Name: Sichuan Testing Center for Biomaterials and Medical Devices Co., Ltd.

Address: Sichuan University Biomaterials Building, No.29, Wangjiang Road, Chengdu, Sichuan, China

Registration No. CNAS L3940

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

Effective Date: 2024-03-25 Expiry Date: 2030-04-11

SCHEDULE 3 ACCREDITED TESTING SCOPE

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
1. Passive Medical Device Products (General)						
1. General items / parameters						
1	Medical Devices	1	Tests for in vitro cytotoxicity	Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity GB/T 16886.5-2017		2024-03-25
				Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity ISO 10993-5: 2009		2024-03-25
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods GB/T 14233.2-2005		2024-03-25
				Biological evaluation of medical devices used in dentistry Part 2: Test method Cytotoxicity tests: Agar diffusion test and filter diffusion test YY/T 0127.9-2009		2024-03-25
				Biological evaluation of medical devices-Nanomaterial: In vitro cytotoxicity tests (MTT assay and LDH assay) YY/T 0993-2015		2024-03-25

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	Skin sensitization test	Biological evaluation of medical devices - Part 10:Tests for irritation and skin sensitization GB/T 16886.10-2017		2024-03-25
				Biological evaluation of medical devices - Part 10: Biological evaluation of medical devices- Part 10: Tests for skin sensitization ISO 10993-10:2021		2024-03-25
				Test for hypersensitivity of medical devices Part 2:Murine Local Lymph Node Assay (LLNA):BrdU-ELISA method YY/T 0879.2-2015		2024-03-25
				Organic silicon material for medical use- Biological evaluation test methods GB/T 16175-2008		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
		3	Irritation test	Biological evaluation of medical devices - Part 23: Tests for irritation GB/T 16886.23-2023		2024-03-25
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008		2024-03-25
				In vitro skin irritation test for medical devices YY/T 1808-2021		2024-03-25
		4	Intracutaneous (intradermal) reactivity test	Biological evaluation of medical devices - Part 23: Tests for irritation GB/T 16886.23-2023		2024-03-25
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Oral irritation test	Biological evaluation of medical devices - Part 23: Tests for irritation GB/T 16886.23-2023		2024-03-25
				Biological evaluation of medical devices used in dentistry-Part 13:Oral mucous irritation test YY/T 0127.13-2018		2024-03-25
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2024-03-25
		6	Ocular irritation test	Biological evaluation of medical devices - Part 23: Tests for irritation GB/T 16886.23-2023		2024-03-25
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2024-03-25
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008		2024-03-25
		7	Vaginal irritation test	Biological evaluation of medical devices - Part 23: Tests for irritation GB/T 16886.23-2023		2024-03-25
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2024-03-25
		8	Rectal irritation test	Biological evaluation of medical devices - Part 23: Tests for irritation GB/T 16886.23-2023		2024-03-25
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2024-03-25
		9	Penile irritation test	Biological evaluation of medical devices - Part 23: Tests for irritation GB/T 16886.23-2023		2024-03-25
				Biological evaluation of medical devices- Part 23: Tests for irritation ISO 10993-23:2021		2024-03-25
		10	Acute systemic toxicity test	Biological evaluation of medical devices - Part 11:Tests for systemic toxicity GB/T 16886.11-2021		2024-03-25
				Biological evaluation of medical devices - Part 11:Tests for systemic toxicity ISO 10993-11:2017		2024-03-25
				Biological evaluation test methods for medical organic silicon materials GB/T 16175-2008		2024-03-25

№	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		2024-03-25
				Biological evaluation of medical devices used in dentistry-Part 2:Test method-Acute oral toxicity test YY/T 0127.14-2009		2024-03-25
		11	Pyrogenicity test	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity GB/T 16886.11-2021		2024-03-25
				Biological evaluation of medical devices - Part 11: Tests for systemic toxicity ISO 10993-11:2017		2024-03-25
				Organic silicon material for medical use- Biological evaluation test methods GB/T 16175-2008		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
				China pharmacopoeia 2020 version Vol Ⅳ General chapters 1142 Pyrogenicity test		2024-03-25
				《United States Pharmacopoeia》 USP-NF <151>		2024-03-25
		12	Bacterial endotoxin test	Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
				China pharmacopoeia 2020 version Vol Ⅳ General chapters 1143 Bacterial endotoxin test		2024-03-25
				Biological evaluation of medical devices-Nanomaterial: Endotoxin test YYT1295-2015		2024-03-25
		13	Sterility test	Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
				China pharmacopoeia 2020 version Vol Ⅳ General chapters 1101 Sterility test		2024-03-25
		14	Tests for subacute systemic toxicity	Biological evaluation of medical devices - Part 11:Tests for systemic toxicity GB/T 16886.11-2021		2024-03-25
				Biological evaluation of medical devices - Part 11: Tests for systemic toxicity ISO 10993-11:2017		2024-03-25

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		№	Item/ Parameter			
				Organic silicon material for medical use- Biological evaluation test methods GB/T 16175-2008		2024-03-25
				Biological evaluation of medical devices used in dentistry Part 15: Test method Subacute and subchronic systemic toxicity test: oral route YY/T 0127.15-2018		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
		15	Tests for subchronic systemic toxicity	Biological evaluation of medical devices - Part 11:Tests for systemic toxicity GB/T 16886.11-2021		2024-03-25
				Biological evaluation of medical devices - Part 11: Tests for systemic toxicity ISO 10993-11:2017		2024-03-25
				Organic silicon material for medical use- Biological evaluation test methods GB/T 16175-2008		2024-03-25
				Biological evaluation of medical devices used in dentistry-Part 15: Test method- Subacute and subchronic systemic toxicity test: oral route YY/T 0127.15-2018		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
		16	Tests for chronic systemic toxicity	Biological evaluation of medical devices - Part 11:Tests for systemic toxicity GB/T 16886.11-2021		2024-03-25
				Biological evaluation of medical devices - Part 11: Tests for systemic toxicity ISO 10993-11:2017		2024-03-25
		17	Tests for systemic toxicity: inhalation route	Biological evaluation of medical devices - Part 11:Tests for systemic toxicity GB/T 16886.11-2021		2024-03-25
				Biological evaluation of medical devices - Part 11: Tests for systemic toxicity ISO 10993-11:2017		2024-03-25
				Biological evaluation of medical devices used in dentistry Part 5:Inhalation toxicity test YY/T 0127.5-2014		2024-03-25
		18	Chromosome aberration test	Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity GB/T		2024-03-25

