

# Medical Device Standard Catalog

## Part One: General Technical Field

### 1. Quality Management of Medical Devices

- (1) Medical device quality management system requirements
- (2) General requirements for quality management of medical devices
- (3) Standards for the production and management of sterile medical devices

### 2. Unique identification of medical devices (UDI)

- (1) UDI basic general
- (2) UDI Informationization

### Three, medical device packaging

- (1) Flexible packaging for medical devices
- (2) Terminally sterilized medical device packaging
- (3) Sterile medical device packaging

### 4. Biological evaluation of medical devices

- (1) Basic general
- (2) Genotoxicity
- (3) Reproductive and developmental toxicity
- (4) Complement activation
- (5) Sensitization
- (6) Evaluation of immunogenicity
- (7) Degradation
- (8) Preclinical animal research and clinical research
- (9) Microbial control
- (10) Animal-derived medical devices
- (11) Other

### 5. General requirements for medical electrical equipment

### 6. General disinfection and sterilization technology

- (1) Terminology and general methods
- (2) Terminal sterilization
- (3) Aseptic processing
- (4) Microbiological methods
- (5) Indicators

### Seven, other

- (1) Principles and requirements for the formulation and selection of medical device standards
- (2) Medical polymer products

Part Two: Fields of Expertise

1. Surgical instruments

- (1) Professional and general fields
- (2) Knife
- (Three) cut
- (Four) pliers
- (5) Tweezers
- (6) Suture needle
- (7) Suture
- (8) Kiss (stitch) combiner
- (9) Other

2. Syringe (needle), puncture equipment

- (1) Professional and general fields
- (2) Syringe
- (3) Injection needle
- (4) Puncture equipment

3. Surgical implants

- (1) Professional and general fields
- (2) Materials
- (3) Orthopedic equipment and tools
- (4) Orthopedic implants
- (5) Cardiovascular implants
- (6) Tissue engineering implants
- (7) Active implants
- (8) Other

Four, family planning equipment

- (1) Mechanical contraceptive devices
- (2) Surgical instruments for obstetrics and gynecology
- (Three) other

5. Medical intravascular catheters and non-intravascular catheters

- (1) Intravascular catheter
- (2) Non-intravascular catheter

6. Dental materials, instruments and equipment

- (1) Professional and general fields
- (2) Tooth filling and restoration materials
- (3) Denture restoration materials and products
- (4) Orthodontic materials and products
- (5) Oral preventive materials and products
- (6) Oral implant materials and products
- (7) Dental equipment
- (8) Dental equipment
- (9) Other

Seven, infusion, blood transfusion, blood sampling, drainage equipment

- (1) Professional and general fields

# ASIA ACTUAL

(2) Infusion apparatus

(3) Blood transfusion and blood collection equipment

(4) Drainage equipment

## 8. Biological evaluation of nanomaterials

## 9. Assisted reproductive medical equipment

## 10. Medical additive manufacturing technology and medical equipment

## 11. Medical biological protection

(1) Medical masks

(2) Medical protective clothing

(3) Surgical gowns, surgical drapes

(4) Medical gloves

(5) Medical protective shoe covers and caps

(6) Biological safety cabinet

## 12. Sanitary materials

(1) Non-absorbable surgical dressing

(2) Absorbable surgical dressing

(3) Contact wound dressing

(4) Bandaging and fixing products

(5) Other

## 13. Disinfection and sterilization equipment

## 14. Medical X-ray equipment and appliances

(1) Professional and general fields

(2) X-ray machine

(3) X-ray computerized tomography equipment ( CT )

(4) Medical X-ray equipment components and appliances

(5) Medical ray protection equipment

## 15. Medical ultrasound equipment

(1) Professional and general fields

(2) Ultrasonic diagnostic equipment

(3) Ultrasonic monitoring equipment

(4) Ultrasound treatment equipment

(5) Medical ultrasonic transducer and others

## 16. Diagnostic electronic equipment

## 17. Monitoring electronic equipment

## 18. Surgery and treatment electronic equipment

## 19. Infant care equipment

## Twenty, patient carrying equipment

## 21. Defibrillator, pacemaker

## 22. Radiotherapy, Nuclear Medicine and Radiation Dosimetry

(1) Professional and general fields

(2) Radiotherapy

(3) Nuclear medicine

(4) Radiation dosimetry

## 23. Medical extracorporeal circulation equipment and devices

(1) Professional and general fields

## **ASIA ACTUAL**

(2) Hemodialysis and related treatment

(Three) peritoneal dialysis

(4) External counterpulsation

(5) Hemoperfusion and plasma separation and its auxiliary devices

(6) Cardiopulmonary bypass

### **24. Respiratory anesthesia equipment and devices**

(1) Professional and general fields

(2) Anesthesia machine and related accessories

(3) Ventilator and related equipment

(4) Medical gas system

(5) Suction device for emergency nursing in hospital

(6) Atomization equipment /atomization device

(7) Tracheal tube and others

### **25. Medical Optics and Instruments**

(1) Optical radiation safety

(2) Ophthalmic optics and instruments

(3) Minimally invasive endoscope system and equipment

(4) Medical microscope

(5) Medical lighting equipment

(6) Laser surgery equipment

(7) Laser treatment equipment

### **26. Physiotherapy equipment**

(1) Electrotherapy equipment

(2) Thermotherapy equipment

(3) Light therapy equipment

(4) Strength therapy equipment

(5) Magnetic therapy equipment

### **27. Bioelectric signal feedback equipment**

### **28. Medical rehabilitation equipment**

### **Twenty-nine. Traditional Chinese Medicine Equipment**

(1) TCM diagnostic equipment

(2) TCM treatment equipment

(3) TCM equipment

### **Thirty, stethoscope**

### **31. Medical laboratories and in vitro diagnostic equipment and reagents**

(1) Quality and capability of medical laboratories

(2) Reference measurement system

(3) General standards in the field of in vitro diagnostics

(4) Product Standards of In Vitro Diagnostic System

(5) Medical laboratory equipment

(6) Instruments and equipment for clinical testing

(7) Blood and body fluids reagents

(8) Clinical biochemical reagents

(9) Immunological reagents

(10) Microbiology reagents

(11) Molecular biology reagents

**32. Other**

(1) Facial flusher

(2) Glass thermometer

(3) Sphygmomanometer and sphygmomanometer

# Part One General Technical Field

## 1. Quality Management of Medical Devices

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Medical device quality management system requirements</b>					
1	YY/T 0287-2017	Medical device quality management system used in regulatory requirements	2017-01-19	2017-05-01	SAC/TC221
2	YY/T 0316-2016	Application of medical device risk management to medical devices	2016-01-26	2017-01-01	SAC/TC221
3	YY/T 0595-2020	Medical device quality management system YY/T0287-2017 application guide	2020-02-21	2020-04-01	SAC/TC221
4	YY/T 0664-2020	Medical device software software life cycle process	2020-09-27	2021-09-01	SAC/TC221
5	YY/T 1406.1-2016	Medical device software- Part 1: Guidelines for YY/T0316 applied to medical device software	2016-03-23	2017-01-01	Standard Management Center
6	YY/T 1437-2016	Medical Device YY/T0316 Application Guide	2016-01-26	2017-01-01	SAC/TC221
7	YY/T 1474-2016	Application of Medical Device Usability Engineering to Medical Devices	2016-01-26	2017-01-01	Standard Management Center
<b>(2) General requirements for quality management of medical devices</b>					
8	YY/T 0466.1-2016	Medical devices used for labeling, marking and providing information symbols for medical devices. Part 1: General requirements	2016-01-26	2017-01-01	SAC/TC221
9	YY/T 0466.2-2015	Medical devices are used for medical device labeling, marking and providing information symbols. Part 2: Symbol formulation, selection and confirmation	2015-03-02	2016-01-01	SAC/TC221

10	YY/T 0468- 2015	Medical Device Quality Management Medical Device Terminology System Data Structure	2015- 03-02	2016-01-01	SAC/TC221
11	YY/T 0869.1- 2016	Medical device adverse event hierarchical coding structure. Part 1 : Event type coding	2016- 01-26	2017-01-01	SAC/TC221
12	YY/T 0869.2- 2016	Medical device adverse event hierarchical coding structure. Part 2 : Evaluation coding	2016- 01-26	2017-01-01	SAC/TC221
<b>(3) Standards for the production and management of sterile medical devices</b>					
13	GB/T 16292- 2010	Testing method of suspended particles in clean room (area) of pharmaceutical industry	2010- 09-02	2011-02-01	State Food and Drug Administration
14	GB/T 16293- 2010	Test method for planktonic bacteria in clean room (area) of pharmaceutical industry	2010- 09-02	2011-02-01	State Food and Drug Administration
15	GB/T 16294- 2010	Test method of sedimentation bacteria in clean room (area) of pharmaceutical industry	2010- 09-02	2011-02-01	State Food and Drug Administration
16	YY/T 0033- 2000	Sterile medical device production management specifications	2000- 08-18	2000-09-15	SAC/TC106

## 2. Unique identification of medical devices ( UDI )

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) UDI basic general</b>					
17	YY/T 1630- 2018	Basic requirements for unique identification of medical devices	2018-12-20	2020-01-01	Standard Management Center
18	YY/T 1681- 2019	Basic terminology of medical device unique identification system	2019-07-24	2020-08-01	Central Procuratorate
<b>(2) UDI Informationization</b>					
19	YY/T 1752- 2020	Basic data set of medical device unique identification database	2020-06-30	2020-10-01	Information Center
20	YY/T 1753- 2020	Guidelines for Filling in the Medical Device Unique Identification Database	2020-06-30	2020-10-01	Information Center

## Three, medical device packaging

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Flexible packaging for medical devices</b>					

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
21	YY/T 1432-2016	Test method for determining the heat-sealing parameters of flexible packaging materials for medical devices by measuring the sealing strength of heat-sealed samples	2016-01-26	2017-01-01	SAC/TC106
22	YY/T 1433-2016	Test method for hot sealing strength (hot tack strength) of flexible packaging materials for medical devices	2016-01-26	2017-01-01	SAC/TC106
23	YY/T 1759-2020	Guidelines for design and evaluation of flexible primary packaging for medical devices	2020-09-27	2021-09-01	SAC/TC106
<b>(2) Terminally sterilized medical device packaging</b>					
24	GB/T 19633.1-2015	Terminally sterilized medical device packaging. Part 1: Requirements for materials, sterile barrier systems and packaging systems	2015-12-10	2016-09-01	SAC/TC200
25	GB/T 19633.2-2015	Terminally sterilized medical device packaging. Part 2: Requirements for confirmation of forming, sealing and assembly process	2015-12-10	2016-09-01	SAC/TC200
26	YY/T 0698.1-2011	Packaging materials for terminally sterilized medical devices. Part 1: Requirements and test methods for blister packaging and co-extrusion plastic film	2011-12-31	2013-06-01	SAC/TC106
27	YY/T 0698.2-2009	Packaging materials for terminally sterilized medical devices. Part 2: Requirements and test methods for sterilization packaging materials	2009-06-16	2010-12-01	SAC/TC106
28	YY/T 0698.3-2009	Packaging materials for terminally sterilized medical devices. Part 3: Paper bags (specified in YY/T 0698.4), combined bags and coiled materials (specified in YY/T 0698.5)	2009-06-16	2010-12-01	SAC/TC106

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		production paper requirements and test methods			
29	YY/T 0698.4-2009	Packaging materials for terminally sterilized medical devices. Part 4 : Paper bag requirements and test methods	2009-06-16	2010-12-01	SAC/TC106
30	YY/T 0698.5-2009	Packaging materials for terminally sterilized medical devices. Part 5 : Requirements and test methods for sealable combination bags and coils composed of breathable materials and plastic films	2009-06-16	2010-12-01	SAC/TC106
31	YY/T 0698.6-2009	Packaging materials for terminally sterilized medical devices. Part 6 : Requirements and test methods for the production of sterile barrier systems for low-temperature sterilization or radiation sterilization	2009-06-16	2010-12-01	SAC/TC106
32	YY/T 0698.7-2009	Packaging materials for terminally sterilized medical devices. Part 7 : Requirements and test methods for sealable adhesive paper used in the production of ethylene oxide or radiation sterilized sterile barrier systems	2009-06-16	2010-12-01	SAC/TC106
33	YY/T 0698.8-2009	Packaging materials for terminally sterilized medical devices. Part 8 : Requirements and test methods for reusable sterilization containers for steam sterilizers	2009-06-16	2010-12-01	SAC/TC106
34	YY/T 0698.9-2009	Packaging materials for terminally sterilized medical devices. Part 9 : Requirements and test methods for non-adhesive polyolefin nonwovens used in the production of sealable	2009-06-16	2010-12-01	SAC/TC106



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		combination bags, coils and lids			
35	YY/T 0698.10-2009	Packaging materials for terminally sterilized medical devices. Part 10: Requirements and test methods for glue-coated polyolefin non-woven fabrics used in the production of sealable combination bags, coils and cover materials	2009-06-16	2010-12-01	SAC/TC106
<b>(3) Sterile medical device packaging</b>					
36	YY/T 0681.1-2018	Sterile medical device packaging test methods. Part 1: Guide to accelerated aging test	2018-12-20	2020-01-01	SAC/TC106
37	YY/T 0681.2-2010	Test methods for packaging of sterile medical devices. Part 2: Sealing strength of soft barrier materials	2010-12-27	2012-06-01	SAC/TC106
38	YY/T 0681.3-2010	Sterile medical device packaging test methods. Part 3: Unconstrained packaging resistance to internal pressure damage	2010-12-27	2012-06-01	SAC/TC106
39	YY/T 0681.4-2021	Sterile medical device packaging test method. Part 4: Dye penetration method to determine the seal leakage of breathable packaging	2021-03-09	2022-04-01	SAC/TC106
40	YY/T 0681.5-2010	Sterile medical device packaging test methods. Part 5: Internal pressure method to detect gross leaks (bubble method)	2010-12-27	2012-06-01	SAC/TC106
41	YY/T 0681.6-2011	Sterile medical device packaging test methods. Part 6: Evaluation of chemical resistance of printing ink and coating on flexible packaging materials	2011-12-31	2013-06-01	SAC/TC106
42	YY/T 0681.7-2011	Sterile medical device packaging test methods. Part 7: Use tape to evaluate the adhesion of printing ink or coating on flexible packaging materials	2011-12-31	2013-06-01	SAC/TC106

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
43	YY/T 0681.8-2011	Sterile medical device packaging test methods. Part 8 : Determination of the weight of the adhesive layer	2011-12-31	2013-06-01	SAC/TC106
44	YY/T 0681.9-2011	Sterile medical device packaging test method. Part 9 : Air pressure inside restraint plate flexible packaging seal burst test	2011-12-31	2013-06-01	SAC/TC106
45	YY/T 0681.10-2011	Sterile medical device packaging test methods. Part 10 : Microbial barrier grading test for breathable packaging materials	2011-12-31	2013-06-01	SAC/TC106
46	YY/T 0681.11-2014	Sterile medical device packaging test methods. Part 11 : Visual inspection of the sealing integrity of medical packaging	2014-06-17	2015-07-01	SAC/TC106
47	YY/T 0681.12-2014	Test methods for packaging of sterile medical devices. Part 12 : Rubbing resistance of soft barrier film	2014-06-17	2015-07-01	SAC/TC106
48	YY/T 0681.13-2014	Sterile medical device packaging test methods. Part 13 : Soft barrier film and composite film resistance to slow puncture	2014-06-17	2015-07-01	SAC/TC106
49	YY/T 0681.14-2018	Test methods for packaging of sterile medical devices. Part 14 : Test for moisture and dry microbial barriers of breathable packaging materials	2018-11-07	2019-11-01	SAC/TC106
50	YY/T 0681.15-2019	Sterile medical device packaging test methods. Part 15 : Performance test of transport containers and systems	2019-10-23	2020-10-01	SAC/TC106
51	YY/T 0681.16-2019	Test methods for packaging of sterile medical devices. Part 16 : Climate resilience test of packaging system	2019-05-31	2020-06-01	SAC/TC106
52	YY/T 0681.17-2019	Sterile medical device packaging test methods. Part 17 : Breathable packaging materials aerosol	2019-10-23	2020-10-01	SAC/TC106

