only for specific clients	2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 7.2.2		2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 7.2.2		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 IEC 60601-1-2：2004 36.201.3.2		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 6.1.3.2		2023-02-14
		8	Immunity Test Levels	Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests IEC 60601-1-2：2007 6.2.1.1	Accrediation only for specific clients	2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 8.9		2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 8.9		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 IEC 60601-1-2：2004 36.202.1		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 6.2.1.1		2023-02-14
		9	Electrostatic discharge (ESD)	Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—	Accrediation only for	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Requirements and tests IEC 60601-1-2：2007 6.2.2	specific clients	
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 8.9		2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 8.9		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 IEC 60601-1-2：2004 36.202.2		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 6.2.2		2023-02-14
		10	Radiated RF electromagnetic fields	Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 8.9, 8.10		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests IEC 60601-1-2：2007 6.2.3	Accrediation only for specific clients	2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 8.9, 8.10		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 IEC 60601-1-2：2004 36.202.3		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 6.2.3		2023-02-14
		11	Electrical fast transients and bursts	Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests IEC 60601-1-2：2007 6.2.4	Accrediation only for specific clients	2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 8.9		2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 8.9		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 IEC 60601-1-2：2004 36.202.4		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 6.2.4		2023-02-14
		12	Surges	Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—	Accrediation only for	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Requirements and tests IEC 60601-1-2：2007 6.2.5	specific clients	
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 8.9		2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 8.9		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 IEC 60601-1-2：2004 36.202.5		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 6.2.5		2023-02-14
		13	Conducted disturbances, induced by RF fields	Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests IEC 60601-1-2：2007 6.2.6	Accrediation only for specific clients	2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 8.9		2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 8.9		2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 IEC 60601-1-2：2004 36.202.6		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 6.2.6		2023-02-14
		14	"Voltage dips, short interruptions and voltage variations on power supply input lines"	Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests IEC 60601-1-2：2007 6.2.7	Accrediation only for specific clients	2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 8.9		2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 8.9		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 IEC 60601-1-2：2004 36.202.7		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for basic safety and essential performance —Collateral standard:Electromagnetic compatibility—Requirements and tests YY9706.102-2021（IEC 60601-1-2：2007，MOD） 6.2.7		2023-02-14
		15	Power frequency magnetic fields	Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—	Accrediation only for	2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Requirements and tests IEC 60601-1-2：2007 6.8.8.1	specific clients	
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2-2014/Amd 1-2020 Edition 4.1 8.9		2023-02-14
				Medical electrical equipment. Part 1-2:General requirements for basic safety and essential performance. Collateral Standard:Electromagnetic disturbances. Requirements and tests IEC 60601-1-2:2014 Edition 4.0 8.9		2023-02-14
				YY9706.102-2021（IEC 60601-1-2：2007，MOD） 6.2.8.1		2023-02-14
				Medical electrical equipment—Part 1-2:General requirements for safety—Collateral standard:Electromagnetic compatibility—Requirements and tests YY0505-2012 （IEC 60601-1-2：2004） 36.202.8.1		2023-02-14
2	Electrical equipment for measurement,control and laboratory use	1	Instructions for use	Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 1:General requirements GB/T18268.1-2010 （IEC61326-1:2005） 9		2023-02-14
				Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 1:General requirements IEC61326-1:2020 9		2023-02-14
				Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 26:Particular requirements—In vitro diagnostic(IVD) medical equipment GB/T18268.26-2010（IEC61326-2-6:2005） 9		2023-02-14
				Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 26:Particular requirements—In vitro diagnostic(IVD) medical equipment IEC61326-2-6:2020 9		2023-02-14

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	Emission requirements	Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 1:General requirements GB/T18268.1-2010（ IEC61326-1:2005） 7	Except for: Click	2023-02-14
				Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 26:Particular requirements—In vitro diagnostic(IVD) medical equipment GB/T18268.26-2010 IEC61326-2-6:2005 7	Except for: Click	2023-02-14
				Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 1:General requirements IEC61326-1:2020 7	Except for: Click	2023-02-14
				Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 26:Particular requirements—In vitro diagnostic(IVD) medical equipment IEC61326-2-6:2020 7	Except for: Click	2023-02-14
		3	Imminity requirements	Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 1:General requirements GB/T18268.1-2010 IEC61326-1:2005 6		2023-02-14
				Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 26:Particular requirements—In vitro diagnostic(IVD) medical equipment GB/T18268.26-2010 IEC61326-2-6:2005 6		2023-02-14
				Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 1:General requirements IEC61326-1:2020 6		2023-02-14
				Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 26:Particular requirements—In vitro diagnostic(IVD) medical equipment IEC61326-2-6:2020 6		2023-02-14
3	Industrial,scientific and medical equipment	1	Disturbance characteristics	Industrial,scientific and medical(ISM)radio-frequency equipment—Disturbance characteristics—Limits and methods of measurement GB 4824-2019 IEC CISPR 11：2016	Except for: Click	2023-02-14

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement IEC CISPR 11-2015+Amd 1-2019		2023-02-14
				Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement IEC CISPR 11-2015+Amd 1-2016	Except for: Click	2023-02-14
		2	Harmomic current emissions	Electromagnetic compatibility. Limits. Limits for harmonic currents produced by equipment connected to public low-voltage systems with input current > 16 A and ≦75 A per phase GB/T 17625.8-2015		2023-02-14
				Electromagnetic compatibility— Limits— Limits for harmomic current emissions(equipment input current《16 A per phase) GB 17625.1-2012 IEC61000-3-2：2009		2023-02-14
				"Limits – Limits for harmonic currents produced by equipment connected to public low-voltage systems with input current >16 A and ≤75 A per phase" IEC61000-3-12:2011		2023-02-14
				Electromagnetic compatibility (EMC). Part 3-2: Limits. Limits for harmonic current emissions (equipment input current ≤16 A per phase) IEC 61000-3-2-2018		2023-02-14
				Electromagnetic compatibility (EMC). Part 3-2: Limits. Limits for harmonic current emissions (equipment input current ≤16 A per phase) IEC 61000-3-2-2018/Amd 1-2020		2023-02-14
				Limits – Limits for harmonic currents produced by equipmentconnected to public low-voltage systems with input current >16 A and ≤75 A per phase IEC 61000-3-12-2011/Amd 1-2021		2023-02-14
		3	Voltage changes,voltage fluctuations and flicker	Electromagnetic compatibility（EMC）—Limits—Limitation of voltage changes,voltage fluctuations and flicker in public low-voltage supply systems,for equipment with rated current《16 A per phase and not subject to conditional connection GB/T		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				17625.2-2007 IEC61000-3-3：2005		
				Electromagnetic compatibility (EMC)-Part 3-3: Limits-Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection IEC 61000-3-3-2013+Amd 1-2017		2023-02-14
				Electromagnetic compatibility. Limits. Limitation of voltage changes,voltage fluctuations and flicker in public low-voltage supply systems for equipment with rated current ≤75 A and subject to conditional connection GB/T 17625.7-2013 15		2023-02-14
				Electromagnetic compatibility（EMC）—Limits—Limitation of voltage changes,voltage fluctuations and flicker in public low-voltage supply systems,for equipment with rated current《16 A per phase and not subject to conditional connection IEC 61000-3-3-2013/Amd 2-2021		2023-02-14
				Electromagnetic Compatibility (Emc)-Part 3-11-Limits-Limitation Of Voltage Changes, Voltage Fluctuations And Flicker In Public Low-Voltage Supply Systems-Equipment With Rated Current ≤ 75 A And Subject To Conditional Connection IEC 61000-3-11-2017		2023-02-14