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		№	Item/ Parameter			
				16886.3-2019		
				In vitro mammalian chromosome aberration test OECD 473:2016		2024-03-25
				Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity ISO 10993-3:2014		2024-03-25
				Test for genotoxicity of medical devices-Part 2:In vitro mammalian chromosome aberration test YY/T0870.2-2019		2024-03-25
				Test for genotoxicity of medical devices- Part 5:Mammalian bone marrow chromosome aberration test YY/T 0870.5-2014		2024-03-25
				Biological evaluation of medical devices used in dentistry-Part 2: Test method-In Vitro mammalian chromosome aberration test YY/T 0127.16-2009		2024-03-25
		19	Micronucleus test	Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity GB/T 16886.3-2019		2024-03-25
				Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity ISO 10993-3:2014		2024-03-25
				Test for genotoxicity of medical devices- Part 4: Mammalian bone marrow erythocyte micronucleus test YY/T 0870.4-2014		2024-03-25
		20	TK gene mutation test using mouse lymphoma cells	Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity GB/T 16886.3-2019		2024-03-25
				Biological evaluation of medical devices - Part 3: Test for genotoxicity,carcinogenicity and reproductive toxicity ISO 10993-3:2014		2024-03-25
				In Vitro Mammalian Cell Gene Mutation Test OECD 490：2016		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Test for genotoxicity of medical devices Part 3: TK gene mutation test using mouse lymphoma cells YY/T0870.3-2019		2024-03-25
				Biological evaluation of medical devices used in dentistry Part 17: Mouse lymphoma cells (TK) gene mutation test YY/T 0127.17-2014		2024-03-25
		21	Salmonella typhimurium reverse mutation assay	Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity GB/T 16886.3-2019		2024-03-25
				Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity ISO 10993-3:2014		2024-03-25
				Bacterial Reverse Mutation Test OECD 471:2020		2024-03-25
				Test for genotoxicity of medical devices- Part 1:Bacterial reverse mutation test YY/T0870.1-2013		2024-03-25
				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		2024-03-25
		22	In Vitro Mammalian Cell Micronucleus Test	Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity GB/T 16886.3-2019		2024-03-25
				Biological evaluation of medical devices - Part 3: Test for genotoxicity,carcinogenicity and reproductive toxicity ISO 10993-3:2014		2024-03-25
				Test for genotoxicity of medical devices- Part 6：In vitro mammalian cell YY/T 0870.6-2019		2024-03-25
				Biological evaluation of nanomaterial medical devices--Test for genotoxicity-In vitro mammalian cell micronucleus test YY/T 1897-2023		2024-03-25

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		№	Item/ Parameter			
		23	Carcinogenicity test	Biological evaluation of medical devices - Part 3: Test for genotoxicity,carcinogenicity and reproductive toxicity GB/T 16886.3-2019	Accredited only for Cell Transformation Assays	2024-03-25
				Biological evaluation of medical devices - Part 3: Test for genotoxicity,carcinogenicity and reproductive toxicity ISO 10993-3:2014	Accredited only for Cell Transformation Assays	2024-03-25
		24	Local effects after implantation	Biological evaluation of medical devices - Part 6: Test for local effects after implantation GB/T 16886.6-2022		2024-03-25
				Biological evaluation of medical devices - Part 6: Test for local effects after implantation ISO 10993-6:2016		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
				Organic silicon material for medical use- Biological evaluation test methods GB/T 16175-2008		2024-03-25
				Tissue engineering medical device products--Standard practice for implantation assessment of absorbable/resorbable biomaterials YY/T 1576-2017		2024-03-25
				Method of tissue histological sample preparation and evaluation for absorbable medical devices after implantation YY/T 1899-2023		2024-03-25
		25	Subcutaneous implant test	Biological evaluation of dental materials-Part 2:Biological evaluation test method of dental materials-Subcutancous implant test YY/T 0127.8-2001		2024-03-25
		26	Bone implant test	Biological evaluation of dental materials-Part 2:Biological evaluation test method of dental materials-Bone implant test YY/T 0127.4-2009		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		27	In vivo thrombosis test	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2022		2024-03-25
				Biological evaluation of medical devices- Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
				Test method for thrombogenicity study -Part 1: Thrombogenicity study in dogs in vascular YY/T 1770.1-2021		2024-03-25
		28	In vitro thrombosis test	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2022		2024-03-25
				Biological evaluation of medical devices- Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
				Blood compatibility tests of haemo YY/T 1920-2023		2024-03-25
		29	Haemolysis test	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2022		2024-03-25
				Biological evaluation of medical devices- Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
				Organic silicon material for medical use- Biological evaluation test methods GB/T 16175-2008		2024-03-25
				Biological evaluation of dental materials-Unit 1: Haemolysis test YY/T 0127.1-1993		2024-03-25
				Test for hemolysis of medical devices-Part1:Meterial induced hemolysis assay YY/T 1651.1-2019		2024-03-25
				Biological evaluation of medical devices-Nanomaterials-Hemolysis test YY/T 1532-2017		2024-03-25

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Blood compatibility tests of haemo YY/T 1920-2023		2024-03-25
		30	Coagulation test	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2022	Accredited only for CT,PT,PTT ,TT	2024-03-25
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
				Blood compatibility tests of haemo YY/T 1920-2023		2024-03-25
				Test method of coagulation for medical devices YY/T 1911-2023		2024-03-25
		31	Platelet function test	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2022		2024-03-25
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
				Test methods of interaction of medical devices with platelet-Part 1:*In vitro* platelet count assay YY/T 1649.1-2019		2024-03-25
				Test method for interactions of medical devices with platelet-Part 2: In vitro platelet activation products (β-TG, PF4 and TxB2) assay YY/T 1649.-2019		2024-03-25
				Blood compatibility tests of haemo YY/T 1920-2023		2024-03-25
		32	Haematology test	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2022		2024-03-25
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2024-03-25