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		filtration method microbial barrier test			
53	YY/T 0681.18-2020	Sterile medical device packaging test methods. Part 18 : Non-destructive inspection of packaging leakage by vacuum attenuation method	2020-03-31	2021-04-01	SAC/TC106

#### 4. Biological evaluation of medical devices

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Basic general</b>					
54	GB/T 16175-2008	Test methods for biological evaluation of medical silicone materials	2008-01-22	2008-09-01	SAC/TC248
55	GB/T 16886.1-2011	Biological Evaluation of Medical Devices Part 1 : Evaluation and Testing in the Process of Risk Management	2011-06-16	2011-12-01	SAC/TC248
56	GB/T 16886.2-2011	Biological Evaluation of Medical Devices Part 2 : Animal Welfare Requirements	2011-12-30	2012-05-01	SAC/TC248
57	GB/T 16886.3-2019	Biological Evaluation of Medical Devices Part 3 : Genetic Toxicity, Carcinogenicity and Reproductive Toxicity Test	2019-06-04	2020-01-01	SAC/TC248
58	GB/T 16886.4-2003	Biological evaluation of medical devices. Part 4 : Test options for interaction with blood	2003-03-05	2003-08-01	SAC/TC248
59	GB/T 16886.5-2017	Biological evaluation of medical devices. Part 5 : In vitro cytotoxicity test	2017-12-29	2018-07-01	SAC/TC248
60	GB/T 16886.6-2015	Biological evaluation of medical devices. Part 6 : Local reaction test after implantation	2015-12-10	2017-04-01	SAC/TC248
61	GB/T 16886.7-2015	Biological evaluation of medical devices. Part 7 : Residues of ethylene oxide sterilization	2015-12-10	2017-01-01	SAC/TC248
62	GB/T 16886.9-2017	Biological Evaluation of Medical Devices Part 9 :	2017-12-29	2018-07-01	SAC/TC248

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		Qualitative and Quantitative Framework of Potential Degradation Products			
63	GB/T 16886.10-2017	Biological evaluation of medical devices. Part 10 : Irritation and skin sensitization test	2017-12-29	2018-07-01	SAC/TC248
64	GB/T 16886.11-2011	Biological evaluation of medical devices. Part 11 : Systemic toxicity test	2011-12-30	2012-05-01	SAC/TC248
65	GB/T 16886.12-2017	Biological evaluation of medical devices. Part 12 : Sample preparation and reference materials	2017-12-29	2018-07-01	SAC/TC248
66	GB/T 16886.13-2017	Biological evaluation of medical devices. Part 13 : Qualitative and quantitative analysis of degradation products of polymer medical devices	2017-12-29	2018-07-01	SAC/TC248
67	GB/T 16886.14-2003	Biological evaluation of medical devices. Part 14 : Qualitative and quantitative ceramic degradation products	2003-03-05	2003-08-01	SAC/TC248
68	GB/T 16886.15-2003	Biological Evaluation of Medical Devices Part 15 : Qualitative and Quantitative Degradation Products of Metals and Alloys	2003-03-05	2003-08-01	SAC/TC248
69	GB/T 16886.16-2013	Biological evaluation of medical devices. Part 16 : Research and design of the toxicokinetics of degradation products and leachables	2013-12-17	2014-08-01	SAC/TC248
70	GB/T 16886.17-2005	Biological evaluation of medical devices. Part 17 : Establishing the allowable limit of leachable substances	2005-11-04	2006-04-01	SAC/TC248
71	GB/T 16886.18-2011	Biological evaluation of medical devices. Part 18 : Material chemical characterization	2011-12-30	2012-05-01	SAC/TC248
72	GB/T 16886.19-2011	Biological evaluation of medical devices. Part 19 :	2011-12-30	2012-05-01	SAC/TC248

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		Material physical chemistry, morphology and surface characterization			
73	GB/T 16886.20-2015	Biological evaluation of medical devices. Part 20 : Principles and methods of immunotoxicology test for medical devices	2015-12-10	2017-01-01	SAC/TC248
74	YY/T 1512-2017	Guidelines for the Implementation of Biological Evaluation in the Risk Management Process of Biological Evaluation of Medical Devices	2017-07-17	2018-07-01	SAC/TC248
<b>(2) Genotoxicity</b>					
75	YY/T 0870.1-2013	Genetic Toxicity Test of Medical Devices Part 1 : Bacterial Reversion Test	2013-10-21	2014-10-01	SAC/TC248
76	YY/T 0870.2-2019	Genetic toxicity test for medical devices. Part 2 : In vitro mammalian cell chromosome aberration test	2019-05-31	2020-06-01	SAC/TC248
77	YY/T 0870.3-2019	Medical device genetic toxicity test Part 3 : TK gene mutation test with mouse lymphoma cells	2019-07-24	2020-08-01	SAC/TC248
78	YY/T 0870.4-2014	Genetic toxicity test of medical devices. Part 4 : Micronucleus test of mammalian bone marrow erythrocytes	2014-06-17	2015-07-01	SAC/TC248
79	YY/T 0870.5-2014	Genetic toxicity test of medical devices. Part 5 : Chromosome aberration test of mammalian bone marrow	2014-06-17	2015-07-01	SAC/TC248
80	YY/T 0870.6-2019	Genetic toxicity test for medical devices. Part 6 : In vitro mammalian cell micronucleus test	2019-07-24	2020-08-01	SAC/TC248
<b>(3) Reproductive and developmental toxicity</b>					
81	YY/T 1292.1-2015	Reproductive and developmental toxicity test of medical devices. Part 1 : Screening test	2015-03-02	2016-01-01	SAC/TC248
82	YY/T 1292.2-2015	Medical device reproduction and developmental toxicity	2015-03-02	2016-01-01	SAC/TC248

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		test. Part 2 : Embryo developmental toxicity test			
83	YY/T 1292.3-2016	Reproductive and developmental toxicity test of medical devices. Part 3 : First- generation reproductive toxicity test	2016-01-26	2017-01-01	SAC/TC248
84	YY/T 1292.4-2017	Reproductive and developmental toxicity test of medical devices. Part 4 : Two-generation reproductive toxicity test	2017-02-28	2018-01-01	SAC/TC248
<b>(4) Complement activation</b>					
85	YY/T 0878.1-2013	Medical Device Complement Activation Test Part 1 : Serum Complete Complement Activation	2013-10-21	2014-10-01	SAC/TC248
86	YY/T 0878.2-2015	Medical device complement activation test Part 2 : Serum alternative pathway complement activation	2015-03-02	2016-01-01	SAC/TC248
87	YY/T 0878.3-2019	Medical device complement activation test Part 3 : Determination of complement activation products ( C3a and SC5b-9 )	2019-07-24	2020-08-01	SAC/TC248
<b>(5) Sensitization</b>					
88	YY/T 0879.1-2013	Medical device sensitization test. Part 1 : Mouse local lymph node test ( LLNA ) radioisotope incorporation method	2013-10-21	2014-10-01	SAC/TC248
89	YY/T 0879.2-2015	Medical device sensitization test Part 2 : Mouse local lymph node test ( LLNA ) BrdU-ELISA method	2015-03-02	2016-01-01	SAC/TC248
<b>(6) Evaluation of immunogenicity</b>					
90	YY/T 1465.1-2016	Evaluation method of immunogenicity of medical devices. Part 1 : In vitro T lymphocyte transformation test	2016-01-26	2017-01-01	SAC/TC248
91	YY/T 1465.2-2016	Evaluation method of immunogenicity of medical devices. Part 2 : Determination of serum immunoglobulin and	2016-01-26	2017-01-01	SAC/TC248

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		complement components by ELISA method			
92	YY/T 1465.3-2016	Evaluation method of immunogenicity of medical devices. Part 3: Plaque forming cell determination agar solid phase method	2016-07-29	2017-06-01	SAC/TC248
93	YY/T 1465.4-2017	Evaluation method of immunogenicity of medical devices. Part 4: Mouse peritoneal macrophages phagocytosis of chicken red blood cells. In vivo method	2017-03-28	2018-04-01	SAC/TC248
4	YY/T 1465.5-2016	Evaluation method of immunogenicity of medical devices. Part 5: Determination of $\alpha$ -Gal antigen clearance rate in animal-derived medical devices with M86 antibody	2016-07-29	2017-06-01	SAC/TC248
95	YY/T 1465.6-2019	Evaluation method of immunogenicity of medical devices. Part 6: Determination of animal spleen lymphocyte subsets by flow cytometry	2019-07-24	2020-08-01	SAC/TC248
96	YY/T 1465.7-2021	Evaluation method of immunogenicity of medical devices. Part 7: Flow cytometry multi-protein quantitative technology	2021-03-09	2022-04-01	SAC/TC248
<b>(7) Degradation</b>					
97	YY/T 0511-2009	Test method for evaluating the degradation and bone formation performance of porous bioceramics in vivo	2009-12-30	2011-06-01	SAC/TC248
98	YY/T 1775.1-2021	Biological evaluation of absorbable medical devices. Part 1: Guidelines for absorbable implants	2021-03-09	2022-04-01	SAC/TC248
<b>(8) Preclinical animal research and clinical research</b>					
99	YY/T 1754.1-2020	Preclinical animal research of medical devices. Part 1: General	2020-09-27	2021-09-01	SAC/TC248
100	YY/T 1754.2-2020	Preclinical animal research of medical devices. Part 2:	2020-09-27	2021-09-01	SAC/TC248

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		Induced diabetic rat skin injury model			
10 1	YY/T 0297-1997	Medical device clinical investigation	1997-08-27	1998-01-01	SAC/TC248
<b>(9) Microbial control</b>					
10 2	YY/T 0615.1-2007	Requirements for labeling "sterile" medical devices Part 1 : Requirements for terminally sterilized medical devices	2007-07-02	2008-03-01	Shandong Center
10 3	YY/T 0615.2-2007	Requirements for labeling "sterile" medical devices. Part 2 : Requirements for aseptically processed medical devices	2007-07-02	2008-03-01	Shandong Center
10 4	YY/T 0618-2017	Routine monitoring and skip batch inspection of bacterial endotoxin test methods for medical devices	2017-02-28	2018-01-01	SAC/TC248
<b>(10) Animal-derived medical devices</b>					
10 5	YY/T 0771.1-2020	Medical devices of animal origin. Part 1 : Risk management applications	2020-03-31	2021-04-01	SAC/TC248
10 6	YY/T 0771.2-2020	Medical devices of animal origin. Part 2 : Control of source, collection and disposal	2020-03-31	2021-04-01	SAC/TC248
10 7	YY/T 0771.3-2009	Medical devices of animal origin. Part 3 : Confirmation of virus and transmissible spongiform encephalopathy ( TSE ) factor removal and inactivation	2009-12-30	2011-06-01	SAC/TC248
1 08	YY/T 0771.4-2015	Medical devices of animal origin. Part 4 : Removal and /or inactivation of transmissible spongiform encephalopathy ( TSE ) factors and the principles of process confirmation analysis	2015-03-02	2016-01-01	SAC/TC248
1 09	YY 0970-2013	Confirmation and routine control of sterilization of sterilization liquid sterilant for single-use	2013-10-21	2014-10-01	SAC/TC248



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		medical devices containing animal-derived materials			
<b>(11) Other</b>					
110	YY/T 1500-2016	Medical device pyrogen test Monocyte activation test Human whole blood ELISA method	2016-07-29	2017-06-01	SAC/TC248
111	YY/T 1649.1-2019	Interaction test between medical devices and platelets. Part 1: In vitro platelet counting method	2019-05-31	2020-06-01	SAC/TC248
112	YY/T 1649.2-2019	Medical device and platelet interaction test Part 2: In vitro platelet activation products ( $\beta$ - TG, PF4 and TxB2) determination	2019-10-23	2020-10-01	SAC/TC248
113	YY/T 1651.1-2019	Hemolysis test for medical devices. Part 1: Material-mediated hemolysis test	2019-05-31	2020-06-01	SAC/TC248
114	YY/T 1670.1-2019	Evaluation of neurotoxicity of medical devices. Part 1: Guidelines for the selection of tests for evaluating potential neurotoxicity	2019-07-24	2020-08-01	SAC/TC248
115	YY/T 1770.1-2021	Thrombosis test of medical devices. Part 1: Thrombosis test in dogs	2021-03-09	2022-04-01	SAC/TC248

## 5. General requirements for medical electrical equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
116	GB 9706.1-2020	Medical electrical equipment Part 1: General requirements for basic safety and basic performance	2020-04-09	2023-05-01	SAC/TC10
117	GB/T 14710-2009	Environmental requirements and test methods for medical electrical appliances	2009-11-15	2010-05-01	SAC/TC10
118	GB 9706.103-2020	Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Basic Performance Collateral Standard: Radiation	2020-12-24	2023-05-01	State Food and Drug Administration

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		Protection of Diagnostic X-ray Equipment			
119	YY 9706.102-2021	Medical Electrical Equipment Part 1-2 : General Requirements for Basic Safety and Basic Performance Collateral Standard: Electromagnetic Compatibility Requirements and Tests	2021-03-09	2023-05-01	SAC/TC10
120	YY 9706.108-2021	Medical Electrical Equipment Part 1-8 : General Requirements for Basic Safety and Basic Performance Collateral Standards: General Requirements, Tests and Guidelines for Medical Electrical Equipment and Alarm Systems in Medical Electrical Systems	2021-03-09	2023-05-01	SAC/TC10
121	YY 9706.111-2021	Medical electrical equipment Part 1-11 : General requirements for basic safety and basic performance. Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in home care environments	2021-03-09	2023-05-01	SAC/TC10
122	YY 9706.112-2021	Medical electrical equipment Part 1-12 : General requirements for basic safety and basic performance. Collateral standard: Requirements for medical electrical equipment and medical electrical systems expected to be used in emergency medical service environments	2021-03-09	2023-05-01	SAC/TC10
123	YY/T 9706.106-2021	Medical Electrical Equipment Part 1-6 : General Requirements for Basic Safety and Basic Performance Collateral Standard: Usability	2021-03-09	2023-05-01	SAC/TC10
124	YY/T 9706.110-2021	Medical Electrical Equipment Part 1-10 : General Requirements for Basic Safety	2021-03-09	2023-05-01	SAC/TC10

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		and Basic Performance Collateral Standard: Development Requirements for Physiological Closed Loop Controllers			
125	YY 1057-2016	General technical conditions for medical foot switches	2016-01-26	2018-01-01	SAC/TC10/SC5
126	YY/T 0841-2011	Medical electrical equipment Periodic testing and post-repair testing of medical electrical equipment	2011-12-31	2013-06-01	SAC/TC10
127	YY/T 1643-2018	Functionality and compatibility test method of remote medical imaging equipment	2018-12-20	2020-01-01	SAC/TC10
128	YY/T 1686-2020	Classification of medical electrical equipment using robotics	2020-02-21	2021-06-01	SAC/TC10
129	YY/T 1738-2020	Energy consumption measurement method for medical electrical equipment	2020-09-27	2021-09-01	SAC/TC10

## 6. General disinfection and sterilization technology

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Terminology and general methods</b>					
130	GB/T 19971-2015	Terminology for sterilization of healthcare products	2015-12-10	2016-09-01	SAC/TC200
131	YY/T 0802-2020	Information provided by the sterilization manufacturer of the medical device for handling re-sterilizable medical devices	2020-06-30	2021-12-01	SAC/TC200
132	YY/T 1478-2016	Traceability information for disinfection and sterilization of reusable medical devices	2016-07-29	2017-06-01	SAC/TC200
133	YY/T 1623-2018	Test method for effectiveness of sterilization process for reusable medical devices	2018-09-21	2019-09-26	SAC/TC200
134	YY/T 1737-2020	Analysis method of medical device bioburden control level	2020-09-27	2021-09-01	SAC/TC200
<b>(2) Terminal sterilization</b>					