		4	Electrostatic discharge immunity test	Electromagnetic compatibility. Testing and measurement techniques. Electrostatic discharge immunity test GB/T 17626.2-2018 IEC 61000-4-2:2008		2023-02-14
		5	Radiated,radio-frequency,electromagnetic field immunity test	Electromagnetic compatibility—Testing and measurement techniques—Radiated,radio-frequency,electromagnetic field immunity test GB/T 17626.3-2016 IEC61000-4-3：2010	Accrediation only for specific clients	2023-02-14
				Amendment 2:Electromagnetic compatibility (EMC). Part 4-3:Testing and measurement techniques. Radiated,radio-		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				frequency,electromagnetic field immunity test IEC 61000-4-3-2020		
		6	Electrical fast transient/burstimmunity test	Electromagnetic compatibility. Testing and measurement techniques. Electrical fast transient/burstimmunity test GB/T 17626.4-2018 /IEC 61000-4-4:2012		2023-02-14
		7	Surge immunity test	Electromagnetic compatibility—Testing and measurement techniques—Surge immunity test GB/T 17626.5-2019 IEC61000-4-5：2014		2023-02-14
				Electromagnetic compatibility—Testing and measurement techniques—Surge immunity test IEC61000-4-5：2014		2023-02-14
				Amendment 1-Electromagnetic compatibility (EMC)-Part 4-5: Testing and measurement techniques-Surge immunity test IEC 61000-4-5:2014+Amd 1-2017		2023-02-14
		8	Power frequency magnetic filed immunity test	Electromagnetic compatibility—Testing and measurement techniques—Power frequency magnetic filed immunity test GB/T 17626.8-2006 IEC 61000-4-8:2001		2023-02-14
				Electromagnetic compatibility—Testing and measurement techniques—Power frequency magnetic filed immunity test IEC 61000-4-8:2009		2023-02-14
		9	Voltage dips,short interruptions and voltage variations immunity tests	Electromagnetic compatibility—Testing and measurement techniques—Voltage dips,short interruptions and voltage variations immunity tests GB/T 17626.11-2008; IEC 61000-4-11:2004		2023-02-14
				Electromagnetic compatibility (EMC)-Part 4-11: Testing and measurement techniques-Voltage dips, short interruptions and voltage variations immunity tests IEC 61000-4-11-2020		2023-02-14
		10	Immunity to conducted disturbances,inducing by radio-	Electromagnetic compatibility (EMC) – Testing and measurement techniques –Immunity to conducted disturbances,inducing by radio-frequency fields IEC61000-4-6:2013		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			frequency fields	Electromagnetic compatibility (EMC) – Testing and measurement techniques –Immunity to conducted disturbances,inducing by radio-frequency fields GB/T17626.6-2017（ IEC61000-4-6:2013）		2023-02-14
		11	Instructions for use	Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 1:General requirements IEC61326-1:2020 9		2023-02-14
				Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 26:Particular requirements—In vitro diagnostic(IVD) medical equipment IEC61326-2-6:2020 9		2023-02-14
		12	Emission requirements	Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 1:General requirements IEC61326-1:2020 7		2023-02-14
				Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 26:Particular requirements—In vitro diagnostic(IVD) medical equipment IEC61326-2-6:2020 7		2023-02-14
		13	IMMUNITY requirements	Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 1:General requirements IEC61326-1:2020 6		2023-02-14
				Electrical equipment for measurement,control and laboratory use—EMC requirements—Part 26:Particular requirements—In vitro diagnostic(IVD) medical equipment IEC61326-2-6:2020 6		2023-02-14
		14	Specification for radio disturbance and immunity measuring apparatus and methods-Part1-2：Radio disturbance and immunity measuring	Specification for radio disturbance and immunity measuring apparatus and methods-Part1-2：Radio disturbance and immunity measuring apparatus-Ancillary equipment-Conducted disturbances GB/T 6113.102-2018 1		2023-02-14

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			apparatus-Ancillary equipment-Conducted disturbances			
4	Industrial，scientific and medical robots	1	Industrial，scientific and medical robots classification	Industrial，scientific and medical robots. Electromagnetic compatibility. Emission methods of measurement and limits GB/T 38336-2019 4		2023-02-14
		2	Emision Limits	Industrial，scientific and medical robots. Electromagnetic compatibility. Emission methods of measurement and limits GB/T 38336-2019 6		2023-02-14
		3	User Documents	Industrial，scientific and medical robots. Electromagnetic compatibility. Emission methods of measurement and limits GB/T 38336-2019 7		2023-02-14
		4	Immunity test requirements	Industrial，scientific and medical robots. Electromagnetic compatibility. Immunity tests GB/T 38326-2019 5		2023-02-14