№	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		2024-03-25
				Blood compatibility tests of haemo YY/T 1920-2023		2024-03-25
		33	Complement system test	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood GB/T 16886.4-2022		2024-03-25
				Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood ISO 10993-4:2017		2024-03-25
				Test for complement activation of medical devices-Part 1:Serum whole complement activation YY/T0878.1-2013		2024-03-25
				Test for complement activation of medical devices-Part 2:Serum alternative pathway complement activation YY/T 0878.2-2015		2024-03-25
				Test methods for infusion, transfusion, injection equipment for medical use-Part 2:Biological test methods GB/T 14233.2-2005		2024-03-25
				Test for complement activation of medical devices- Part 3：Test for complement activation of medical devices- Part 3：Assay for the product of complement activation (C3a and SC5b-9) YY/T 0878.3-2019		2024-03-25
				Blood compatibility tests of haemo YY/T 1920-2023		2024-03-25
		34	Degrade test of polymeric medical devices	Biological evaluation of medical devices-Part 13: Identification and quantification of degradation products from polymeric medical devices GB/T 16886.13-2017	Only test Quality loss, Intrinsic viscosity, Infrared spectroscopy, Thermal analysis, pH，	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					Qualitative and quantitative analysis of degradation products	
				Biological evaluation of medical devices-Part 13: Identification and quantification of degradation products from polymeric medical devices ISO 10993-13:2010	Only test Quality loss, Intrinsic viscosity, Infrared spectroscopy, Thermal analysis, pH，Qualitative and quantitative analysis of degradation products	2024-03-25
		35	Degrade test of ceramics	Biological evaluation of medical devices- Part 14:Identification and quantification of degradation products from ceramics GB/T 16886.14-2003	Only test Mass loss, pH value, Surface morphology, X-ray diffraction analysis,	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					Metal ion analysis	
				Biological evaluation of medical devices- Part 14:Identification and quantification of degradation products from ceramics ISO 10993-14:2001	Only test Mass loss, pH value, Surface morphology, X-ray diffraction analysis, Metal ion analysis	2024-03-25
		36	Principles and methods for immunotoxicology testing	Biological evaluation of medical devices-Part 20: Principles and methods for immunotoxicology testing of medical devices ISO/TS 10993-20:2006		2024-03-25
				Biological evaluation of medical devices-Part 20: Principles and methods for immunotoxicology testing of medical devices GB/T 16886.20-2015		2024-03-25
				Tissue engineered medical products- Part 14: Standard Practice for evaluation of immune responses of substrate and scaffolds products: ELISA tests YY/T 0606.14-2014		2024-03-25
				Tissue engineered medical products — Standard practice for evaluation of immune responses of substrate and scaffolds products: Lymphocyte proliferation tests YY/T 0606.15-2023		2024-03-25
				Tissue engineered medical products-Part 20: Standard practice for evaluation of Immune responses of substrates and scaffold products: Cell Migration tests YY/T 0606.20-2014		2024-03-25
				Immunogenic evaluation method of medical devices —Part 6: Determination of animal spleen lymphocyte subsets by flow cytometry YY/T 1465.6-2019		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Tissue engineering medical device products-Bioactive ceramics-Method to measure cell migration in porous materials YY/T 1744-2020		2024-03-25
				Immunogenic evaluation method of medical devices-Part 7: Liquid phase multiplex protein quantification technique by flow cytometry YY/T 1465.7-2021		2024-03-25
				Immunogenic evaluation method of medical devices - Part 1: T Lymphocyte transformation test in vitro YY/T 1465.1-2016		2024-03-25
				Immunogenic evaluation method of medical devices - Part 2: Serum immunoglobulin and complement component detection Enzyme-linked immunoadsordent assay YY/T 1465.2-2016		2024-03-25
				Immunogenic evaluation method of medical devices Part 3：Plaque forming cells assay Agar gel solid-phase method YY/T 1465.3-2016		2024-03-25
				Immunogenic evaluation method of medical devices - Part 5: Determination of α-Gal antigen clearance in medical devices utilizing animal tissues and their derivatives with M86 antibody YY/T 1465.5-2016		2024-03-25
				Tissue engineering medical device products - Remnant α-Gal antigen determination in scaffold materials utilizing animal tissues and their derivatives YY/T 1561-2017		2024-03-25
				Immunogenic evaluation method of medical devices —Part 4:Phagocytosis of mouse peritoneal macrophages on chicken erythrocytes—Ex-vivo method YY/T 1465.4-2017		2024-03-25
		37	Test in vivo degradation	Biological evaluation of medical devices-Part 9: Framework for identification and quantification of potential degradation products GB/T16886.9-2022	Accredited only for gravimetric analysis	2024-03-25
				Biological evaluation of medical devices-Part 9: Framework for identification and quantification of potential degradation products	Accredited only for	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ISO 10993-9:2019	gravimetric analysis	
				Biological evaluation of medical devices - Part 6: Test for local effects after implantation GB/T 16886.6-2022		2024-03-25
				Biological evaluation of medical devices - Part 6: Test for local effects after implantation ISO 10993-6:2016		2024-03-25
				Biological evaluation of medical devices-Part 13:Identification and quantification of degradation products from polymeric medical devices GB/T 16886.13-2017	Accredited only for gravimetric analysis	2024-03-25
				Biological evaluation of medical devices-Part 14:Identification and quantificaton of degradation products from ceramics GB/T16886.14-2003	Accredited only for gravimetric analysis	2024-03-25
				Biological evaluation of medical devices-Part 15:Inentificatoin and quantificatoin of degradation products from metals and alloys GB/T16886.15-2022	Accredited only for gravimetric analysis	2024-03-25
				Biological evaluation of medical devices- Part 16: Toxicokinetic study design for degradation products and leachables GB/T 16886.16-2021		2024-03-25
		38	Identification and quantification of degradation products from metals and alloys	Biological evaluation of medical devices- Part 15: Identification and quantification of degradation products from metals and alloys GB/T 16886.15-2022	Only test Mass loss, pH value, Surface morphology, Metal ion analysis	2024-03-25
				Biological evaluation of medical devices- Part 15: Identification and quantification of degradation products from metals and alloys	Only test Mass loss,	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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				ISO 10993-15:2019	pH value, Surface morphology, Metal ion analysis	
		39	Toxicokinetic study design for degradation products and leachables	Biological evaluation of medical devices- Part 16: Toxicokinetic study design for degradation products and leachables GB/T 16886.16-2021		2024-03-25
				Biological evaluation of medical devices- Part 16: Toxicokinetic study design for degradation products and leachables ISO 10993-16:2017		2024-03-25
		40	Endodonic usage test	Biological evaluation of medical devices used in dentistry Part 3: Endodontic usage test YY/T 0127.3-2014		2024-03-25
				Dentistry - evaluation of biocompatibility of medical devices used in dentistry ISO 7405:2018		2024-03-25
		41	Pulp and dentine usage test	Biological evaluation of dental materials-Part 7:Biological evaluation test method of dental materials-Pulp and dentine usage test YY/T 0127.7-2017		2024-03-25
				Dentistry - evaluation of biocompatibility of medical devices used in dentistry ISO 7405:2018		2024-03-25
		42	Pulp capping test	Biological evaluation of medical devices used in dentistry Part 11:pulp capping test YY/T0127.11-2014		2024-03-25
				Dentistry - evaluation of biocompatibility of medical devices used in dentistry ISO 7405:2018		2024-03-25
		43	Residues DNA	Tissue engineered medical product -Part 25:Quantification of remnant DNA in biological materials utilizing animal tissues and their derivatives： Fluorescence method YY/T 0606.25-2014		2024-03-25
				Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 3407 Detection of exogenous DNA residues by second fluorescence staining		2024-03-25