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
135	GB 18278.1-2015	Sterilization of medical and health care products. Part 1 : Requirements for the development, validation and routine control of the sterilization process of medical devices	2015-12-10	2017-01-01	SAC/TC200
136	GB 18279.1-2015	Sterilization of Medical and Healthcare Products Ethylene Oxide Part 1 : Requirements for the Development, Validation and Routine Control of the Sterilization Process of Medical Devices	2015-12-10	2017-01-01	SAC/TC200
137	GB 18280.1-2015	Radiation for sterilization of medical and health care products. Part 1 : Requirements for the development, validation and routine control of the sterilization process of medical devices	2015-12-31	2017-07-01	SAC/TC200
138	GB 18280.2-2015	Radiation for sterilization of healthcare products. Part 2 : Establishing sterilization dose	2015-12-31	2017-07-01	SAC/TC200
139	GB/T 18279.2-2015	Sterilization of Medical and Health Care Products Ethylene Oxide Part 2 : Application Guide of GB 18279.1	2015-12-10	2017-07-01	SAC/TC200
140	GB/T 18280.3-2015	Radiation for sterilization of healthcare products. Part 3 : Dose measurement guidelines	2015-12-31	2018-01-01	SAC/TC200
141	GB/T 19974-2018	The characteristics of sterilization factors for medical and health care products and the general requirements for the development, validation and routine control of the sterilization process of medical devices	2018-05-14	2019-06-01	SAC/TC200
142	YY 0602-2007	Special requirements for the use of hot air or hot inert gas to process medical materials and dry	2007-01-31	2008-02-01	SAC/TC200

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		heat sterilizers for the test chamber			
143	YY/T 0884-2013	Material evaluation of medical and healthcare products suitable for radiation sterilization	2013-10-21	2014-10-01	SAC/TC200
144	YY/T 1263-2015	Material evaluation of medical devices suitable for dry heat sterilization	2015-03-02	2016-01-01	SAC/TC200
145	YY/T 1264-2015	Material evaluation of medical devices suitable for ozone sterilization	2015-03-02	2016-01-01	SAC/TC200
146	YY/T 1265-2015	Material evaluation of medical devices suitable for moist heat sterilization	2015-03-02	2016-01-01	SAC/TC200
147	YY/T 1266-2015	Material evaluation of medical devices suitable for hydrogen peroxide sterilization	2015-03-02	2016-01-01	SAC/TC200
148	YY/T 1267-2015	Material evaluation of medical devices suitable for ethylene oxide sterilization	2015-03-02	2016-01-01	SAC/TC200
149	YY/T 1268-2015	Ethylene oxide sterilization product addition and process equivalent	2015-03-02	2016-01-01	SAC/TC200
150	YY/T 1276-2016	Development, validation and routine control requirements for the dry heat sterilization process of medical devices	2016-03-23	2017-01-01	SAC/TC200
151	YY/T 1302.1-2015	Physical and microbiological performance requirements for ethylene oxide sterilization. Part 1 : Physical requirements	2015-03-02	2016-01-01	SAC/TC200
152	YY/T 1302.2-2015	Physical and microbiological performance requirements for ethylene oxide sterilization. Part 2 : Microbiological requirements	2015-03-02	2016-01-01	SAC/TC200
153	YY/T 1402-2016	Test method for suitability of medical device steam sterilization process challenge device	2016-03-23	2017-01-01	SAC/TC200

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
154	YY/T 1403-2017	Requirements for sub-package sterilization of ethylene oxide	2017-03-28	2018-04-01	SAC/TC200
155	YY/T 1463-2016	Guidelines for the selection of microbial challenges and infection sites for medical device sterilization confirmation	2016-01-26	2017-01-01	SAC/TC200
156	YY/T 1464-2016	Medical device sterilization low-temperature steam formaldehyde sterilization process development, validation and routine control requirements	2016-01-26	2017-01-01	SAC/TC200
157	YY/T 1544-2017	Basic guarantee requirements for the safety and effectiveness of ethylene oxide sterilization	2017-05-02	2018-04-01	SAC/TC200
158	YY/T 1600-2018	Product Family and Process Category of Moist Heat Sterilization of Medical Devices	2018-01-19	2019-01-01	SAC/TC200
159	YY/T 1607-2018	Method for setting radiation sterilization dose of medical equipment	2018-06-26	2019-07-01	SAC/TC200
160	YY/T 1608-2018	Sampling method for radiation sterilization verification dose experiment and sterilization dose review of medical devices	2018-06-26	2019-07-01	SAC/TC200
161	YY/T 1612-2018	Test method of medical sterilization steam quality	2018-09-28	2019-10-01	SAC/TC200
162	YY/T 1613-2018	Characteristics and control requirements of irradiation sterilization process for medical devices	2018-09-28	2019-10-01	SAC/TC200
163	YY/T 1733-2020	Guide for Dose Distribution Test of Irradiation Device for Radiation Sterilization of Medical Devices	2020-09-27	2022-06-01	SAC/TC200
<b>(3) Aseptic processing</b>					
164	YY/T 0567.1-2013	Aseptic processing of healthcare products. Part 1: General requirements	2013-10-21	2014-10-01	SAC/TC200

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
165	YY/T 0567.2-2021	Aseptic processing of healthcare products. Part 2 : Sterilization and filtration	2021-03-09	2022-04-01	SAC/TC200
166	YY/T 0567.3-2011	Aseptic processing of healthcare products. Part 3 : Lyophilization	2011-12-31	2013-06-01	SAC/TC200
167	YY/T 0567.4-2011	Aseptic processing of healthcare products. Part 4 : On-line cleaning technology	2011-12-31	2013-06-01	SAC/TC200
168	YY/T 0567.5-2011	Aseptic processing of healthcare products. Part 5 : On-line sterilization	2011-12-31	2013-06-01	SAC/TC200
169	YY/T 0567.6-2011	Aseptic processing of healthcare products. Part 6 : Isolator system	2011-12-31	2013-06-01	SAC/TC200
170	YY/T 0567.7-2016	Aseptic processing of healthcare products. Part 7 : Alternative processing of medical devices and combined products	2016-07-29	2017-06-01	SAC/TC200
<b>(4) Microbiological methods</b>					
171	GB/T 19973.1-2015	Microbiological methods for sterilization of medical devices Part 1 : Determination of the total number of microorganisms on the product	2015-12-10	2016-09-01	SAC/TC200
172	GB/T 19973.2-2018	Microbiological methods of sterilization of medical devices. Part 2 : Sterility test for the definition, confirmation and maintenance of sterilization process	2018-03-15	2019-04-01	SAC/TC200
173	YY/T 1479-2016	Sterility test method of membrane filter	2016-07-29	2017-06-01	SAC/TC200
<b>(5) Indicators</b>					
174	GB 18281.1-2015	Biological indicators for sterilization of healthcare products. Part 1 : General rules	2015-12-10	2017-01-01	SAC/TC200
175	GB 18281.2-2015	Biological indicators for sterilization of healthcare	2015-12-10	2017-01-01	SAC/TC200

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		products. Part 2 : Biological indicators for sterilization of ethylene oxide			
176	GB 18281.3- 2015	Biological indicators for sterilization of health care products. Part 3 : Biological indicators for moist heat sterilization	2015-12-10	2017-01-01	SAC/TC200
177	GB 18281.4- 2015	Biological indicators for sterilization of health care products. Part 4 : Biological indicators for dry heat sterilization	2015-12-10	2017-01-01	SAC/TC200
178	GB 18281.5- 2015	Biological indicators for sterilization of health care products. Part 5 : Biological indicators for low- temperature steam formaldehyde sterilization	2015-12-10	2017-01-01	SAC/TC200
179	GB 18282.1- 2015	Sterilization chemical indicators for medical and health care products. Part 1 : General rules	2015-12-10	2017-01-01	SAC/TC200
180	GB 18282.3- 2009	Sterilization chemical indicators for medical and health care products. Part 3 : Class II indicator system for <b>BD</b> steam penetration test	2009-11-15	2010-12-01	SAC/TC200
181	GB 18282.4- 2009	Sterilization chemical indicators for health care products. Part 4 : Class II indicators for alternative <b>BD</b> vapor penetration tests	2009-11-15	2010-12-01	SAC/TC200
182	GB 18282.5- 2015	Sterilization chemical indicators for medical and health care products. Part 5 : Class II indicators for <b>BD</b> air exclusion test	2015-12-10	2017-01-01	SAC/TC200
183	GB/T 19972- 2018	Guidelines for Selection, Use and Results Judgment of Biological Indicators for Sterilization of Healthcare Products	2018-03-15	2018-10-01	SAC/TC200



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
184	GB/T 24628-2009	Medical and health care products sterilization biological and chemical indicator test equipment	2009-11-15	2010-05-01	SAC/TC200
185	GB/T 32310-2015	Guidelines for the Selection, Use and Results Judgment of Sterilization Chemical Indicators for Healthcare Products	2015-12-10	2016-09-01	SAC/TC200

## Seven, other

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Principles and requirements for the formulation and selection of medical device standards</b>					
186	YY/T 0467-2016	Guidelines for the selection of standards for the recognized basic principles of the safety and performance of medical devices for the protection of medical devices	2016-01-26	2017-01-01	SAC/TC221
187	YY/T 1000.1-2005	Formulation of medical device industry standards Part 1: Stage division, code and procedures	2005-07-18	2006-06-01	Shandong Center
188	YY/T 1000.2-2005	Formulation of Medical Device Industry Standards Part 2: Work Guidelines	2005-07-18	2006-06-01	Shandong Center
189	YY/T 91051-1999	Medical device industry standard system table	1999-01-01	2013-06-27	State Food and Drug Administration
190	YY/T 1473-2016	Guidelines for standardization of medical devices involve standard formulation of safety requirements	2016-01-26	2017-01-01	SAC/TC221
<b>(2) Medical polymer products</b>					
191	YY/T 0313-2014	Medical polymer product packaging and manufacturers provide information requirements standards	2014-06-17	2015-07-01	SAC/TC106
192	YY/T 0586-2016	X-ray opacity test method for medical polymer products	2016-01-26	2017-01-01	SAC/TC106
193	YY/T 1119-2008	Terminology for medical polymer products	2008-10-17	2010-01-01	Shandong Center

# Part Two Fields of expertise

## 1. Surgical instruments

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Professional and general fields</b>					

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
194	YY/T 0076-1992	Technical requirements for coating classification of metal parts	1992-01-20	1992-07-01	SAC/TC94
195	YY/T 0149-2006	Corrosion resistance test method of stainless steel medical equipment	2006-06-19	2007-05-01	SAC/TC94
196	YY/T 0171-2008	Surgical instrument packaging, marking and instructions for use	2008-10-17	2010-01-01	SAC/TC94
197	YY/T 0294.1-2016	Metallic materials for surgical instruments. Part 1 : Stainless steel	2016-03-23	2017-01-01	SAC/TC94
198	YY/T 1052-2004	Surgical instrument logo	2004-11-08	2005-11-01	SAC/TC94
<b>(2) Knife</b>					
199	GB 8662-2006	Matching size of scalpel blade and scalpel handle	2006-09-14	2007-05-01	SAC/TC94
200	YY/T 0072-2010	General technical conditions for ophthalmic knives	2010-12-27	2012-06-01	SAC/TC94
201	YY 0174-2019	Surgical blade	2019-05-31	2020-06-01	SAC/TC94
202	YY 0175-2005	Scalpel handle	2005-07-18	2006-06-01	SAC/TC94
203	YY/T 0454-2008	Sterile scalpel with plastic handle	2008-10-17	2010-01-01	SAC/TC94
<b>(Three) cut</b>					
204	YY/T 0176-2006	General technical conditions for medical scissors	2006-06-19	2007-05-01	SAC/TC94
205	YY 0672.2-2011	Endoscopic instruments Part 2 : Scissors for laparoscopy	2011-12-31	2013-06-01	SAC/TC94
206	YY/T 0176.9-2011	Eye Scissors	2011-12-31	2013-06-01	SAC/TC94
207	YY/T 0596-2006	Medical Scissors	2006-06-19	2007-05-01	SAC/TC94
208	YY/T 1135-2008	Bone scissors	2008-10-17	2010-01-01	SAC/TC94
<b>(Four) pliers</b>					
209	GB/T 2766-2006	General technical requirements for piercing hemostatic forceps	2006-08-24	2007-01-01	SAC/TC94
210	YY/T 0077-2013	General technical conditions of throat forceps	2013-10-21	2014-10-01	SAC/TC94
211	YY/T 0078-1992	General technical requirements for tracheal foreign body forceps	1992-01-20	1992-07-01	SAC/TC94

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
212	YY/T 0173-2010	Surgical instruments gill shafts, screws and rivets	2010-12-27	2012-06-01	SAC/TC94
213	YY/T 0173.4-2005	Surgical instruments lip hooks, lip teeth, locking teeth, egg-shaped finger rings	2005-07-18	2006-06-01	SAC/TC94
214	YY/T 0687-2008	General technical requirements for non-cutting articulated surgical instruments	2008-10-17	2010-01-01	SAC/TC94
215	YY/T 1058-2004	The length, width, thickness and diameter of the gill shaft of surgical instruments	2004-11-08	2005-11-01	SAC/TC94
216	YY/T 1076-2004	General technical requirements for tube biopsy forceps for endoscopy	2004-11-08	2005-11-01	SAC/TC94
217	YY/T 0177-2005	Tissue forceps	2005-07-18	2006-06-01	SAC/TC94
218	YY/T 0178-2010	Rectal and sigmoid colon biopsy forceps	2010-12-27	2012-06-01	SAC/TC94
219	YY/T 0246-2010	Nasopharyngeal biopsy forceps	2010-12-27	2012-06-01	SAC/TC94
220	YY/T 0452-2003	Hemostatic forceps	2003-06-20	2004-01-01	SAC/TC94
221	YY/T 0597-2006	Clip applier	2006-06-19	2007-05-01	SAC/TC94
222	YY/T 1015-2016	Eye needle holder	2016-01-26	2017-01-01	SAC/TC94
223	YY/T 1021-2005	Dental extraction forceps	2005-07-18	2006-06-01	SAC/TC94
224	YY/T 1031-2016	Needle Holding Pliers	2016-03-23	2017-01-01	SAC/TC94
225	YY/T 1472.1-2016	Thoracic small incision instruments. Part 1 : Skateboard forceps	2016-01-26	2017-01-01	SAC/TC94
<b>(5) Tweezers</b>					
226	YY/T 0295.1-2005	General technical conditions for medical tweezers	2005-07-18	2006-06-01	SAC/TC94
227	YY/T 0686-2017	Medical tweezers	2017-03-28	2018-04-01	SAC/TC94
228	YY/T 0819-2010	Ophthalmic forceps	2010-12-27	2012-06-01	SAC/TC94
<b>(6) Suture needle</b>					
229	YY 0877-2013	Purse-string suture needle	2013-10-21	2014-10-01	SAC/TC94
230	YY/T 0043-2016	Medical suture needle	2016-03-23	2017-01-01	SAC/TC94

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(7) Suture</b>					
231	YY 0167-2020	Non-absorbable surgical suture	2020-02-26	2021-03-01	SAC/TC94
232	YY 1116-2020	Absorbable surgical suture	2020-02-26	2021-03-01	SAC/TC94
233	YY/T 1746-2020	Test method for breaking strength of absorbable surgical suture after hydrolysis in vitro	2020-09-27	2021-09-01	SAC/TC94
<b>(8) Kiss (stitch) combiner</b>					
234	YY/T 0245-2008	General technical conditions for kiss (stitch) combiner	2008-04-25	2009-06-01	SAC/TC94
235	YY 0875-2013	Linear stapler and components	2013-10-21	2014-10-01	SAC/TC94
236	YY 0876-2013	Linear cutting stapler and components	2013-10-21	2014-10-01	SAC/TC94
237	YY/T 1415-2016	Skin stapler	2016-03-23	2017-01-01	SAC/TC94
<b>(9) Other</b>					
238	YY 0075-2005	Lacrimal probe	2005-07-18	2006-06-01	SAC/TC94
239	YY/T 0073-2013	Lacrimal sac retractor	2013-10-21	2014-10-01	SAC/TC94
240	YY/T 0079-2016	Medical metal clip	2016-03-23	2017-01-01	SAC/TC94
241	YY/T 0179-2005	T-shaped opener	2005-07-18	2006-06-01	SAC/TC94
242	YY/T 0180-2013	Eyelid Retractor	2013-10-21	2014-10-01	SAC/TC94
243	YY/T 0189-2008	Nose	2008-10-17	2010-01-01	SAC/TC94
244	YY/T 0190-2008	Anoscope	2008-10-17	2010-01-01	SAC/TC94
245	YY/T 0191-2011	Abdominal suction tube	2011-12-31	2013-06-01	SAC/TC94

## 2. Syringe (needle) , puncture equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Professional and general fields</b>					
246	GB/T 1962.1-2015	Syringes, injection needles and other medical devices 6% (Ruhr) tapered joints. Part 1 : General requirements	2015-12-10	2017-01-01	SAC/TC95