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		№	Item/ Parameter			
				Tissue engineered medical products-Quantification of remnant DNA in biological materials utilizing animal tissues and their derivatives: Fluorescence method YY/T 1876-2023		2024-03-25
		44	Test for reproductive and developmental toxicity	Test for reproductive and developmental toxicity of medical devices Part 1: Screening test YY/T 1292.1-2015		2024-03-25
				Test for reproductive and developmental toxicity of medical devices Part 2: Prenatal developmental toxicity test YY/T 1292.2-2015		2024-03-25
		45	In vitro mouse embryo assay	Medical devices for human in vitro assisted reproductive technology —In vitro mouse embryo assay YY/T 1434-2016		2024-03-25
				Medical devices for human assisted reproductive technology-A method used for staining blastocysts and cell number count YY/T 1688-2021		2024-03-25
		46	Determination of biocompatibility by ocular study with rabbit eyes	Ophthalmic optics-Contact lenses and contact lenses care products-Determination of biocompatibility by ocular study with rabbit eyes GB/T 28538-2023		2024-03-25
				Ophthalmic optics-Contact lenses and contact lenses care products-Determination of biocompatibility by ocular study with rabbit eyes ISO 9394:2012		2024-03-25
		47	Microbial limit test	Chinese pharmacopoeia 2020 version Vol Ⅳ General chapters 1105 Microbial limit test for non-sterile products: microbial count		2024-03-25
				Chinese pharmacopoeia 2020 version Vol Ⅳ General chapters 1106 Microbial limit test for non-sterile products: method of controlled bacteria test		2024-03-25
		48	A population of microorganisms	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2024-03-25
		49	Coliform bacteria	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2024-03-25
		50	Pseudomonas aeruginosa	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		51	Staphylococcus aureus	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2024-03-25
		52	Hemolytic streptococcus	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2024-03-25
		53	Total number of fungal colonies	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2024-03-25
		54	Qualitative of fungi	Hygienic standard for disposable sanitary products GB 15979-2002 Annex B		2024-03-25
		55	Sterilization testing	Hygienic standard for disposable sanitary products GB 15979-2002 Annex C		2024-03-25
		56	Antibacterial performance test	Hygienic standard for disposable sanitary products GB 15979-2002 Annex C		2024-03-25
		57	Antibiotic residue	China pharmacopoeia 2020 version Vol Ⅳ General chapters 3408 Antibiotic residue test (culture method)		2024-03-25
		58	E.COLI Host Cell Proteins residue	China pharmacopoeia 2020 version Vol Ⅳ General chapters 3412 Measurement of E.COLI Host Cell Proteins		2024-03-25
		59	Yeast Cell Proteins residue	China pharmacopoeia 2020 version Vol Ⅳ General chapters 3414 Measurement of yeast Cell Proteins		2024-03-25
		60	In vivo mammalian alkaline comet assay	Test for genotoxicity of medical devices-Part 7:In vivo mammalian alkaline comet assay YY/T0870.7-2023		2024-03-25
		61	Abnormal toxicity	Chinese pharmacopoeia 2020 version of the fourth general chapters 1141 abnormal toxicity test		2024-03-25
		62	Neurotoxicity	Evaluation of neurotoxicity of medical devices-Part 1:Standard guide for selecting tests to evaluate potential neurotoxicity YY/T 1670.1-2019		2024-03-25
		63	Model of skin defect in induced diabetic rats	Preclinical animal study of medical devices Part 2: Model of skin defect in induced diabetic rats YY/T 1754.2-2020		2024-03-25
		64	Animal diabetes type 2 refractory	Standard test models for primary wound dressing performance evaluation-Part 6: Animal diabetes type 2 refractory wound		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			wound surface model	surface model for wound healing evaluation YY/T 1477.6-2020		
		65	Animal ventral incisional hernia model	Preclinical animal study of medical devices--Part 3: Animal ventral incisional hernia model for evaluating the histological reaction and biomechanical performance of the hernia repair patch YY/T 1754.3-2023		2024-03-25
		66	Biological evaluation of absorbable implants	Biological evaluation of absorbable medical devices-Part 1:Guidance for absorbable implants YY/T 1775.1-2021		2024-03-25
		67	Biological evaluation of nanomaterials	Biological evaluation of medical devices--Part 22:Guidance on nanomaterials GB/Z 16886.22-2022		2024-03-25
		68	Preclinical evaluation of dental implant systems Animal test	Dentistry Preclinical evaluation of dental implant systems Animal test methods YY/T 0522-2009		2024-03-25
		69	Melting temperature range	Determination of melting temperature range for precious metals and their alloys-Testing method of thermal analysis GB/T 1425-2021		2024-03-25
		70	Solidus-Liquidus temperature range	Self-fluxing alloy powders-Determination of solidus-Liquidus temperature range YS/T 533-2006		2024-03-25
		71	Solidus temperature and liquidus temperature	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 0661 Thermal Analysis		2024-03-25
		72	IR	General rules for infrared analysis GB/T6040-2019		2024-03-25
		73	Relative Density	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 0601 Determination Method (Pycnometer Method)		2024-03-25
		74	Lidocaine hydrochloride	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 0512 High performance liquid chromatography		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		75	Protein content	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 0731 protein content determination method （The third method ）		2024-03-25
		76	Sulfate	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 0802 Sulfate Inspection Method		2024-03-25
		77	Carbonization	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 0842 carbonization inspection method		2024-03-25
		78	Moisture content	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 0832 Moisture Determination Method （The second method）		2024-03-25
		79	Particle size and particle size distribution	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 0982 Particle size and particle size distribution measurement method (the first method, the second method manual sieving method)		2024-03-25
		80	Ash content	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 2302 Ash Determination Method		2024-03-25
		81	Residual carbodiimide	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 3206 carbodiimide residue determination method		2024-03-25
		82	Free formaldehyde	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 3207 Free Formaldehyde Determination Method （The second method）		2024-03-25
		83	Optical rotation	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 0621 Optical rotation measurement method		2024-03-25
		84	Fat content	National Food Safety Standard Determination of Fat in Food GB 5009.6-2016	Only use the first method and the second method	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		85	Density	Plastics-Methods fordetermining the density of non-cellular plastics-Part1： Immersion method，liquid pyknometer method and titration method GB/T1033.1-2008	Only use Immersion method	2024-03-25
		86	Corrosion resistance	Medical instruments of stainless steel- Test methods of corrosion resistance YY/T 0149-2006 9		2024-03-25
		87	Radiopacity	Medical polymer products-Test methods of radiopacity YY/T 0586-2016		2024-03-25
		88	Hardness	Fine ceramics（advanced ceramics，advanced technical ceramics）-Test method for hardness of monolithic ceramics at room temperature GB/T 16534-2009	Except for knoop hardness	2024-03-25
		89	Radiopacity	Dentistry-Test method for determining radio-opacity of materials YY/T 1646-2019		2024-03-25
		90	Elastic moduli	Test methods for elastic moduli of fine ceramics (advanced ceramics, advanced technical ceramics) - Bending method GB/T 10700-2006		2024-03-25
		91	Transition temperature	Implants of Surgery-differential scanning calorimetry of poly ether ether ketone （PEEK）polymers and compounds for use in implantable medical devices YY/T 1707-2020		2024-03-25
		92	Compressive properties	Plastics - Detemination of compressive properties GB/T 1041-2008		2024-03-25
		93	Specific optical rotation	Chemical reagent - General method for the determination of specific optical rotatory power（specific optical rotation） GB/T 613-2007		2024-03-25
		94	Density and apparent porostiy	Test methods for density and apparent porostiy of fine ceramics GB/T 25995-2010		2024-03-25
		95	Apparent porosity and bulk density	Test method for apparent porosity and bulk density of porous ceramic GB/T 1966-1996		2024-03-25
		96	Crystallite size and micro-strain	Determination of crystallite size and micro-strain of nano-materials - X-ray diffraction line broadening method GB/T 23413-2009		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		97	Static immersion test	Dentistry—Corrosion test methods for metallic materials YY/T 0528-2018 4.1		2024-03-25
		98	Sulfide tarnish test（cyclic immersion）	Dentistry—Corrosion test methods for metallic materials YY/T 0528-2018 4.3		2024-03-25
		99	Sulfide tarnish test（static immersion）	Dentistry—Corrosion test methods for metallic materials YY/T 0528-2018 4.4		2024-03-25
		100	Static immersion test with periodic analysis	Dentistry—Corrosion test methods for metallic materials YY/T 0528-2018 4.5		2024-03-25
		101	Abrasion performance	Pastics-Test method for wear by rolling GB/T 5478-2008		2024-03-25
		102	Dentin tubule blockage rate test method (scanning electron microscopy observation method)	Dentistry-In vitro evaluation methods of the occlusion effect of dentinal tubules YY/T 1829-2022 5		2024-03-25
		103	Moisture content	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 0832 Moisture determination method （First method Coulometric titration method）		2024-03-25
		104	Ethylene oxide sterilization residuals	Biological evaluation of medical devices-Part 7 : Ethylene oxide sterilization residuals GB/T 16886.7-2015		2024-03-25
		105	Molecular weight of type I collagen	Tissue engineering medical device products-Collagen protein-Part 2 : Determination of molecular weight of type I collagen-Sodium dodecyl sulfate polyacrylamide gel electrophoresis YY/T 1805.2-2021		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		106	Residual of ethylene chlorohydrin	Determination of residual of ethylene chlorohydrin(ECH) from plasticizedpolyvinyl chloride infusion equipments for single use YY/T 1690-2020		2024-03-25
		107	Anti-calcification evaluation	Anti-calcification evaluation of animal derived cardiovascular implants-Test for rat subcutaneous implantation YY/T 1859-2022		2024-03-25
		108	Protein content	Chinese pharmacopoeia 2020 version Vol Ⅳ general Chapters 0731 Protein Content Determination Method （the Fourth Method）		2024-03-25
2. Passive Medical Device Products (Special)						
(1）Passive Surgical Instruments (Classification Catalog 02)						
1	Medical forceps		All Parameters	Medical forceps YY/T0686-2017		2024-03-25
2	Absorbable surgical suture		All parameters	Absorbable surgical suture-Test method for breaking strength in vitrohydrolytic degradation YY/T 1746-2020		2024-03-25
3	Suture		All parameters	Implants for sports medicine-Tensile testing method for suture YY/T 1832-2022		2024-03-25
4	Absorbable surgical suture		Part of parameters	Absorbable surgical suture YY 1116-2020	Not detecting needle and thread connection strength, biological evaluation, labeling	2024-03-25
5	Non-absorbable surgical suture		Part of parameters	Non-absorbable surgical suture YY 0167-2020	Not detecting biological	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					evaluation, labeling	
(2)Neurological and cardiovascular surgical instruments (Classification Catalog 03)						
1	Central venous catheters		All Parameters	Intravascular catheters-Sterile and single-use catheters-Part3：central venous catheters YY 0285.3-2017		2024-03-25
2	Balloon dilatation catheters		All Parameters	Intravascular catheters-Sterile and single-use catheters-Part4：Balloon dilatation catheters YY 0285.4-2017		2024-03-25
(3) Orthopedic surgical instruments (classification catalog 04)						
1	Orthopaedics clamp(scissor)		All Parameters	General technique requirements for orthopaedics clamp(scissor) YY/T1122-2017		2024-03-25
2	Orthopaedics saw		All Parameters	General technique requirements for orthopaedics saw YY/T1137-2017		2024-03-25
3	Orthopedic chisel		All Parameters	General technique requirements for orthopedic chisel YY/T 1141-2017		2024-03-25
4	Guides for orthopaedic surgery		Part of parameters	General requirements of guides for orthopaedic surgery YY/T 1845-2022	Not detecting material composition	2024-03-25
(4) Blood transfusion, dialysis, and extracorporeal circulation devices (classification catalog 10)						
1	Peritoneal dialysis tube		Part of Parameters	Peritoneal dialysis tube YY 0030-2004	Except for radiation detectability	2024-03-25
2	Silicone tubes and elastomeric		All Parameters	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008		2024-03-25

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

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	parts for infusion and transfusion					
(5) Passive Implant Devices (Classification Catalog 13)						
1	Poly（lactide）	1	Determination of lactide monomer	Determination of lactide monomer residual in poly (lactide) for surgical implants YY/T 1776-2021		2024-03-25
2	3D printing titanium alloy implant	1	Metal ion precipitation evaluation method	additive manufacturing medical product-3D printing titanium alloy implant metal ion precipitation evaluation method YYT 1802-2021		2024-03-25
3	Test methods for boning properties of tissue adhesives-Part2: Strength in T-peel by tension loading	1	Strength in lap-shear by tension loading	Test methods for boning properties of tissue adhesives-Part1: Strength in lap-shear by tension loading YY/T 0729.1-2009		2024-03-25
		2	Strength in T-peel by tension loading	Test methods for boning properties of tissue adhesives-Part2: Strength in T-peel by tension loading YY/T 0729.2-2009		2024-03-25
		3	Tension strength	Test methods for boning properties of tissue adhesives-Part3:Tension strength YY/T 0729.3-2009		2024-03-25
		4	Wound closure strength	Test methods for boning properties of tissue adhesives-Part4: Wound closure strength YY/T 0729.4-2009		2024-03-25
4	Hip joint prostheses		Part of parameters	Hip joint prostheses YY 0118-2016	Except for fatigue property, total artificial hip abrasion, X-ray detection,C,H,O,N,S,Cl	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
5	Implant for surgery-forgings and castings for bone joint prosthesis-forgings with titanium 6-aluminium 4-vanadium alloy		Part of parameters	Implant for surgery-forgings and castings for bone joint prosthesis-forgings with titanium 6-aluminium 4-vanadium alloy YY0117.1-2005	Except for C,H,O,N,S	2024-03-25
6	Implants for Osteosyn-thesis-Metallic bone screws		Part Parameters	Implants for Osteosyn- thesis-Metallic bone screws YY 0018-2016	Except for C,H,O,N,S	2024-03-25
7	Implants for ostesynthesis part 2-Metallic intramedullary nailing		Part Parameters	Implants for ostesynthesis part 2-Metallic intramedullary nailing YY/T0019.2-2011	Except for C,H,O,N,S	2024-03-25
8	Implant for surgery-forgings and castings for bone joint prosthesis-castings with titanium 6-aluminium 4-vanadium alloy		Part of parameters	Implant for surgery-forgings and castings for bone joint prosthesis-castings with titanium 6-aluminium 4-vanadium alloy YY 0117.2-2005	Except for C,H,O,N,S，internal quality	2024-03-25
9	Implants for osteosynthesis-		Part Parameters	Implants for osteosynthesis-Metallic bone plates YY 0017-2016	Except for C,H,O,N,S	2024-03-25