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
247	GB/T 1962.2-2001	Syringes, injection needles and other medical devices 6% (Luer) tapered joints. Part 2 : Locking joints	2001-09-18	2002-02-01	SAC/TC95
<b>(2) Syringe</b>					
248	GB 15810-2019	Sterile syringe for single use	2019-10-14	2020-11-01	SAC/TC95
249	YY/T 0573.2-2018	Sterile syringes for single use. Part 2 : Syringes for power driven syringe pumps	2018-09-28	2019-10-01	SAC/TC95
250	YY/T 0573.3-2019	Sterile syringes for single use. Part 3 : Self-destructive fixed-dose vaccine syringes	2019-05-31	2020-06-01	SAC/TC95
251	YY/T 0573.4-2020	Sterile syringes for single use. Part 4 : Prevent reuse of syringes	2020-02-26	2021-03-01	SAC/TC95
252	YY 91016-1999	Terminology for all glass syringes	1987-06-16	1988-01-01	SAC/TC95
253	YY 1001.1-2004	Glass Syringe Part 1 : All Glass Syringe	2004-10-10	2005-09-01	SAC/TC95
254	YY 1001.2-2004	Glass Syringe Part 2 : Blue Core All Glass Syringe	2004-10-10	2005-09-01	SAC/TC95
255	YY 91017-1999	Test method for tightness of all-glass syringe body	1987-06-16	1988-01-01	SAC/TC95
256	YY/T 0243-2016	Pistons for single-use sterile syringes	2016-03-23	2017-01-01	SAC/TC95
257	YY/T 0497-2018	Sterile insulin syringe for single use	2018-04-11	2019-05-01	SAC/TC95
258	YY/T 0820-2010	Dental barrel syringe	2010-12-27	2012-06-01	SAC/TC95
259	YY/T 0821-2010	Disposable syringe for single use	2010-12-27	2012-06-01	SAC/TC95
260	YY/T 0907-2013	Medical needleless syringes-requirements and test methods	2013-10-21	2014-10-01	SAC/TC95
261	YY/T 0908-2013	Single-use injection filter	2013-10-21	2014-10-01	SAC/TC95
262	YY/T 0909-2013	Single use low resistance syringe	2013-10-21	2014-10-01	SAC/TC95
263	YY/T 1768.1-2021	Medical needle injection system requirements and test methods. Part 1 : Needle injection system	2021-03-09	2022-04-01	SAC/TC95
264	YY/T 1768.2-2021	Medical needle injection system requirements and test methods. Part 2 : Needles	2021-03-09	2022-04-01	SAC/TC95

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(3) Injection needle</b>					
265	GB/T 18457-2015	Manufacture of stainless steel needle tubes for medical devices	2015-12-10	2017-01-01	SAC/TC95
266	GB 15811-2016	Sterile injection needle for single use	2016-06-14	2018-01-01	SAC/TC95
267	YY/T 0296-2013	Disposable injection needle identification color code	2013-10-21	2014-10-01	SAC/TC95
268	YY/T 0282-2009	Injection needle	2009-06-16	2010-10-01	SAC/TC95
269	YY/T 0587-2018	Sterile dental injection needles for single use	2018-04-11	2019-05-01	SAC/TC95
<b>(4) Puncture equipment</b>					
270	YY 0321.1-2009	One-time use anesthesia puncture kit	2009-06-16	2010-12-01	SAC/TC95
271	YY/T 0321.2-2021	Single-use anesthesia needle	2021-03-09	2022-04-01	SAC/TC95
272	YY 0321.3-2009	Single-use anesthesia filter	2009-06-16	2010-12-01	SAC/TC95
273	YY/T 1783-2021	Repeated use of abdominal puncture for endoscopic surgical instruments	2021-03-09	2022-04-01	SAC/TC94
274	YY/T 0980.1-2016	Single-use biopsy needles. Part 1 : General requirements	2016-03-23	2017-01-01	SAC/TC95
275	YY/T 0980.2-2016	Single use biopsy needle Part 2 : Manual type	2016-01-26	2017-01-01	SAC/TC95
276	YY/T 0980.3-2016	Disposable biopsy needle. Part 3 : Motorized assembly type	2016-07-29	2017-06-01	SAC/TC95
277	YY/T 0980.4-2016	Disposable biopsy needle Part 4 : Motorized one-piece	2016-07-29	2017-06-01	SAC/TC95
278	YY/T 1148-2009	Lumbar puncture needle	2009-06-16	2010-12-01	SAC/TC95
279	YY/T 1710-2020	Abdominal puncture for single use	2020-02-26	2021-03-01	SAC/TC94

### 3. Surgical implants

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Professional and general fields</b>					
280	GB/T 24629-2009	Surgical implants orthopedic implants maintenance and operation guide	2009-11-15	2010-05-01	SAC/TC110

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
281	GB/T 25440.1-2010	Removal and analysis of surgical implants. Part 1 : Removal and handling	2010-11-10	2011-05-01	SAC/TC110
282	GB/T 25440.2-2010	Removal and analysis of surgical implants. Part 2 : Analysis of removal of metal surgical implants	2010-11-10	2011-05-01	SAC/TC110
283	GB/T 25440.3-2010	Removal and analysis of surgical implants. Part 3 : Analysis of removal of polymer surgical implants	2010-11-10	2011-05-01	SAC/TC110
284	GB/T 25440.4-2010	Removal and analysis of surgical implants. Part 4 : Analysis of removal of ceramic surgical implants	2010-11-10	2011-05-01	SAC/TC110
285	YY/T 0340-2009	Basic principles of surgical implants	2009-12-30	2011-06-01	SAC/TC110
286	YY/T 0640-2016	General requirements for passive surgical implants	2016-07-29	2017-06-01	SAC/TC110
287	YY/T 0682-2008	Minimal data group for surgical implants	2008-10-17	2010-01-01	SAC/TC110
288	YY/T 0728-2009	Usage of the terms "valgus" and "varus" of surgical implants in orthopedics	2009-06-16	2010-12-01	SAC/TC110
289	YY/T 0987.1-2016	Surgical implant MR compatibility of a Part : security mark	2016-03-23	2017-01-01	SAC/TC110
290	YY/T 0987.2-2016	Magnetic resonance compatibility of surgical implants. Part 2 : Magnetically induced displacement test method	2016-03-23	2017-01-01	SAC/TC110
291	YY/T 0987.3-2016	Magnetic resonance compatibility of surgical implants. Part 3 : Image artifact evaluation method	2016-03-23	2017-01-01	SAC/TC110
292	YY/T 0987.4-2016	Magnetic resonance compatibility of surgical implants. Part 4 : Radio frequency heating test method	2016-03-23	2017-01-01	SAC/TC110
293	YY/T 0987.5-2016	Magnetic resonance compatibility of surgical implants. Part 5 : Magnetic torque test method	2016-03-23	2017-01-01	SAC/TC110
<b>(2) Materials</b>					
294	GB 4234.1-2017	Metallic materials for surgical implants. Part 1 : Forged stainless steel	2017-12-29	2019-07-01	SAC/TC110
295	GB 4234.4-2019	Metallic materials for surgical implants. Part 4 : Casting cobalt - chromium - molybdenum alloy	2019-10-14	2021-05-01	SAC/TC110

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
296	YY/T 0605.5-2007	Metallic materials for surgical implants. Part 5 : Forged cobalt - chromium - tungsten - nickel alloy	2007-01-31	2008-01-01	SAC/TC110
297	YY/T 0605.6-2007	Metallic materials for surgical implants. Part 6 : Forged cobalt - nickel - chromium - molybdenum alloy	2007-01-31	2008-01-01	SAC/TC110
298	YY/T 0605.7-2007	Metallic materials for surgical implants. Part 7 : Forgeable and cold-workable cobalt - chromium - nickel - molybdenum - iron alloys	2007-01-31	2008-01-01	SAC/TC110
299	YY/T 0605.8-2007	Metallic materials for surgical implants. Part 8 : Forged cobalt - nickel - chromium - molybdenum - tungsten - iron alloy	2007-01-31	2008-01-01	SAC/TC110
300	YY 0605.9-2015	Metallic materials for surgical implants. Part 9 : Forged high-nitrogen stainless steel	2015-03-02	2017-01-01	SAC/TC110
301	YY 0605.12-2016	Metallic materials for surgical implants. Part 12 : Wrought cobalt - chromium - molybdenum alloy	2016-01-26	2018-01-01	SAC/TC110
302	GB 23102-2008	Surgical implant metal material Ti-6Al-7Nb alloy processing material	2008-12-30	2010-03-01	SAC/TC110
303	GB 24627-2009	Nickel - titanium shape memory alloy processed materials for medical devices and surgical implants	2009-11-15	2010-12-01	SAC/TC110
304	GB/T 36983-2018	Porous tantalum material for surgical implants	2018-12-28	2021-01-01	SAC/TC110
305	GB/T 36984-2018	X-ray CT detection method of porous metal materials for surgical implants	2018-12-28	2021-01-01	SAC/TC110
306	GB/T 19701.1-2016	Surgical implants. Ultra-high molecular weight polyethylene. Part 1 : Powder	2016-12-13	2018-07-01	SAC/TC110
307	GB/T 19701.2-2016	Surgical implants. Ultra-high molecular weight polyethylene. Part 2 : Molding compound	2016-12-13	2018-07-01	SAC/TC110
308	YY/T 0772.3-2009	Surgical implants. Ultra-high molecular weight polyethylene. Part 3 : Accelerated aging methods	2009-12-30	2011-06-01	SAC/TC110
309	YY/T 0772.4-2009	Surgical implants. Ultra-high molecular weight polyethylene. Part 4 : Oxidation index test method	2009-12-30	2011-06-01	SAC/TC110
310	YY/T 0772.5-2009	Surgical implants. Ultra-high molecular weight polyethylene. Part 5 : Morphological evaluation methods	2009-12-30	2011-06-01	SAC/TC110



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
311	GB/T 22750-2008	High-purity alumina ceramic materials for surgical implants	2008-12-30	2009-12-01	SAC/TC110
312	YY/T 1294.2-2015	Ceramic materials for surgical implants. Part 2 : Zirconia toughened high-purity alumina matrix composites	2015-03-02	2016-01-01	SAC/TC110
313	GB 23101.1-2008	Surgical implants. Hydroxyapatite. Part 1 : Hydroxyapatite ceramics	2008-12-30	2010-03-01	SAC/TC110
314	GB 23101.2-2008	Surgical implants. Hydroxyapatite. Part 2 : Hydroxyapatite coating	2008-12-30	2010-03-01	SAC/TC110
315	GB/T 23101.3-2010	Surgical implants. Hydroxyapatite. Part 3 : Chemical analysis and characterization of crystallinity and phase purity	2010-09-02	2011-08-01	SAC/TC110
316	GB/T 23101.4-2008	Surgical implants. Hydroxyapatite. Part 4 : Determination of coating bond strength	2008-12-30	2010-03-01	SAC/TC110
317	YY/T 0966-2014	Surgical implant metal material pure tantalum	2014-06-17	2015-07-01	SAC/TC110
318	YY/T 1615-2018	General requirements for titanium and titanium alloy anodic oxide films for surgical implants	2018-11-07	2019-11-01	SAC/TC110
319	YY/T 0343-2002	Surgical metal implant liquid penetration test	2002-09-24	2003-04-01	SAC/TC110
320	YY/T 0512-2009	Classification of Microstructure of Metallic Materials of Surgical Implants $\alpha + \beta$ Titanium Alloy Bars	2009-12-30	2011-06-01	SAC/TC110
321	YY/T 0641-2008	Standard Method for Measuring Phase Transition Temperature of NiTi Alloy by Thermal Analysis	2008-04-25	2009-06-01	SAC/TC110
322	YY/T 1771-2021	Bending - free recovery method to test the phase transition temperature of nickel-titanium shape memory alloy	2021-03-09	2022-04-01	SAC/TC110
323	YY/T 1074-2002	Pitting Potential of Stainless Steel Products for Surgical Implants	2002-09-24	2003-04-01	SAC/TC110
324	YY/T 1427-2016	Test solutions and conditions for static and dynamic corrosion tests of implantable materials and medical devices for surgical implants	2016-01-26	2017-01-01	SAC/TC110
325	YY/T 1552-2017	Surgical implants: Open circuit potential measurement method for evaluating the long-term corrosion behavior of metal implant materials and medical devices	2017-09-25	2018-10-01	SAC/TC110

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
326	YY/T 1565-2017	Non-destructive inspection of surgical implants. Radiographic inspection of cast metal surgical implants	2017-03-28	2018-04-01	SAC/TC110
327	YY/T 1772-2021	Test method for galvanic corrosion in the electrolyte of surgical implants	2021-03-09	2022-04-01	SAC/TC110
328	YY 0459-2003	Surgical implant acrylic resin bone cement	2003-06-20	2004-01-01	SAC/TC110
329	YY 0484-2004	Surgical implant two-component addition molding vulcanized silicone rubber	2004-07-16	2005-08-01	Shandong Center
330	YY/T 0510-2009	Surgical implant post and malonic ester resin with amorphous polylactide - glycolide copolymer resin	2009-12-30	2011-06-01	SAC/TC110
331	YY/T 0660-2008	Standard Specification for Polyetheretherketone ( PEEK ) Polymer for Surgical Implants	2008-04-25	2009-06-01	SAC/TC110
332	YY/T 0661-2017	Semi-crystalline polylactide polymer and copolymer resin for surgical implants	2017-09-25	2018-10-01	SAC/TC110
333	YY/T 0811-2010	Standard requirements for high-dose radiation cross-linked ultra-high molecular weight polyethylene products for surgical implants	2010-12-27	2012-06-01	SAC/TC110
334	YY/T 1431-2016	Surgical implant medical grade ultra-high molecular weight polyethylene yarn	2016-01-26	2017-01-01	SAC/TC110
335	YY/T 0473-2004	In vitro degradation test of polylactide copolymers and blends for surgical implants	2004-03-23	2005-01-01	SAC/TC248
336	YY/T 0474-2004	In vitro degradation test of L-lactide resin and products for surgical implants	2004-03-23	2005-01-01	SAC/TC248
337	YY/T 0813-2010	Standard method for in-situ determination of molecular network parameters of cross-linked ultra-high molecular weight polyethylene ( UHMWPE )	2010-12-27	2012-06-01	SAC/TC110
338	YY/T 0814-2010	Standard Test Method for Evaluating Trans-Vinylene Content in Ultra-High Molecular Weight Polyethylene Products After Radiation for Surgical Implants by Infrared Spectroscopy	2010-12-27	2012-06-01	SAC/TC110
339	YY/T 0815-2010	Differential Scanning Calorimetry to Determine the Melting Enthalpy, Crystallinity and Melting Point of UHMWPE	2010-12-27	2012-06-01	SAC/TC110
340	YY/T 1429-2016	Surgical implants. Acrylic resin bone cements. Acrylic resin bone cements for orthopedic surgery. Test method for flexural fatigue properties of acrylic resin bone cements	2016-01-26	2017-01-01	SAC/TC110