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	Metallic bone plates				，corrosion resistance, fatigue properties	
10	Implants for surgery-Hydroxyapatite-Part 2:Coating of hydroxyapatite		All Parameters	Implants for surgery-Hydroxyapatite-Part 2:Coating of hydroxyapatite GB23101.2-2008		2024-03-25
11	Ceramics hydroxyapatite		All Parameters	Implants for surgery-Hydroxyapatite-Part 1:Ceramics hydroxyapatite GB23101.1-2008/ISO13779-1:2008		2024-03-25
12	Implant for surgery-forgings and castings for bone joint prosthesis-castings cobalt-chrimium-molybdenumalloy		Part of parameters	Implant for surgery-forgings and castings for bone joint prosthesis-castings cobalt-chrimium-molybdenumalloy YY0117.3-2005	Except for C,H,O,N,S，internal quality	2024-03-25
13	Standard Specification for Composition of Anorganic Bone for Surgical Implants		All Parameters	Standard Specification for Composition of Anorganic Bone for Surgical Implants ASTM F1581-2008		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
14	Hydroxyapatite Powder		All Parameters	Hydroxyapatite Powder YY 0303-1998		2024-03-25
15	Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation		All Parameters	Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation ASTM F1088-23/YY/T 0683-2008		2024-03-25
16	Standard Specification for Glass and Glass Ceramic Biomaterials for Implantation		All Parameters	Standard Specification for Glass and Glass Ceramic Biomaterials for Implantation ASTM F1538-2003		2024-03-25
17	InFUSEBone Graft/LT-CAGELumbar Tapered Fusion Devices		All Parameters	U.S. Food and Drug Administration (FDA) [Web site]. InFUSEBone Graft/LT-CAGELumbar Tapered Fusion Devices FDA P000058		2024-03-25
18	Chitosan		All Parameters	Tissue engineered medical products part 7: chitosan YY/T 0606.7-2008		2024-03-25
19	Alginate		Part of parameters	Tissue engineered medical products part 8: alginate YY/T 0606.8-2008	Except for NMR, average molecular weight, molecular weight	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					distribution	
20	Sodium hyaluronate		All Parameters	Tissue engineered medical products part 9: sodium hyaluronate YY/T 0606.9—2007		2024-03-25
21	Cross-linked sodium hyaluronate gel for plastic Surgery		All Parameters	Cross-linked sodium hyaluronate gel for plastic Surgery YY/T 0962-2021		2024-03-25
22	Medical sodium hyaluronate gel		Part Parameters	Medical sodium hyaluronate gel YY/T 0308-2015	Except for Refractive Index	2024-03-25
23	Implants for Surgery Bioglass and glass ceramic biomaterials		All Parameters	Implants for Surgery Bioglass and glass ceramic biomaterials YY/T 0964-2014		2024-03-25
24	Medical carboxymethyl chitosan		Part of parameters	Medical carboxymethylchitosan YY/T 0953-2020	Except for weight average molecular weight and molecular weight distribution	2024-03-25
25	Implants for Surgery - Acrylic resin cements		All Parameters	Implants for Surgery -Acrylic resin cements YY 0459-2003		2024-03-25
26	Standard		Part of parameters	Standard specification for polyetheretherketone(PEEK) polymers	Except for	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	specification for polyetherether ketone(PEEK) polymers for surgical implant applications			for surgical implant applications YY/T 0660-2008	notched impact strength	
27	Poly(L-lactide) resins and fabricated forms for surgical implants-In vitro degradation testing		All Parameters	Poly(L-lactide) resins and fabricated forms for surgical implants-In vitro degradation testing YY/T 0474-2004		2024-03-25
28	Polylactide resin		Part of parameters	standard specification for semi-crystalline poly（lactide）polymer and copolymer resin for surgical implants YY/T 0661-2017	Except for water residue，H-NMR，C-NMR，Molar Mass (GPC)	2024-03-25
29	Type I collagen		Part of parameters	YY/T 1453-2016	Except for peptide map, fat content	2024-03-25
30	Collagen sponge		All parameters	Collagen sponge YY/T 1511-2017		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
31	Nonactive surgical implas-Type I collagen implants-Specific requirements		All parameters	Nonactive surgical implants-Type I collagen implants-Specific requirements YY 0954-2015		2024-03-25
32	Corneal cell carrier membrane		All Parameters	Corneal cell carrier membrane STCBM/FB-001-2017		2024-03-25
33	Skeletal pins and wires		All Parameters	Implant for surgery-Skeletal pins and wires-Part1：Material and mechanical requirements YY/T 0345.1-2020	Except for C,H,O,N,S	2024-03-25
34	Hydroxyapatite andbeta-tricalciumphosphatebonesubstitutes		Part of parameters	Implants for surgery—Calciumphosphates—Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitute YY/T 1558.3-2017	Except for Interconnections, CT for Macropores size	2024-03-25
35	Chitosan		Part of parameters	Tissue engineering medical device products-Chitosan YY/T 1699-2020	Except for Weight average molecular weight and relative molecular mass distribution	2024-03-25
36	Sodium hyaluronate		Part of parameters	Tissue engineering medical device products - Sodium hyaluronate YY/T 1571-2017	Except for weight average	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					molecular weight and molecular weight distribution coefficient	
37	Medical devices Symbols to be used with medical device labels, labelling and information to be supplied-Part 1:General requirements		All Parameters	Medical devices Symbols to be used with medical device labels, labelling and information to be supplied-Part 1:General requirements YY/T 0466.1-2016		2024-03-25
38	Deep-frozen bone grafts and freeze bone grafts		All Parameters	Allogeneic grafts-Part2：Deep-frozen bone grafts and freeze bone grafts YY/T 0513.2-2020		2024-03-25
39	Demineralized bone grafts		All Parameters	Allogeneic grafts-Part3：Demineralized bone grafts YY/T 0513.3-2020		2024-03-25
40	Medical instruments of stainless steel-Test methods of corrosion resistance		Part Parameters	Medical instruments of stainless steel-Test methods of corrosion resistance YY/T 0149-2006	Except for Pressure Steam Method	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
41	MedicalgradeTi-6Al-4V/Ti-6Al-4VELIpowder usedfor additivemanufacturing		Part of parameters	MedicalgradeTi-6Al-4V/Ti-6Al-4VELIpowderusedfor additive manufacturing YY/T 1701-2020	Except for chemical compositio n	2024-03-25
42	Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia(Y-TZP)		Part of parameters	Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia(Y-TZP) YY/T 1715-2020	Only test bulk density, chemical compositio n, microstructure, Young's modulus, hardness	2024-03-25
43	Dental collagen membrane		Part of parameters	General technical requirements for dental collagen membrane YY/T 1794-2021	Except for Structure	2024-03-25
44	Silicone elastomer		All Parameters	General specification for surgical implants made of silicone elastomer YY0334-2022		2024-03-25
45	Hydroxyapatite nanospheres		Part of parameters	Biological evaluation of medical devices-Part 22 :Guidance on nanomaterials GB/Z 16886.22-2022	Only Chemical compositio n and purity, Particle size and particle size	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					distribution, Shape, Dispersivity are detected	
46	Medical pure tantalum powder for additive manufacturing		Part of parameters	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022	Not detecting chemical composition	2024-03-25
47	Osteoinductive calcium phosphate bioceramics		Part of parameters	Implants for surgery-Osteoinductive calcium phosphate bioceramics GB/T 41672-2022	Not detecting microporosity rate, biocompatibility evaluation, bone induction evaluation	2024-03-25
48	Animal-derived patch		Part of parameters	Implants for surgery-General requirements for animal-derived patch products YY/T 1788-2021	Not detecting reagent residues, biological evaluation, immunogenicity evaluation	2024-03-25
49	Recombinant collagen		Part of parameters	Recombinant collagen protein YY/T1849-2022	Not detecting	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	protein				thermal stability, peptide map, terminal amino acid sequence, molecular weight (mass spectrometry), isoelectric point, exogenous DNA residue (quantitative PCR method), CHO cell protein residue, residual antibiotic content, additives, content (characteristic peptide method),	