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
341	YY/T 1430-2016	Test method for small punching of ultra-high molecular weight polyethylene for surgical implants	2016-01-26	2017-01-01	SAC/TC110
342	YY/T 1507.1-2016	Determination of impurity elements in ultra-high molecular weight polyethylene powder for surgical implants. Part 1 : Determination of titanium ( Ti ) element content by ICP-MS	2016-07-29	2017-06-01	SAC/TC110
343	YY/T 1507.2-2016	Determination of impurity elements in ultra-high molecular weight polyethylene powder for surgical implants. Part 2 : Determination of chlorine ( Cl ) element content by ion chromatography	2016-07-29	2017-06-01	SAC/TC110
344	YY/T 1507.3-2016	Surgical implants measuring ultrahigh molecular weight polyethylene powder with the impurity element in the first 3 Part ICP-MS determination of calcium (Method of Ca) element content	2016-07-29	2017-06-01	SAC/TC110
345	YY/T 1507.4-2016	Surgical implant the measuring ultrahigh molecular weight polyethylene powder in the first impurity element 4 Part ICP-MS assay aluminum (Method of Al) element content	2016-07-29	2017-06-01	SAC/TC110
346	YY/T 1776-2021	Determination of Lactide Monomer Content in Polylactic Acid for Surgical Implants	2021-03-09	2022-04-01	SAC/TC110
347	YY/T 1678-2019	Method for detecting molecular weight and molecular weight distribution of polylactic acid and its copolymer for surgical implants	2019-10-23	2020-10-01	SAC/TC110
348	YY/T 1707-2020	Differential scanning calorimetry of polyetheretherketone polymer and its composites for surgical implants implanted in medical devices	2020-02-21	2021-01-01	SAC/TC110
349	YY/T 0683-2008	Beta - Tricalcium Phosphate for Surgical Implants	2008-10-17	2010-01-01	SAC/TC110
350	YY/T 0964-2014	Surgical implants bioglass and glass ceramic materials	2014-06-17	2015-07-01	SAC/TC110
351	YY/T 1558.3-2017	Surgical implants. Calcium phosphate. Part 3 : Hydroxyapatite and $\beta$ - tricalcium phosphate bone substitutes	2017-09-25	2018-10-01	SAC/TC110
352	YY/T 1715-2020	Yttrium oxide stabilized tetragonal zirconia ( Y-TZP ) ceramic material for surgical implants	2020-06-30	2021-06-01	SAC/TC110
353	YY/T 1447-2016	In Vitro Evaluation of Apatite Forming Ability of Surgical Implant Material	2016-01-26	2017-01-01	SAC/TC110

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
354	YY/T 1640-2018	Test method for solubility of calcium phosphate particles, products and coatings of surgical implants	2018-12-20	2020-01-01	SAC/TC110
355	YY/T 0988.1-2016	A first coating surgical implants 1Part: Cobalt -28 Chromium -6 Mo powder	2016-03-23	2017-01-01	SAC/TC110
356	YY/T 0988.2-2016	Surgical implant coating. Part 2: Titanium and titanium- 6 aluminum -4 vanadium alloy powder	2016-03-23	2017-01-01	SAC/TC110
357	YY/T 0988.11-2016	Surgical implant coating. Part 11: Calcium phosphate coating and metal coating tensile test method	2016-03-23	2017-01-01	SAC/TC110
358	YY/T 0988.12-2016	Surgical implant coatings. Part 12: Calcium phosphate coating and metal coating shear test method	2016-03-23	2017-01-01	SAC/TC110
359	YY/T 0988.13-2016	Surgical implant coatings. Part 13: Shear and bending fatigue test methods for calcium phosphate, metal and calcium phosphate /metal composite coatings	2016-03-23	2017-01-01	SAC/TC110
360	YY/T 0988.14-2016	Surgical implant coating. Part 14: Stereological evaluation method of porous coating	2016-03-23	2017-01-01	SAC/TC110
361	YY/T 0988.15-2016	Surgical implant coatings. Part 15: Test method for wear resistance of metal thermal spray coatings	2016-03-23	2017-01-01	SAC/TC110
362	YY/T 1706.1-2020	Surgical implants. Metal surgical implants. Plasma sprayed pure titanium coating. Part 1: General requirements	2020-02-21	2021-01-01	SAC/TC110
<b>(3) Orthopedic equipment and tools</b>					
363	YY/T 0726-2020	General requirements for passive surgical implant combination devices	2020-06-30	2021-06-01	SAC/TC110
364	YY/T 0508-2009	Special requirements for external fixation bracket	2009-12-30	2011-06-01	SAC/TC110
365	YY/T 1137-2017	General technical conditions for bone saws	2017-05-02	2018-04-01	SAC/TC110
366	YY/T 1141-2017	General technical conditions for osteotome	2017-09-25	2018-10-01	SAC/TC110
367	YY/T 0957.1-2014	Orthopedic tools screwing joints. Part 1: Wrenches for hexagon socket screws	2014-06-17	2015-07-01	SAC/TC110
368	YY/T 0957.2-2014	Orthopedic tools, screwing joints. Part 2: Screwdrivers for slotted, cross-slot and cross-slot head screws	2014-06-17	2015-07-01	SAC/TC110

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
369	YY/T 0958.1-2014	Orthopedic drilling equipment. Part 1: Drills, taps and countersunk cutters	2014-06-17	2015-07-01	SAC/TC110
370	YY/T 1122-2017	General technical requirements for rongeurs (scissors)	2017-03-28	2018-04-01	SAC/TC110
371	YY/T 1127-2006	Rongeur	2006-06-19	2007-05-01	SAC/TC110
372	YY/T 1133-2020	Passive surgical implant combined instrument metal bone drill	2020-06-30	2021-06-01	SAC/TC110

#### (4) Orthopedic implants

373	GB/T 12417.1-2008	Passive surgical implants. Bone joint and joint replacement implants. Part 1: Special requirements for bone joint implants	2008-12-15	2010-02-01	SAC/TC110/S C1
374	GB/T 12417.2-2008	Passive surgical implants. Bone joint and joint replacement implants. Part 2: Special requirements for joint replacement implants	2008-12-15	2010-02-01	SAC/TC110/S C1
375	YY 0117.1-2005	Surgical implants, bone and joint prosthesis forging, casting Ti6Al4V titanium alloy forgings	2005-12-07	2006-12-01	SAC/TC110/S C1
376	YY 0117.2-2005	Surgical implants, bone and joint prostheses, forging and casting ZTi6Al4V titanium alloy castings	2005-12-07	2006-12-01	SAC/TC110/S C1
377	YY 0117.3-2005	Surgical implants, bone and joint prostheses forging, castings, cobalt-chromium-molybdenum alloy castings	2005-12-07	2006-12-01	SAC/TC110/S C1
378	YY/T 0652-2016	Separation and characterization of wear debris of implant materials from polymer and metal materials	2016-01-26	2017-01-01	SAC/TC110/S C1
379	YY/T 0920-2014	Passive surgical implants. Joint replacement implants. Particular requirements for hip replacement implants	2014-06-17	2015-07-01	SAC/TC110/S C1
380	YY/T 0809.1-2010	Surgical implants and total hip joint prostheses. Part 1: Classification and dimensioning	2010-12-27	2012-06-01	SAC/TC110/S C1
381	YY/T 0809.2-2020	Surgical implants and total hip joint prostheses. Part 2: Metal, ceramic and plastic articular surfaces	2020-09-27	2021-09-01	SAC/TC110/S C1
382	YY/T 0809.4-2018	Surgical implant parts and total hip joint prostheses. Part 4: Fatigue performance test and performance requirements of the stemmed femoral component	2018-09-28	2019-10-01	SAC/TC110/S C1
383	YY/T 0809.6-2018	Part of surgical implants and total hip joint prostheses. Part 6: Neck fatigue performance	2018-09-21	2019-09-26	SAC/TC110/S C1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		test and performance requirements of the shank femoral component			
384	YY/T 0809.8-2010	Surgical implants and total hip joint prostheses. Part 8 : Fatigue performance of the stemmed femoral component with torque action	2010-12-27	2012-06-01	SAC/TC110/S C1
385	YY/T 0809.10-2014	Surgical implants. Half hip and total hip joint prosthesis. Part 10 : Determination of the static resistance of the combined femoral head	2014-06-17	2015-07-01	SAC/TC110/S C1
386	YY/T 0809.12-2020	Surgical implants and total hip joint prostheses. Part 12 : Test method for acetabular cup deformation	2020-06-30	2021-06-01	SAC/TC110/S C1
387	YY/T 0809.13-2020	Surgical implants and total hip joint prostheses. Part 13 : Determination of the fixed anti-torsion torque of the head of the stemmed femoral component	2020-02-21	2021-01-01	SAC/TC110/S C1
388	YY/T 0651.1-2016	Surgical implants. Wear of total hip joint prostheses. Part 1 : Load and displacement parameters of wear testing machine and related test environment conditions	2016-01-26	2017-01-01	SAC/TC110/S C1
389	YY/T 0651.2-2020	Surgical implants. Wear of total hip prostheses. Part 2 : Measurement methods	2020-09-27	2021-09-01	SAC/TC110/S C1
390	YY/T 0651.3-2020	Surgical implants. Wear of total hip joint prostheses. Part 3 : Load and displacement parameters of orbital bearing type wear testing machine and related test environment conditions	2020-06-30	2021-06-01	SAC/TC110/S C1
391	YY 0118-2016	Joint replacement implant hip prosthesis	2016-01-26	2018-01-01	SAC/TC110/S C1
392	YY/T 1705-2020	Method for measuring the impact resistance of surgical implant hip joint prosthesis ceramic femoral head	2020-02-21	2021-01-01	SAC/TC110/S C1
393	YY/T 1714-2020	Standard method for finite element analysis of non-combined metal hip joint femoral stem	2020-06-30	2021-06-01	SAC/TC110/S C1
394	YY/T 1720-2020	Test method for separating force of combined acetabular components	2020-02-26	2021-03-01	SAC/TC110/S C1
395	YY/T 0919-2014	Passive surgical implants. Joint replacement implants. Particular requirements for knee replacement implants.	2014-06-17	2015-07-01	SAC/TC110/S C1
396	YY 0502-2016	Joint replacement implants knee prosthesis	2016-01-26	2018-01-01	SAC/TC110/S C1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
397	YY/T 0924.1-2014	Surgical implant components and total knee joint prosthesis components. Part 1: Classification, definition and dimensioning	2014-06-17	2015-07-01	SAC/TC110/S C1
398	YY/T 0924.2-2014	Surgical implant parts and total knee joint prosthesis parts. Part 2: Metal, ceramic and plastic articular surfaces	2014-06-17	2015-07-01	SAC/TC110/S C1
399	YY/T 0810.1-2010	Surgical implants. Total knee prostheses. Part 1: Determination of the fatigue performance of the tibial tray	2010-12-27	2012-06-01	SAC/TC110/S C1
400	YY/T 1426.1-2016	Surgical implants. Wear of total knee joint prostheses. Part 1: Load and displacement parameters of load-controlled wear testers and related test environmental conditions	2016-01-26	2017-01-01	SAC/TC110/S C1
401	YY/T 1426.2-2016	Surgical implants. Wear of total knee prostheses. Part 2: Measurement methods	2016-01-26	2017-01-01	SAC/TC110/S C1
402	YY/T 1426.3-2017	Surgical implants. Wear of total knee joint prostheses. Part 3: Load and displacement parameters of displacement-controlled wear testers and related test environmental conditions	2017-09-25	2018-10-01	SAC/TC110/S C1
403	YY/T 1736-2020	Test method for evaluating the durability and deformation of knee tibial pads under high flexion conditions	2020-06-30	2021-06-01	SAC/TC110/S C1
404	YY/T 1762-2020	Test method for dynamic fatigue performance of metal tibial tray component of unicondylar knee replacement prosthesis	2020-09-27	2021-09-01	SAC/TC110/S C1
405	YY/T 1765-2020	Test method of restraint degree of total knee joint prosthesis	2020-09-27	2021-09-01	SAC/TC110/S C1
406	YY/T 0963-2014	Joint replacement implants shoulder joint prosthesis	2014-06-17	2015-07-01	SAC/TC110/S C1
407	YY/T 1634-2018	Joint replacement implants and shoulder joint prosthesis glenoid loosening or separation dynamic evaluation test method	2018-12-20	2020-01-01	SAC/TC110/S C1
408	YY/T 1647-2019	Static shear evaluation test method for glenoid locking mechanism of joint replacement implant shoulder joint prosthesis	2019-10-23	2020-10-01	SAC/TC110/S C1
409	YY 0341.1-2020	Passive surgical implants. Bone joint and spinal implants. Part 1: Special requirements for bone joint implants	2020-09-27	2022-06-01	SAC/TC110/S C1
410	YY 0341.2-2020	Passive surgical implants. Bone joint and spinal implants. Part 2: Special requirements for spinal implants	2020-09-27	2022-06-01	SAC/TC110/S C1
411	YY/T 0856-2011	Bone joint implant metal angle fixator	2011-12-31	2013-06-01	SAC/TC110/S C1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
412	YY 0017-2016	Bone joint implant metal bone plate	2016-07-29	2018-06-01	SAC/TC110/S C1
413	YY 0018-2016	Bone joint implant metal bone screw	2016-07-29	2018-06-01	SAC/TC110/S C1
414	YY/T 1655-2019	Bone joint implant bone plate and bone screw fretting corrosion test method	2019-05-31	2020-06-01	SAC/TC110/S C1
415	YY/T 0509-2009	Standard requirements and test methods for bioabsorbable internal fixation plates and screws	2009-12-30	2011-06-01	SAC/TC110/S C1
416	YY 0346-2002	Bone joint implant metal femoral neck fixation nail	2002-09-24	2003-04-01	SAC/TC110/S C1
417	YY/T 0345.1-2020	Metal spicules for surgical implants. Part 1 : General requirements	2020-06-30	2021-06-01	SAC/TC110/S C1
418	YY/T 0345.2-2014	Metal bone pins for surgical implants. Part 2 : Schanz pin size	2014-06-17	2015-07-01	SAC/TC110/S C1
419	YY/T 0345.3-2014	Surgical implants. Metal bone pins. Part 3 : Kirschner wires	2014-06-17	2015-07-01	SAC/TC110/S C1
420	YY/T 0956-2014	General requirements for U-shaped nails for orthopedics of surgical implants	2014-06-17	2015-07-01	SAC/TC110/S C1
421	YY/T 0342-2020	Measurement of Bending Strength and Rigidity of Bone Plate of Surgical Implant	2020-09-27	2021-09-01	SAC/TC110/S C1
422	YY/T 0662-2008	Mechanical performance requirements and test methods of metal bone screws with asymmetric threads and spherical lower surface of surgical implants	2008-04-25	2009-06-01	SAC/TC110/S C1
423	YY/T 1503-2016	Test method for fatigue performance of metal bone plates of surgical implants	2016-07-29	2017-06-01	SAC/TC110/S C1
424	YY/T 1504-2016	Test method for the axial pull-out force of metal bone screws of surgical implants	2016-07-29	2017-06-01	SAC/TC110/S C1
425	YY/T 1505-2016	Test method for self-tapping performance of metal bone screws for surgical implants	2016-07-29	2017-06-01	SAC/TC110/S C1
426	YY/T 1506-2016	Test method for turning torque of metal bone screws for surgical implants	2016-07-29	2017-06-01	SAC/TC110/S C1
427	YY/T 0591-2011	Bone joint implant metal interlocking intramedullary nail	2011-12-31	2013-06-01	SAC/TC110/S C1



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
428	YY/T 0019.1-2011	Surgical implant intramedullary nail system. Part 1: Trilobal or V-shaped intramedullary nail in cross section	2011-12-31	2013-06-01	SAC/TC110/S C1
429	YY/T 0019.2-2011	Surgical implant intramedullary nail system. Part 2: Intramedullary nail	2011-12-31	2013-06-01	SAC/TC110/S C1
430	YY/T 0727.1-2009	Surgical implant metal intramedullary nail system. Part 1: Intramedullary nail	2009-11-15	2010-12-01	SAC/TC110/S C1
431	YY/T 0727.2-2009	Surgical implants. Metal intramedullary nail system. Part 2: Locking components	2009-11-15	2010-12-01	SAC/TC110/S C1
432	YY/T 0727.3-2009	Surgical implants. Metal intramedullary nail system. Part 3: Measuring the diameter of connecting instruments and medullary cavity expanders	2009-11-15	2010-12-01	SAC/TC110/S C1
433	YY/T 0812-2010	Metal cables and cables for surgical implants	2010-12-27	2012-06-01	SAC/TC110/S C1
434	YY/T 0816-2010	Surgical implant sutures and other surgical flexible metal wires	2010-12-27	2012-06-01	SAC/TC110/S C1
435	YY/T 1428-2016	Terms related to spinal implants	2016-01-26	2017-01-01	SAC/TC110/S C1
436	YY/T 0119.1-2014	Spinal implants. Spinal internal fixation system components. Part 1: General requirements	2014-06-17	2015-07-01	SAC/TC110/S C1
437	YY/T 0119.2-2014	Spinal implants. Spinal internal fixation system components. Part 2: Metal spinal screws	2014-06-17	2015-07-01	SAC/TC110/S C1
438	YY/T 0119.3-2014	Spinal implants. Spinal internal fixation system components. Part 3: Metal spinal plate	2014-06-17	2015-07-01	SAC/TC110/S C1
439	YY/T 0119.4-2014	Spinal implants. Spinal internal fixation system components. Part 4: Metal spinal rods	2014-06-17	2015-07-01	SAC/TC110/S C1
440	YY/T 0119.5-2014	Spinal implants. Spinal internal fixation system components. Part 5: Test method for determination of static and fatigue bending strength of metal spinal screws	2014-06-17	2015-07-01	SAC/TC110/S C1
441	YY/T 0857-2011	Test method of spinal implants in vertebral body resection model	2011-12-31	2013-06-01	SAC/TC110/S C1
442	YY/T 0961-2014	Static and fatigue performance evaluation method of spinal implant spinal internal fixation system components and connecting devices	2014-06-17	2015-07-01	SAC/TC110/S C1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
443	YY/T 1560-2017	Test method of occipitocervical and occipitocervical thoracic implants in spinal implant vertebral body resection model	2017-03-28	2018-04-01	SAC/TC110/S C1
444	YY/T 1502-2016	Spinal implant interbody fusion cage	2016-07-29	2017-06-01	SAC/TC110/S C1
445	YY/T 0959-2014	Test method of mechanical properties of spinal implant interbody fusion cage	2014-06-17	2015-07-01	SAC/TC110/S C1
446	YY/T 0960-2014	Test method for static axial compression subsidence of spinal implant interbody fusion cage	2014-06-17	2015-07-01	SAC/TC110/S C1
447	YY/T 1559-2017	Static and dynamic performance test method of spinal implant intervertebral disc prosthesis	2017-03-28	2018-04-01	SAC/TC110/S C1
448	YY/T 1563-2017	Spinal implants and total disc prostheses function, motion and wear evaluation test methods	2017-03-28	2018-04-01	SAC/TC110/S C1

**(5) Cardiovascular implants**

449	GB/T 39381.1-2020	Cardiovascular implants, vascular drug-device combination products. Part 1: General requirements	2020-11-19	2021-12-01	SAC/TC110/S C2
450	GB 12279-2008	Cardiovascular implant artificial heart valve	2008-12-31	2009-12-1	SAC/TC110/S C2
451	YY/T 0695-2008	Standard Test Method of Cyclic Potential Polarization for Corrosion Sensitivity of Small Implanted Devices	2008-10-17	2010-01-01	SAC/TC110/S C2
452	YY/T 1449.3-2016	Cardiovascular implants, artificial heart valves. Part 3: Transcatheter implantable artificial heart valves	2016-01-26	2017-01-01	SAC/TC110/S C2
453	YY 0500-2004	Cardiovascular implants artificial blood vessels	2004-11-08	2005-11-01	SAC/TC110/S C2
454	YY/T 0663.1-2014	Cardiovascular implants and endovascular devices Part 1: Endovascular prostheses	2014-06-17	2015-07-01	SAC/TC110/S C2
455	YY/T 0663.2-2016	Cardiovascular implants and endovascular devices. Part 2: Vascular stents	2016-07-29	2017-06-01	SAC/TC110/S C2
456	YY/T 0663.3-2016	Cardiovascular implants and endovascular devices. Part 3: Vena cava filter	2016-03-23	2017-01-01	SAC/TC110/S C2
457	YY/T 0693-2008	Characterization of stent size characteristics	2008-10-17	2010-01-01	SAC/TC110/S C2
458	YY/T 0694-2020	Standard test method for elastic retraction of balloon expandable stents	2020-06-30	2021-06-01	SAC/TC110/S C2

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
459	YY/T 0807-2010	Standard test method for the stability of balloon-expandable vascular stents pre-installed on the delivery system	2010-12-27	2012-06-01	SAC/TC110/S C2
460	YY/T 0808-2010	Standard test method for in vitro pulsation durability of vascular stents	2010-12-27	2012-06-01	SAC/TC110/S C2
461	YY/T 0858-2011	Balloon expansion vessel stent and stent system three-point bending test method	2011-12-31	2013-06-01	SAC/TC110/S C2
462	YY/T 0859-2011	A guide to the finite element analysis method of metal vascular stents under uniform radial load	2011-12-31	2013-06-01	SAC/TC110/S C2
463	YY/T 1660-2019	Radial load test method for balloon expansion and self-expanding vascular stent	2019-07-24	2020-08-01	SAC/TC110/S C2
464	YY/T 1553-2017	Cardiovascular implant cardiac occluder	2017-09-25	2018-10-01	SAC/TC110/S C2
465	YY/T 1758-2020	Cardiovascular implant pulmonary valved catheter	2020-09-27	2021-09-01	SAC/TC110/S C2
466	YY/T 1564-2017	Cardiovascular implant pulmonary artery valved tube in vitro pulsating flow performance test method	2017-03-28	2018-04-01	SAC/TC110/S C2

**(6) Tissue engineering implants**

467	GB/T 36988-2018	Guidance on Human Resources Organization Operation Specification for Tissue Engineering	2018-12-28	2021-01-01	SAC/TC110/S C3
468	YY/T 0606.3-2007	Tissue Engineering Medical Products Part 3 : General Classification	2007-01-31	2008-01-01	SAC/TC110/S C3
469	YY/T 0606.10-2008	Tissue-engineered medical products. Part 10 : Guidelines for in-body evaluation of implants for repairing or regenerating articular cartilage	2008-04-25	2009-06-01	SAC/TC110/S C3
470	YY/T 0606.12-2007	Tissue Engineering Medical Products Part 12 : Processing Guidelines for Cells, Tissues and Organs	2007-01-31	2008-01-01	SAC/TC110/S C3
471	YY/T 0606.13-2008	Tissue engineering medical products. Part 13 : Automatic cell counting method	2008-04-25	2009-06-01	SAC/TC110/S C3
472	YY/T 0606.14-2014	Tissue engineering medical products. Part 14 : Test methods for evaluating the immune response of substrates and scaffolds: ELISA method	2014-06-17	2015-07-01	SAC/TC110/S C3
473	YY/T 0606.15-2014	Tissue engineering medical products. Part 15 : Test methods for evaluating the immune	2014-06-17	2015-07-01	SAC/TC110/S C3

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		response of substrates and stents - lymphocyte proliferation test			
474	YY/T 0606.20-2014	Tissue engineering medical products. Part 20 : Test methods for evaluating the immune response of substrates and scaffolds: cell migration test	2014-06-17	2015-07-01	SAC/TC110/S C3
475	YY/T 0606.25-2014	Tissue engineering medical products. Part 25 : Determination of DNA residues in biological materials of animal origin : Fluorescence staining method	2014-06-17	2015-07-01	SAC/TC110/S C3
476	YY/T 1435-2016	Guidelines for the characterization of hydrogels for tissue-engineered medical device products	2016-07-29	2017-06-01	SAC/TC110/S C3
477	YY/T 1445-2016	Tissue Engineering Medical Device Product Terminology	2016-07-29	2017-06-01	SAC/TC110/S C3
478	YY/T 1562-2017	Guide for cell viability test of biomaterial scaffolds for tissue engineering medical device products	2017-03-28	2018-04-01	SAC/TC110/S C3
479	YY/T 1570-2017	Terminology and classification of skin substitutes (substances) for tissue engineering medical device products	2017-05-02	2018-04-01	SAC/TC110/S C3
480	YY/T 1576-2017	Tissue engineering medical device product absorbable material implantation test	2017-08-18	2018-09-01	SAC/TC110/S C3
481	YY/T 1616-2018	Guidelines for performance and testing of biomaterial scaffolds for tissue engineering medical device products	2018-11-07	2019-11-01	SAC/TC110/S C3
482	YY/T 1574-2017	Guidelines for fixation or microencapsulation of alginate gels for tissue engineering medical device products	2017-08-18	2018-09-01	SAC/TC110/S C3
483	YY/T 1577-2017	Guidelines for evaluating the microstructure of polymer scaffolds for tissue engineering medical device products	2017-08-18	2018-09-01	SAC/TC110/S C3
484	YY/T 1716-2020	Characterization of ceramic and mineral scaffolds for tissue engineering medical device products	2020-06-30	2021-06-01	SAC/TC110/S C3
485	YY/T 1744-2020	Method for measuring cell migration in bioactive ceramic porous material of tissue engineering medical device product	2020-09-27	2021-09-01	SAC/TC110/S C3
486	YY/T 1453-2016	Tissue engineering medical device product type I collagen characterization method	2016-07-29	2017-06-01	SAC/TC110/S C3
487	YY/T 1561-2017	Detection of residual $\alpha$ -Gal antigen of animal-derived scaffold materials in tissue engineering medical device products	2017-03-28	2018-04-01	SAC/TC110/S C3

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
488	YY/T 0513.1-2019	Allogeneic restorative materials. Part 1 : Basic requirements for tissue library	2019-10-23	2020-10-01	Central Procuratorate
489	YY/T 0513.2-2020	Allogeneic restorative materials. Part 2 : Cryogenic frozen bone and freeze-dried bone	2020-06-30	2021-06-01	Central Procuratorate
490	YY/T 0513.3-2020	Allogeneic restorative materials. Part 3 : Demineralized bone	2020-02-21	2021-01-01	Central Procuratorate
491	YY/T 1680-2020	Evaluation of in vivo osteoinductive properties of demineralized bone materials for allogeneic repair materials	2020-02-21	2021-01-01	Central Procuratorate
492	YY/T 1575-2017	Guidelines for the evaluation of bone formation activity of tissue engineered medical device products for repair and replacement of bone tissue implants	2017-08-18	2018-09-01	SAC/TC110/S C3
493	YY/T 1598-2018	Tissue engineering medical device product bone used for spinal fusion surgical implant bone repair or regeneration evaluation test guide	2018-04-11	2019-05-01	SAC/TC110/S C3
494	YY/T 1679-2021	Guidelines for the preclinical evaluation of critical-size bone defects in the bones of tissue-engineered medical device products	2021-03-09	2022-04-01	SAC/TC110/S C3
495	YY/T 1636-2018	In vivo magnetic resonance evaluation method for tissue engineering medical device products to regenerate knee cartilage	2018-12-20	2020-01-01	SAC/TC110/S C3
496	YY/T 0953-2020	Medical carboxymethyl chitosan	2020-09-27	2021-09-01	SAC/TC110/S C3
497	YY/T 1571-2017	Tissue engineering medical device product sodium hyaluronate	2017-05-02	2018-04-01	SAC/TC110/S C3
498	YY/T 1654-2019	Tissue engineering medical device product sodium alginate	2019-05-31	2020-06-01	SAC/TC110/S C3
499	YY/T 1699-2020	Tissue engineering medical device product chitosan	2020-02-21	2021-01-01	SAC/TC110/S C3

**(7) Active implants**

500	GB 16174.1-2015	Surgical implants. Active implantable medical devices. Part 1 : General requirements for safety, marking and information provided by the manufacturer	2015-12-10	2017-07-01	SAC/TC110/S C4
501	GB 16174.2-2015	Surgical implants. Active implantable medical devices. Part 2 : Pacemakers	2015-12-10	2017-07-01	SAC/TC110/S C4
502	YY 0989.6-2016	Surgical implants. Active implantable medical devices. Part 6 : Specific requirements for	2016-01-26	2018-01-01	SAC/TC110/S C4

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		active implantable medical devices (including implantable defibrillators) for the treatment of tachyarrhythmia			
503	YY 0989.7-2017	Surgical implants. Active implantable medical devices. Part 7 : Particular requirements for cochlear implant systems	2017-07-17	2018-01-01	SAC/TC110/S C4
504	YY/T 0491-2004	Small cross-section connector for implantable cardiac pacemaker	2004-10-10	2005-09-01	SAC/TC110/S C4
505	YY/T 0492-2017	Implantable cardiac pacemaker lead wire	2017-03-28	2018-04-01	SAC/TC110/S C4
506	YY/T 0946-2014	Cardiac defibrillator DF- 1 connector assembly size and test requirements for implantable cardiac defibrillators	2014-06-17	2015-07-01	SAC/TC110/S C4
507	YY/T 0972-2016	Dimensions and test requirements of quadrupole connector system for active implantable medical devices implantable heart rhythm regulation equipment	2016-03-23	2017-01-01	SAC/TC110/S C4
<b>(8) Other</b>					
508	GB/T 25304-2010	Special requirements for non-vascular self-expanding metal stents	2010-11-10	2011-05-01	SAC/TC110/S C2
509	YY 0647-2008	Passive surgical implants. Specific requirements for breast implants	2008-04-25	2009-12-01	SAC/TC110
510	YY/T 1457-2016	Passive surgical implant silicone gel-filled breast implants. Determination of oligosiloxane substances	2016-01-26	2017-01-01	SAC/TC110
511	YY/T 1555.1-2017	Specific requirements for silicone gel filled breast implants. Performance requirements for silicone gel fillings. Part 1 : Requirements for the limit of volatile substances	2017-03-28	2018-04-01	SAC/TC110
512	YY/T 1555.2-2018	Specific requirements for silicone gel filled breast implants. Performance requirements for silicone gel fillings. Part 2 : Requirements for the limit of extractable substances	2018-12-20	2020-01-01	SAC/TC110
513	YY/T 0684-2008	Labeling and packaging of implantable neurostimulators for neurosurgery implants	2008-10-17	2010-01-01	SAC/TC110
514	YY/T 0685-2008	Neurosurgical implant self-closing intracranial aneurysm clip	2008-09-21	2010-01-01	SAC/TC110
515	YY/T 0917-2014	Neurosurgery implant plastic prefabricated skull plate	2014-06-17	2015-07-01	SAC/TC110

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
516	YY/T 0928-2014	Neurosurgery implant prefabricated skull plate	2014-06-17	2015-07-01	SAC/TC110
517	YY 0333-2010	Soft tissue expander	2010-12-27	2012-06-01	Shandong Center
518	YY 0334-2002	General requirements for silicone rubber surgical implants	2002-04-25	2002-10-01	Shandong Center
519	YY/T 0954-2015	Passive surgical implant - type I collagen implant	2015-03-02	2017-01-01	SAC/TC110
520	YY/T 0962-2014	Cross-linked sodium hyaluronate gel for plastic surgery	2014-06-17	2015-07-01	SAC/TC110
521	YY/T 0965-2014	Special requirements for passive surgical implants and artificial ligaments	2014-06-17	2015-07-01	SAC/TC110

#### Four, family planning equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Mechanical contraceptive devices</b>					
522	GB 3156-2006	OCu intrauterine device	2006-09-14	2007-05-01	SAC/TC169
523	GB 11235-2006	VCu intrauterine device	2006-09-14	2007-05-01	SAC/TC169
524	GB 11234-2006	Uterine-shaped intrauterine device	2006-09-14	2007-05-01	SAC/TC169
525	GB 11236-2006	TCu intrauterine device	2006-09-14	2007-05-01	SAC/TC169
526	YY/T 0182-2013	IUD removal hook	2013-10-21	2014-10-01	SAC/TC169
527	YY/T 0183-2013	IUD placement fork	2013-10-21	2014-10-01	SAC/TC169
528	YY/T 0470-2004	One-time use round uterine intrauterine contraceptive device placement device	2004-03-23	2005-01-01	SAC/TC169
529	YY/T 0886-2013	General requirements for single-use intrauterine device placement devices	2013-10-21	2014-10-01	SAC/TC169
530	YY/T 1404-2016	Technical requirements and test methods of copper for copper-containing intrauterine contraceptive devices	2016-03-23	2017-01-01	SAC/TC169