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					heterogeneity analysis, characterization of primary mechanism, circular dichroism spectroscopy, microcalorimetry, protease sensitivity analysis, glycogram/ glycosylation modification analysis, biological function Stability and biological evaluation	
50	Recombinant humanized collagen protein		Part of parameters	Recombinant humanized collagen protein YY/T1888-2023	Not detecting isoelectric points, amino acid	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					sequence confirmation, peptide segment coverage, terminal amino acid sequence, peptide map, molecular weight (mass spectrometry), exogenous DNA residue (quantitative PCR method), CHO cell protein residue, additive content, residual antibiotic content, amino acid heterogenei	

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					ty analysis, circular dichroism spectroscopy, micro differential scanning calorimetry, Raman spectroscopy, stability, biological evaluation	
51	Mussel adhesive proteins		Part of parameters	Coatings of surgical implants-Part 3:Mussel adhesive proteins YY/T 0988.3-2021	Not detecting degradation or biocompatibility detection	2024-03-25
52	Hydroxyapatite powder		Part of parameters	Implants for surgery-Hydroxyapatite-Part 6 : Powders GB/T 23101.6-2022	Not detecting specific surface area and solubility product	2024-03-25
53	Betartricalcium phosphate powder		Part of parameters	Medical-grade betartricalcium phosphate powder for additive manufacturing YY/T 1910-2023	Not detecting specific surface area	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
54			Part of parameters	Characterization of physical and chemical properties of degradable biomedical metallic materials YY/T 1812-2022	Not detecting chemical composition, Bending strength，internal quality, impact strength, fatigue performance, durability, nuclear magnetic resonance compatibility, X-ray opacity, and usability	2024-03-25
55			Part of parameters	Evaluation method for in vitro degradation performance of biomedical materials-Part 1：Degradable polyester YY/T1806.1-2021	Not detecting relative molecular weight and its distribution, tensile strength,	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					radial support, permeability, Seam strength	
56			Part of parameters	Biological evaluation of medical devices-Part 18: Chemical characterization of medical device materials within a risk management process GB/T 16886.18-2022	Only infrared spectrophotometry, gas chromatography, liquid chromatography, inductively coupled plasma atomic emission spectrometry, X-ray diffraction method are tested	2024-03-25
(6) Infusion, care, and protective equipment (classified in catalog 14)						
1	Medical transfusion, infusion and injection apparatus		Part Parameters	Test methods for infusion, transfusion, injection equipments for medical use-Part 1: Chemical analysis methods GB/T 14233.1-2022		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	part1：chemical analysis methods					
2	Sterile and single-use catheters		All Parameters	Intravascular catheters-Sterile and single-use catheters-Part1：General requirements YY 0285.1-2017		2024-03-25
3	Test method for primary wound dressing-Part1: Aspects of absorbency		All Parameters	Test method for primary wound dressing-Part1: Aspects of absorbency YY/T 0471.1-2004		2024-03-25
4	Test method for primary wound dressing-Part2:Moisture vapour transmission rate of permeable film dressings		All Parameters	Test method for primary wound dressing-Part2:Moisture vapour transmission rate of permeable film dressings YY/T 0471.2-2004		2024-03-25
5	Test method for primary wound dressing-Part3:Waterproofness		All Parameters	Test method for primary wound dressing-Part3:Waterproofness YY/T 0471.3-2004		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
6	Primary wound dressing of part4:Conformability		All parameters	Test method for primary wound dressing-Part4:Conformability YY/T 0471.4-2004		2024-03-25
7	Primary wound dressing Part5: Bacterial barrier properties		All parameters	primary wound dressing-Part5: Bacterial barrier properties YY/T 0471.5-2017 5		2024-03-25
8	Alginate dressing		All parameters	Contacting wound dressing-Part 5：Alginate dressing YY 1293.5-2017		2024-03-25
9	Hydrocolloid dressing		All parameters	Contacting wound dressing-Part 4：Hydrocolloid dressing YY/T 1293.4-2016		2024-03-25
10	Polyurethane foam dressing		All parameters	Contacting wound dressing-Part 2：Polyurethane foam dressing YY/T 1293.2-2022		2024-03-25
11	Medical adhesive bandages		All parameters	medical adhesive bandages-General requirements YY/T 0148-2006		2024-03-25
12	Mussel adhesive protein dressing		All parameters	Contacting wound dressing Part 6 : Mussel adhesive protein dressing YY/T 1293.6-2020		2024-03-25
(7) Ophthalmic instruments (classification catalog 16)						
1	Ophthalmic optics--Contact lens care products		Part parameters	Ophthalmic optics--Contact lens care products-Part 7;Biological evaluation test methods YY/T 0719.7-2011	Not measured ingestion and release of preservativ	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					es	
(8) Dental Instruments (Classification Catalogue 17)						
1	Wrought titanium and titanium dental implant		All Parameters	Wrought titanium and titanium dental implant YY 0315-2016	Except for C,H,O,N,S	2024-03-25
2	Plasma sprayed hydroxyapatite coated titanium dental implant		All Parameters	Plasma sprayed hydroxyapatite coated titanium dental implant YY0304-2023	Except for C,H,O,N,S	2024-03-25
3	Dental materials Testing of adhesion to tooth structure		All Parameters	Dental materials Testing of adhesion to tooth structure YY/T 0519-2022		2024-03-25
4	Fluoride compounds used for dental carious prevention		All Parameters	Fluoride compounds used for dental carious prevention YY/T0823-2020		2024-03-25
5	Root-canal lubricating &cleaning agent with EDTA		All Parameters	Root-canal lubricating &cleaning agent with EDTA YY/T 0516-2009		2024-03-25
6	Titanium and titanium alloy dental implant attachments		All parameters	Titanium and titanium alloy dental implant attachments YY/T 0520-2009	Except for C,H,O,N,S	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
7	Zinc oxide/eugenol and zinc oxide/non-eugenol cements		All Parameters	Dentistry-Zinc oxide/eugenol and zinc oxide/non-eugenol cements YY 0272-2023		2024-03-25
8	Zirconia ceramics		All parameters	Zirconia ceramics STCBM/FB-006-2017		2024-03-25
9	Polymer-based crown and bridge materials		All Parameters	Dentistry-polymer-based crown and bridge materials YY 0710-2009		2024-03-25