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
531	YY/T 1405-2016	Requirements and tests for reusable natural and silicone rubber vaginal diaphragms of mechanical contraceptive devices	2016-03-23	2017-01-01	SAC/TC169
532	YY/T 1471-2016	Technical requirements and test methods of indomethacin-containing silicone rubber for copper-containing intrauterine devices	2016-01-26	2017-01-01	SAC/TC169
533	YY/T 1567-2017	Technical requirements and test methods for female condoms	2017-09-25	2018-10-01	SAC/TC169
<b>(2) Surgical instruments for obstetrics and gynecology</b>					
534	YY 0006-2013	Metal double wing vagina dilator	2013-10-21	2014-10-01	SAC/TC169
535	YY 0091-2013	Cervical dilator	2013-10-21	2014-10-01	SAC/TC169
536	YY 0092-2013	Cervical biopsy forceps	2013-10-21	2014-10-01	SAC/TC169
537	YY 0336-2020	Sterile vaginal dilator for single use	2020-03-31	2021-04-01	SAC/TC169
538	YY 1023-2013	Cervical forceps	2013-10-21	2014-10-01	SAC/TC169
539	YY 1024-2013	Fallopian tube extraction hook	2013-10-21	2014-10-01	SAC/TC169
540	YY/T 0090-2014	Uterine curette	2014-06-17	2015-07-01	SAC/TC169
541	YY/T 0172-2014	Uterine probe	2014-06-17	2015-07-01	SAC/TC169
542	YY/T 0181-2013	Fallopian tube extraction plate	2013-10-21	2014-10-01	SAC/TC169
543	YY/T 0925-2014	Perineal Scissors	2014-07-01	2015-07-01	SAC/TC169
544	YY/T 0979-2016	One-time use abortion suction tube	2016-03-23	2017-01-01	SAC/TC169
545	YY/T 1025-2014	Abortion suction tube	2014-06-17	2015-07-01	SAC/TC169
546	YY/T 1470-2016	Disposable umbilical cord cutter (cutting)	2016-01-26	2017-01-01	SAC/TC169
547	YY/T 1554-2017	Fallopian tube catheter	2017-05-02	2018-04-01	SAC/TC169
548	YY/T 1568-2017	Pessary	2017-03-28	2018-04-01	SAC/TC169
549	YY/T 1704.1-2020	Single-use cervical dilator Part 1 : Progressive	2020-02-21	2021-01-01	SAC/TC169
550	YY/T 1704.2-2020	One-time use cervical dilator Part 2 : Inflatable	2020-02-21	2021-01-01	SAC/TC169



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
(Three) other					
551	YY/T 0184-2014	Forceps for vasectomy	2014-06-17	2015-07-01	SAC/TC169

## 5. Medical intravascular catheters and non-intravascular catheters

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
(1) Intravascular catheter					
552	YY 0285.1-2017	Intravascular catheters : Sterile single-use catheters. Part 1 : General requirements	2017-07-17	2019-01-01	Shandong Center
553	YY 0285.3-2017	Intravascular catheters : Sterile single-use catheters. Part 3 : Central venous catheters	2017-07-17	2019-01-01	SAC/TC106
554	YY 0285.4-2017	Intravascular catheters : Sterile single-use catheters. Part 4 : Balloon dilatation catheters	2017-07-17	2019-01-01	SAC/TC106
555	YY 0285.5-2018	Intravascular catheters : Sterile single-use catheters. Part 5 : Trocar peripheral catheters	2018-02-24	2019-03-01	SAC/TC106
556	YY/T 0285.6-2020	Intravascular catheters : Sterile single-use catheters. Part 6 : Subcutaneous implantable drug delivery devices	2020-09-27	2021-09-01	SAC/TC106
557	YY 0450.1-2020	Sterile intravascular catheter accessories for single use. Part 1 : Guiding instruments	2020-02-25	2021-08-01	SAC/TC106
558	YY 0450.2-2003	Disposable sterile intravascular catheter accessories part 2 trocar peripheral catheter tube plug	2003-02-09	2003-09-01	Shandong Center
559	YY/T 0450.3-2016	Disposable sterile intravascular catheter accessories Part 3 Balloon inflation device for balloon dilatation catheter	2016-07-29	2017-06-01	Shandong Center
(2) Non-intravascular catheter					

560	GB/T 15812.1-2005	Non-intravascular catheters. Part 1: General performance test methods	2005-03-23	2005-12-01	SAC/TC106
561	YY/T 1536-2017	Standard test model for evaluating sliding performance of non-intravascular catheter surface	2017-03-28	2018-04-01	SAC/TC106
562	YY 0030-2004	Peritoneal Dialysis Tube	2004-07-16	2005-08-01	Shandong Center
563	YY 0325-2016	Sterile urinary catheter for single use	2016-03-23	2018-01-01	SAC/TC106
564	YY 0483-2004	Design and test method of disposable enteral nutrition catheter, enteral feeding device and their connecting parts	2004-07-16	2005-08-01	Shandong Center
565	YY 0488-2004	Sterile rectal catheter for single use	2004-07-16	2005-08-01	Shandong Center
566	YY 0489-2004	Sterile drainage catheter and auxiliary equipment for single use	2004-07-16	2005-08-01	Shandong Center
567	YY/T 0487-2010	Disposable sterile hydrocephalus shunt and its components	2010-12-27	2012-06-01	Shandong Center
568	YY/T 0880-2013	One-time use breast positioning wire and its guide needle	2013-10-21	2014-10-01	SAC/TC106
569	YY/T 0872-2013	Test method of ureteral stent	2013-10-21	2014-10-01	SAC/TC106
570	YY/T 0817-2010	Physical performance requirements and test methods of enteral nutrition catheter with positioning balloon	2010-12-27	2012-06-01	Shandong Center

## 6. Dental materials, instruments and equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Professional and general fields</b>					
571	GB/T 9937-2020	Dental terms	2020-12-14	2021-07-01	SAC/TC99
572	<u>GB/T 9938-2013</u>	Indicating method of dentition and oral area in dentistry	2013-12-31	2015-06-01	SAC/TC99
573	YY 0271.1-2016	Dental water-based cements. Part 1: Powder /liquid acid-base cements	2016-01-26	2018-06-01	SAC/TC99

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
574	YY 0271.2-2016	Dental water-based cement Part 2 : Light-curing cement	2016-01-26	2018-06-01	SAC/TC99
575	YY 0272-2009	Dentistry zinc oxide /eugenol cement and zinc oxide cement without eugenol	2009-06-16	2010-12-01	SAC/TC99
576	YY 91053-1999	Stomatological equipment and equipment terminology equipment	1985-06-20	1985-10-01	SAC/TC99/SC1
577	YY/T 0127.1-1993	Biological test methods for oral materials Hemolysis test	1993-07-01	1993-10-01	SAC/TC99
578	YY/T 0127.3-2014	Biological evaluation of dental medical devices. Part 3 : Root canal application test	2014-06-17	2015-07-01	SAC/TC99
579	YY/T 0127.4-2009	Biological Evaluation of Oral Medical Devices Unit 2 : Test Method Bone Implantation Test	2009-12-30	2011-06-01	SAC/TC99
580	YY/T 0127.5-2014	Biological evaluation of oral medical devices. Part 5 : Inhalation toxicity test	2014-06-17	2015-07-01	SAC/TC99
581	YY/T 0127.6-1999	Biological Evaluation of Oral Materials Unit 2 : Dominant Lethal Test of Biological Test Methods for Oral Materials	1999-06-07	1999-10-01	SAC/TC99
582	YY/T 0127.7-2017	Biological evaluation of dental medical device materials. Part 7 : Dental pulp and dentin application test	2017-04-01	2018-04-01	SAC/TC99
583	YY/T 0127.8-2001	Biological Evaluation of Oral Materials Unit 2 : Biological Test Methods of Oral Materials .Subcutaneous Implantation Test	2001-03-12	2001-08-01	SAC/TC99
584	YY/T 0127.9-2009	Biological Evaluation of Oral Medical Devices Unit 2 : Test Method Cytotoxicity Test: Agar Diffusion Method and Membrane Diffusion Method	2009-12-30	2011-06-01	SAC/TC99
585	YY/T 0127.10-2009	Biological Evaluation of Oral Medical Devices Unit 2 : Test Method Salmonella Typhimurium Reversion Test ( Ames Test)	2009-06-16	2010-12-01	SAC/TC99
586	YY/T 0127.11-2014	Biological evaluation of dental medical devices. Part 11 : Pulp capping test	2014-06-17	2015-07-01	SAC/TC99
587	YY/T 0127.12-2008	Biological Evaluation of Dental Medical Devices in	2008-04-25	2009-06-01	SAC/TC99

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		Dentistry Unit 2 : Test Method Micronucleus Test			
588	YY/T 0127.13-2018	Biological evaluation of oral medical devices. Part 13 : Oral mucosal irritation test	2018-04-24	2019-05-01	SAC/TC99
589	YY/T 0127.14-2009	Biological Evaluation of Oral Medical Devices Unit 2 : Test Method Acute Oral Systemic Toxicity Test	2009-06-16	2010-12-01	SAC/TC99
590	YY/T 0127.15-2018	Biological evaluation of oral medical devices. Part 15 : Subacute and subchronic systemic toxicity test: oral route	2018-04-24	2019-05-01	SAC/TC99
591	YY/T 0127.16-2009	Biological Evaluation of Oral Medical Devices Unit 2 : Test Methods In Vitro Chromosome Aberration Test of Mammalian Cells	2009-12-30	2011-06-01	SAC/TC99
592	YY/T 0127.17-2014	Biological Evaluation of Dental Medical Devices Part 17 : Mouse Lymphoma Cell ( TK ) Gene Mutation Test	2014-06-17	2015-07-01	SAC/TC99
593	YY/T 0127.18-2016	Biological evaluation of oral medical devices. Part 18 : Dentin barrier cytotoxicity test	2016-01-26	2017-01-01	SAC/TC99
594	YY/T 0268-2008	Biological Evaluation of Dental Medical Devices in Dentistry Unit 1 : Evaluation and Testing	2008-04-25	2009-06-01	SAC/TC99
595	YY/T 0112-1993	Simulated oral environment cold and heat fatigue test method	1993-02-10	1993-05-01	SAC/TC99
596	YY/T 0113-2015	Test method for abrasion resistance of dentistry composite resin	2015-03-02	2016-01-01	SAC/TC99
597	YY/T 0518-2009	Polymer-based adhesives for dental restorations	2009-12-30	2011-06-01	SAC/TC99
598	YY/T 0519-2009	Test of bonding between dental materials and tooth structure	2009-12-30	2011-06-01	SAC/TC99
599	YY/T 0528-2018	Test method for corrosion of metal materials in dentistry	2018-02-24	2019-03-01	SAC/TC99
600	YY/T 0623-2008	Determination method of soluble fluoride in dental materials	2008-04-25	2009-12-01	SAC/TC99

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
601	YY/T 0631-2008	Determination of the color stability of dental materials	2008-04-25	2009-06-01	SAC/TC99
602	YY/T 0769-2009	Phosphoric acid etching agent for dental use	2009-12-30	2011-06-01	SAC/TC99
603	YY/T 1599-2018	Dentistry polymer-based restorative materials polymerization shrinkage test method - laser distance measurement method	2018-02-24	2019-03-01	SAC/TC99
604	YY/T 1646-2019	Dentistry test method for X-ray resistance of materials	2019-10-23	2020-10-01	SAC/TC99
<b>(2) Tooth filling and restoration materials</b>					
605	YY 0717-2009	Dental root canal sealing material	2009-12-30	2011-06-01	SAC/TC99
606	YY 1042-2011	Dentistry polymer-based restorative materials	2011-12-31	2013-06-01	SAC/TC99
607	YY/T 0495-2009	Root canal filling tip	2009-12-30	2011-06-01	SAC/TC99
608	YY/T 0715-2009	Dental amalgam capsules	2009-12-30	2011-06-01	SAC/TC99
609	YY/T 1026-2019	Dentistry dental amalgam	2019-07-23	2020-02-01	SAC/TC99
610	YY/T 0990-2015	Guidelines for clinical trials of polymer-based dental restoration materials	2015-03-02	2016-01-01	SAC/TC99
611	YY/T 0824-2011	Dental calcium hydroxide pulp capping and backing materials	2011-12-31	2013-06-01	SAC/TC99
612	YY/T 0515-2009	Corrosion test of dental amalgam	2009-12-30	2011-06-01	SAC/TC99
<b>(3) Denture restoration materials and products</b>					
613	GB 17168-2013	Metal materials for dental fixation and mobile restoration	2013-12-31	2015-06-01	SAC/TC99
614	GB 30367-2013	Dental ceramic materials	2013-12-31	2015-06-01	SAC/TC99
615	YY 0270.1-2011	Denture base polymer . Part 1 : Denture base polymer	2011-12-31	2013-06-01	SAC/TC99
616	YY 0300-2009	Artificial teeth for dental restoration	2009-06-16	2010-12-01	SAC/TC99
617	YY 0303-1998	Medical hydroxyapatite powder	1998-04-08	1998-10-01	SAC/TC99
618	YY 0462-2018	Dental plaster products	2018-06-19	2019-07-01	SAC/TC99
619	YY 0493-2011	Dentistry elastomer impression material	2011-12-31	2013-06-01	SAC/TC99
620	YY 0621.1-2016	Dentistry compatibility test Part 1 : Metal - ceramic system	2016-01-26	2018-01-01	SAC/TC99

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
621	YY/T 0621.2-2020	Dentistry compatibility test Part 2 : Ceramic - ceramic system	2020-02-25	2021-03-01	SAC/TC99
622	YY 0710-2009	Dentistry polymer-based crown and bridge materials	2009-06-16	2010-12-01	SAC/TC99
623	YY 0714.1-2009	Dental soft liner materials for movable dentures. Part 1 : Materials for short-term use	2009-06-16	2010-12-01	SAC/TC99
624	YY 0714.2-2016	Dental soft liner materials for movable dentures. Part 2 : Long-term use materials	2016-01-26	2018-01-01	SAC/TC99
625	YY 1027-2018	Dentistry hydrocolloid impression material	2018-06-19	2019-07-01	SAC/TC99
626	YY/T 0463-2011	Dentistry casting investment materials and refractory substitute materials	2011-12-31	2013-06-01	SAC/TC99
627	YY/T 0496-2016	Dental casting wax and base wax	2016-01-26	2017-01-01	SAC/TC99
628	YY/T 0517-2009	Dental prefabricated root canal post	2009-12-30	2011-06-01	SAC/TC99
629	YY/T 0527-2009	Dentistry copy material	2009-12-30	2011-06-01	SAC/TC99
630	YY/T 0826-2011	Dental temporary polymer-based crown and bridge materials	2011-12-31	2013-06-01	SAC/TC99
631	YY/T 0911-2014	Dentistry polymer-based materials	2014-06-17	2015-07-01	SAC/TC99
632	YY/T 0912-2015	Dental brazing materials	2015-03-02	2016-01-01	SAC/TC99
633	YY/T 0914-2015	Dental laser welding	2015-03-02	2016-01-01	SAC/TC99
634	YY/T 1280-2015	Denture Adhesive	2015-03-02	2016-01-01	SAC/TC99
635	YY/T 1637-2018	Dental magnetic attachment	2018-12-20	2019-06-01	SAC/TC99
<b>(4) Orthodontic materials and products</b>					
636	YY/T 0270.2-2011	Dentistry base polymer. Part 2 : Orthodontic base polymer	2011-12-31	2013-06-01	SAC/TC99
637	YY/T 0269-2009	Orthodontic bracket bonding material	2009-12-30	2011-06-01	SAC/TC99
638	YY/T 0624-2016	Dental Orthodontic Elastomer Accessories	2016-03-23	2017-01-01	SAC/TC99
639	YY/T 0625-2016	Orthodontic Wire	2016-03-23	2017-01-01	SAC/TC99
640	YY/T 0915-2015	Orthodontic brackets and buccal tubes	2015-03-02	2016-01-01	SAC/TC99

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
641	YY/T 0991-2015	Clinical Trial Guidelines for Orthodontic Brackets	2015-03-02	2016-01-01	SAC/TC99
642	YY/T 1703-2020	Coil spring for orthodontics	2020-02-21	2021-01-01	SAC/TC99
643	YY/T 1779-2021	Dental orthodontic anchor nail	2021-03-09	2022-04-01	SAC/TC99
<b>(5) Oral preventive materials and products</b>					
644	YY 0622-2008	Dental resin based pit and fissure sealer	2008-04-25	2009-12-01	SAC/TC99
645	YY/T 0823-2020	Dental fluoride anti-caries material	2020-02-26	2021-03-01	SAC/TC99
646	YY/T 0825-2011	Dental bleaching products	2011-12-31	2013-06-01	SAC/TC99
647	YY/T 0632-2008	Method for determination of peroxide content in tooth bleaching materials	2008-04-25	2009-06-01	SAC/TC99
<b>(6) Oral implant materials and products</b>					
648	YY 0304-2009	Plasma sprayed hydroxyapatite coating - titanium-based dental implant	2009-12-30	2011-06-01	SAC/TC99
649	YY 0315-2016	Titanium and titanium alloy artificial dental implants	2016-01-26	2018-01-01	SAC/TC99
650	YY/T 0520-2009	Dental implant attachments made of titanium and titanium alloys	2009-12-30	2011-06-01	SAC/TC99
651	YY/T 0522-2009	Animal test methods for preclinical evaluation of dental implant systems in dentistry	2009-12-30	2011-06-01	SAC/TC99
652	YY/T 0523-2009	Dental implant development guide for dentistry	2009-12-30	2011-06-01	SAC/TC99
653	YY/T 0524-2009	Technical file content of dental implant system in dentistry	2009-12-30	2011-06-01	SAC/TC99
654	YY/T 0525-2009	Dentistry Oral and Maxillofacial Surgery Bone Filling and Bone Augmenting Implantable Materials Technical Document Content	2009-12-30	2011-06-01	SAC/TC99
655	YY/T 0526-2009	Technical document content of tissue regeneration guide membrane material for dentistry and maxillofacial surgery	2009-12-30	2011-06-01	SAC/TC99
656	YY/T 1281-2015	Clinical performance of manual torque instruments for dental implants	2015-03-02	2016-01-01	SAC/TC99