10	Artificial teeth for dental prostheses		part of Parameters	Dentistry-Artificial teeth for dental prostheses YY 0300-2009	Except for radioactivity	2024-03-25
11	Elastomeric impression materials		All Parameters	Elastomeric impression materials YY0493-2022		2024-03-25
12	Orthodontic base polymers		All parameters	Dentistry-Base polymers-Part 2:Orthodontic base polymers YY 0270.2-2011		2024-03-25
13	Resin-modified cements		All Parameters	Dental water-based cements-Part 2:Resin-modified cements YY0271.2-2016		2024-03-25
14	Denture base polymers		All parameters	Dentistry-Base polymers-Part 1:Denture base polymers YY 0270.1-2011		2024-03-25
15	Dental prefabricated root post		All Parameters	Dental prefabricated root post YY/T 0517-2009	Except for C,H,O,N,S	2024-03-25
16	Dental root canal sealing materials		Part of Parameters	Dental root canal sealing materials YY 0717-2023	Except for Microbial hazard	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
17	Dental pluggers		All Parameters	Dental pluggers YY/T 0275-2011		2024-03-25
18	Orthodontic bracket adhesive materials		All Parameters	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009		2024-03-25
19	Powder/liquid acid-base cements		Part of parameters	Dentistry-Water-based cements-Part 1:Powder/liquid acid-base cements YY0271.1-2016	Except for optical properties	2024-03-25
20	Phosphoric etching gel		All Parameters	Phosphoric etching gel YY/T 0769-2009		2024-03-25
21	Dentistry-Orthodontic products-Orthodontic elastomeric auxiliaries		All Parameters	Dentistry-Orthodontic products-Orthodontic elastomeric auxiliaries YY/T 0624-2016		2024-03-25
22	Dental resin-based pit and fissure sealants		All Parameters	Dental resin-based pit and fissure sealants YY 0622-2008		2024-03-25
23	Dental polymer based adhesives for restoratives		All Parameters	Dental polymer based adhesives for restoratives YY/T 0518-2009		2024-03-25
24	Dentistry-Polymer-based die materials		All Parameters	Dentistry-Polymer-based die materials YY/T0911-2014		2024-03-25
25	Dental temporary polymer-based		All Parameters	Dental temporary polymer-based crown and bridge materials YY/T 0826-2011		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	crown and bridge materials					
26	Dentistry-Orthodontic products: Wires		All Parameters	Dentistry-Orthodontic products: Wires YY/T 0625-2016		2024-03-25
27	Dentistry-Metallic materials for fixed and romovable restorations and appliances		All Parameters	Dentistry-Metallic materials for fixed and romovable restorations and appliances GB 17168-2013		2024-03-25
28	Dentistry-Soft lining materials for removable dentures-Part2:Materials for long-term use		All Parameters	Dentistry-Soft lining materials for removable dentures-Part2: Materials for long-term use YY 0714.2-2016		2024-03-25
29	Dentistry-Soft lining materials for removable dentures-Part1:Materials for short-term use		All Parameters	Dentistry-Soft lining materials for removable dentures-Part1: Materials for short-term use YY 0714.1-2009		2024-03-25
30	Dentistry-Ceramic		Part of parameters	Dentistry-Ceramic materials GB 30367-2013	Except for radioactivit	2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	materials				y	
31	Dental calcium hydroxide pulp capping and lining materials		All Parameters	Dental calcium hydroxide pulp capping and lining materials YY/T 0824-2011		2024-03-25
32	Dental materials-of colour stability	1	colour stability	Dental materials-Determination of colour stability YY/T 0631-2008		2024-03-25
33	Dentistry-Denture adhesives		Part of parameters	Dentistry-Denture adhesives YY/T 1280-2015	Except for microbiological items	2024-03-25
34	Customised activity denture		All Parameters	Customised activity denture STCBM/FB-005-2017		2024-03-25
35	Dentistry-Brackets and tubes for use in orthodontics		All Parameters	Dentistry-Brackets and tubes for use in orthodontics YY/T 0915-2015		2024-03-25
36	Custom orthodontic appliances / retainers		All parameters	Custom orthodontic appliances / retainers STCBM/ FB-003-2017		2024-03-25
37	Dentistry—Additive manufacturing—Selective laser melting metallic materials for fixed and removable		All parameters	Dentistry— Additive manufacturing—Selective laser melting metallic materials for fixed and removable restorations and appliances STCBM/FB-007-2019		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	restorations and appliances					
38	Custom fixed denture		All Parameters	Custom fixed denture STCBM/FB-004-2017		2024-03-25
39	Hydrocolloidimpression materials		Part of parameters	Dentistry-Hydrocolloidimpression materials YY 1027-2018	Except for Tensile bond strength	2024-03-25
40	Dentistry-Casting and Baseplate waxes		All parameters	Dentistry-Casting and Baseplate waxes YY/T 0496-2016		2024-03-25
41	Metal-ceramic systems		All Parameters	Dentistry-Compatibility testing-Part1：Metal-ceramic systems YY 0621.1-2016		2024-03-25
42	Selective laser melting metallic materials for fixed and removable restorations and appliances		All Parameters	Dentistry Additive manufacturing — Selective laser melting metallic materials for fixed and removable restorations and appliances YY/T 1702-2020		2024-03-25
43	Steel and carbide dental drills		All parameters	dental rotary instruments specification for steel and carbide bur YY 91064-1999		2024-03-25
44	Polymer-based restorative materials		All Parameters	Dentistry-Polymer-based restorative materials YY 1042-2011		2024-03-25
45	Dental materials	1	Test method of soluble fluoride of	Test method of soluble fluoride of dental materials YY 0623-2008		2024-03-25

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
46	Dental drill		Part of parameters	Dentistry-Test methods for rotary instruments YY/T 0874-2013		2024-03-25
47	Ceramic-ceramic systems		All Parameters	Dentistry-Compatibility testing-Part2：Ceramic-ceramic systems YY/T 0621.2-2020/ISO 9693-2:2016		2024-03-25
48	Dental bleach materials	1	Test method of perioxide component	Dental bleach materials-Test method of perioxide component YY/T 0632-2008		2024-03-25
49	Dental root-canal obturating points		All Parameters	Dental root-canal obturating points YY 0495-2009		2024-03-25
50	Dental gypsum		All Parameters	Dental- gypsum products YY 0462-2003		2024-03-25
51	Casting investments and refractory die materials		All Parameters	Dentistry - Casting investments and refractory die materials YY/T 0463-2011		2024-03-25
52	Diaphragm for orthodontic aligner		Part parameters	Dentistry-Diaphragm for orthodontic aligner YY/T 1819-2022	Except tensile strength and tensile attenuation	2024-03-25
53	Drills used in dental implant surgery		All parameters	Dentistry-General requirements for drills used in dental implant surgery YY/T 1064-2022		2024-03-25