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
657	YY/T 1305-2015	Guidelines for clinical trials of titanium and titanium alloy dental implants	2015-03-02	2016-01-01	SAC/TC99
658	YY/T 1619-2018	The terminology of dental implant system and related processes	2018-09-28	2019-04-01	SAC/TC99
659	YY/T 1689-2019	Marking system for dental implants in dentistry	2019-10-23	2020-10-01	SAC/TC99
660	YY/T 1794-2021	General technical requirements for oral collagen membrane	2021-03-10	2022-04-01	SAC/TC99
661	YY/T 0521-2018	Dentistry - Implant - Dynamic Fatigue Test of Intraosseous Dental Implant	2018-04-11	2019-05-01	SAC/TC99
<b>(7) Dental equipment</b>					
662	GB 9706.260-2020	Medical electrical equipment Part 2-60 : Specific requirements for basic safety and basic performance of dental equipment	2020-11-17	2023-05-01	State Food and Drug Administration
663	YY/T 0628-2020	Dentistry dental equipment graphic symbols	2020-06-30	2021-06-01	SAC/TC99/SC1
664	YY/T 1012-2004	Dental handpiece coupling size	2004-10-10	2005-09-01	SAC/TC99/SC1
665	YY/T 1285-2015	Dental equipment location information system in the working area of dental health care staff	2015-03-02	2016-01-01	SAC/TC99/SC1
666	YY 0055-2018	Dental curing light	2018-09-28	2020-04-01	SAC/TC99/SC1
667	YY 0059.1-1991	Dental Handpiece No. 4 Dental Straight Handpiece	1991-11-21	1992-09-01	SAC/TC99/SC1
668	YY 0059.2-1991	Dental Handpiece No. 7 Dental Straight Handpiece	1991-11-21	1992-09-01	SAC/TC99/SC1
669	YY 0059.3-1991	Dental handpiece 4 and No. 7 dental contra-angle handpiece	1991-11-21	1992-09-01	SAC/TC99/SC1
670	YY 1045.1-2009	Dental Handpiece Part 1 : High Speed Gas Turbine Handpiece	2009-06-16	2010-12-01	SAC/TC99/SC1
671	YY 1045.2-2010	Dental handpiece part 2 : straight handpiece and contra-angle handpiece	2010-12-27	2012-06-01	SAC/TC99/SC1
672	YY 0835-2011	Dental amalgam separator	2011-12-31	2013-06-01	SAC/TC99/SC1
673	YY 0836-2011	Dental handpiece dental low-voltage electric motor	2011-12-31	2013-06-01	SAC/TC99/SC1



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
674	YY 0837-2011	Dental handpiece dental air motor	2011-12-31	2013-06-01	SAC/TC99/SC1
675	YY/T 0058-2015	Dental patient chair	2015-03-02	2016-01-01	SAC/TC99/SC1
676	YY/T 0273-2009	Dental amalgam blender	2009-11-15	2010-12-01	SAC/TC99/SC1
677	YY/T 0514-2018	Dental hose connector for pneumatic dental handpiece	2018-01-19	2019-01-01	SAC/TC99/SC1
678	YY/T 0629-2021	Central suction source equipment for dentistry	2021-03-09	2022-04-01	SAC/TC99/SC1
679	YY/T 0905.2-2013	Dental equipment. Part 2 : Compressor system	2013-10-21	2014-10-01	SAC/TC99/SC1
680	YY/T 1043.1-2016	Dental treatment machine. Part 1 : General requirements and test methods	2016-03-23	2017-01-01	SAC/TC99/SC1
681	YY/T 1043.2-2018	Dentistry dental treatment machine part 2 : gas, water, suction and waste water system	2018-12-20	2020-01-01	SAC/TC99/SC1
682	YY/T 1044-2018	Movable dental treatment machine	2018-12-20	2020-01-01	SAC/TC99/SC1
683	YY/T 1120-2021	Dental lamp	2021-03-09	2023-05-01	SAC/TC99/SC1
684	YY/T 1401-2016	Teeth whitening cold light instrument	2016-03-23	2017-01-01	SAC/TC99/SC1
685	YY/T 1485-2016	Dental implant machine	2016-07-29	2017-06-01	SAC/TC99/SC1
686	YY/T 1602-2018	Dental root canal preparation machine	2018-01-19	2019-01-01	SAC/TC99/SC1
687	YY/T 1684-2020	Dental apex locator	2020-03-31	2021-10-01	SAC/TC99/SC1
688	YY/T 1691-2020	Dental handpiece torque transmitter	2020-02-21	2021-06-01	SAC/TC99/SC1
689	YY/T 1692-2020	Dental hot-melt gutta-percha filling machine	2020-02-21	2021-06-01	SAC/TC99/SC1
690	YY/T 1755-2021	Dental blasting mobile phone and sandblasting powder	2021-03-09	2022-04-01	SAC/TC99/SC1
691	YY/T 1147-2004	General technical requirements for electric dental drills	2004-10-10	2005-09-01	SAC/TC99
692	YY/T 1400-2016	Determination of the resistance of surface materials of dental equipment in dentistry to chemical disinfectants	2016-03-23	2017-01-01	SAC/TC99/SC1
693	YY/T 1411-2016	A test method for dentistry to evaluate measures to improve or maintain the microbiological quality of	2016-03-23	2017-01-01	SAC/TC99/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		treatment water for dental treatment machines			
<b>(8) Dental equipment</b>					
694	YY 91010-1999	Fitting size of dental rotary instrument	1985-04-02	1985-12-01	SAC/TC99/SC1
695	YY/T 0281-1995	Test method for connection firmness of dental surgical instruments	1995-11-14	1996-05-01	SAC/TC99/SC1
696	YY/T 1501-2016	Dentistry dental instruments graphic symbols	2016-07-29	2017-06-01	SAC/TC99/SC1
697	GB/T 36917.1-2018	Cutting tools for dental laboratory. Part 1 : Steel cutting tools for laboratory	2018-12-28	2020-01-01	SAC/TC99/SC1
698	GB/T 36917.2-2018	Cutting tools for dental laboratory. Part 2 : Cemented carbide cutting tools for laboratory	2018-12-28	2020-01-01	SAC/TC99/SC1
699	YY 0302.1-2010	Rotary dental burs. Part 1 : Steel and cemented carbide burs	2010-12-27	2012-06-01	SAC/TC99/SC1
700	YY 0302.2-2016	Dental burs for rotary instruments. Part 2 : Dressing burs	2016-03-23	2018-01-01	SAC/TC99/SC1
701	YY 91064-1999	Technical requirements for dental rotary instrument steel and cemented carbide dental drills	1985-01-26	1985-05-01	SAC/TC99/SC1
702	YY 0761.1-2009	Dental Diamond Rotary Instruments Part 1 : Dimensions, Requirements, Marking and Packaging	2009-12-31	2011-06-01	SAC/TC99/SC1
703	YY/T 0761.2-2014	Dental Diamond Rotary Instruments Part 2 : Cutting Disk	2014-06-17	2015-07-01	SAC/TC99/SC1
704	YY/T 0805.3-2010	Dental rotary diamond instruments. Part 3 : Particle size, naming and color code	2010-12-27	2012-06-01	SAC/TC99/SC1
705	YY 0803.1-2010	Dental root canal instruments. Part 1 : General requirements and test methods	2010-12-27	2012-06-01	SAC/TC99/SC1
706	YY/T 0803.2-2020	Root canal instruments in dentistry. Part 2 : Enlarged drill	2020-06-30	2021-12-01	SAC/TC99/SC1
707	YY 0803.3-2016	Root canal instruments in dentistry. Part 3 : Compressor	2016-01-26	2018-01-01	SAC/TC99/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
708	YY/T 0803.4-2015	Root canal instruments in dentistry. Part 4: Auxiliary instruments	2015-03-02	2016-01-01	SAC/TC99/SC1
709	YY/T 0803.5-2016	Dental root canal instruments. Part 5: Shaping and cleaning instruments	2016-07-29	2017-06-01	SAC/TC99/SC1
710	YY/T 0275-2011	Dental filling device	2011-12-31	2013-06-01	SAC/TC94
711	YY/T 0873.1-2013	Digital coding system for dental rotary instruments. Part 1: General characteristics	2013-10-21	2014-10-01	SAC/TC99/SC1
712	YY/T 0873.2-2014	Digital coding system for dental rotary instruments. Part 2: Shape	2014-06-17	2015-07-01	SAC/TC99/SC1
713	YY/T 0873.3-2014	Digital coding system for dental rotary instruments. Part 3: Characteristics of burs and cutting tools	2014-06-17	2015-07-01	SAC/TC99/SC1
714	YY/T 0873.4-2014	Digital coding system for dental rotary instruments. Part 4: Characteristics of diamond instruments	2014-06-17	2015-07-01	SAC/TC99/SC1
715	YY/T 0873.5-2014	Digital coding system for dental rotary instruments. Part 5: Characteristics of root canal instruments	2014-06-17	2015-07-01	SAC/TC99/SC1
716	YY/T 0873.6-2015	Dentistry (Science) Digital Encoding System of Rotating Instruments Part 6: Characteristics of Grinding Instruments	2015-03-02	2016-01-01	SAC/TC99/SC1
717	YY/T 0873.7-2014	Digital coding system for dental rotary instruments. Part 7: Characteristics of mandrels and special instruments	2014-06-17	2015-07-01	SAC/TC99/SC1
718	YY/T 0913-2015	Mandrel for dental rotary instrument	2015-03-02	2016-01-01	SAC/TC99/SC1
719	YY/T 0967.1-2015	Dental Rotary Instrument Pole Part 1: Metal Pole	2015-03-02	2016-01-01	SAC/TC99/SC1
720	YY/T 0967.2-2015	Dental Rotary Instrument Pole Part 2: Plastic Pole	2015-03-02	2016-01-01	SAC/TC99/SC1
721	YY/T 0967.3-2016	Dental rotating instrument rods. Part 3: Ceramic rods	2016-07-29	2017-06-01	SAC/TC99/SC1
722	YY/T 1011-2014	Dental Rotary Instruments - Nominal Diameter and Marking	2014-06-17	2015-07-01	SAC/TC99/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
723	YY/T 0874-2013	Test methods for dental rotating instruments	2013-10-21	2014-10-01	SAC/TC99/SC1
724	YY/T 1604-2018	Dental Rotary Polishing Equipment	2018-01-19	2019-01-01	SAC/TC99/SC1
725	YY/T 1014-2021	Dental Probe	2021-03-09	2022-04-01	SAC/TC99/SC1
726	YY/T 1284.1-2015	Dental forceps. Part 1 : General requirements	2015-03-02	2016-01-01	SAC/TC99/SC1
727	YY/T 1284.2-2015	Dental Tweezers Part 2 : Double Curved Type	2015-03-02	2016-01-01	SAC/TC99/SC1
728	YY/T 1284.3-2015	Dental forceps Part 3 : Single curved type	2015-03-02	2016-01-01	SAC/TC99/SC1
729	YY/T 1486-2016	General requirements for dental implant equipment and related auxiliary equipment in dentistry	2016-07-29	2017-06-01	SAC/TC99/SC1
730	YY/T 1487.1-2016	Dentistry. Dental rubber dam technique. Part 1 : Punch	2016-07-29	2017-06-01	SAC/TC99/SC1
731	YY/T 1487.2-2018	Dentistry. Dental rubber dam equipment. Part 2 : Clamps	2018-09-21	2019-09-26	SAC/TC99/SC1
732	YY/T 1614-2018	Apertures of rotating instruments such as disc-shaped and wheel-shaped dentistry	2018-09-28	2019-10-01	SAC/TC99/SC1
733	YY/T 1622.1-2018	Dental Periodontal Probe Part 1 : General Requirements	2018-11-07	2019-11-01	SAC/TC99/SC1
734	YY/T 1683-2019	Dental Chisels	2019-10-23	2021-04-01	SAC/TC99/SC1
735	YY/T 1693-2020	Dentistry Maxillary Sinus Membrane Lifter	2020-02-26	2021-09-01	SAC/TC99/SC1
736	YY/T 1696-2020	Dental shaping knife	2020-06-30	2021-12-01	SAC/TC99/SC1
737	YY/T 1756-2021	Dentistry reusable periodontal ligament injection holder	2021-03-09	2022-04-01	SAC/TC99/SC1
738	YY/T 0274-2011	Tooth scraper	2011-12-31	2013-06-01	SAC/TC94
739	YY/T 0170-2011	Tooth elevator	2011-12-31	2013-06-01	SAC/TC94
<b>(9) Other</b>					
740	GB/T 36108-2018	Technical requirements of CAD software for dental fixation	2018-03-15	2018-10-01	SAC/TC99
741	GB/T 39111-2020	Technical requirements for dental model 3D scanner	2020-10-14	2021-10-01	SAC/TC99
742	YY 0711-2009	Dental Moisture Absorbent Paper Tip	2009-12-30	2011-06-01	SAC/TC99
743	YY/T 0516-2009	Dental EDTA root canal lubricating /cleaning agent	2009-12-30	2011-06-01	SAC/TC99

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
744	YY/T 1702-2020	Dental Additive Manufacturing Laser Selective Melting of Metal Materials for Oral Fixation and Mobile Restoration	2020-02-21	2021-01-01	SAC/TC99

## Seven, infusion, blood transfusion, blood sampling, drainage equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
(1) Professional and general fields					
745	GB/T 14233.1-2008	Medical transfusion, blood transfusion, and injection equipment inspection methods. Part 1: Chemical analysis methods	2008-11-03	2009-10-01	SAC/TC106
746	GB/T 14233.2-2005	Medical transfusion, blood transfusion, and injection equipment inspection methods. Part 2: Biological test methods	2005-11-17	2006-05-01	SAC/TC106
747	YY/T 0926-2014	Quantitative analysis of bis(2-ethylhexyl) phthalate (DEHP) in medical polyvinyl chloride medical devices	2014-06-14	2015-07-01	SAC/TC106
748	YY/T 0927-2014	Guidelines for the determination of bis(2-ethylhexyl) phthalate (DEHP) dissolution in polyvinyl chloride medical devices	2014-06-14	2015-07-01	SAC/TC106
749	YY/T 1550.1-2017	Guide for research on compatibility of single-use infusion devices and drugs. Part 1: Research on drug adsorption	2017-02-28	2018-01-01	SAC/TC106
750	YY/T 1550.2-2019	Guide for research on compatibility of single-use infusion devices and drugs. Part 2: Research on known leachables	2019-07-24	2020-08-01	SAC/TC106
751	YY/T 1556-2017	Inspection method for particle contamination of medical infusion, blood	2017-03-28	2018-04-01	SAC/TC106

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		transfusion and injection equipment			
752	YY/T 1639-2018	Method for determination of residual amount of diphenylmethane diisocyanate ( MDI ) in disposable polyurethane infusion devices	2018-12-20	2020-01-01	SAC/TC106
753	YY/T 1658-2019	Method for measuring the amount of cyclohexanone dissolved in blood transfusion apparatus	2019-05-31	2020-06-01	SAC/TC106
754	YY/T 1690-2020	Method for determination of 2-chloroethanol residue in disposable polyvinyl chloride infusion equipment	2020-02-21	2021-01-01	SAC/TC106
755	YY/T 0031-2008	Silicone rubber tubing and elastic parts for infusion and blood transfusion	2008-10-17	2009-10-01	SAC/TC106
756	YY/T 0114-2008	Special polyethylene materials for medical infusion, blood transfusion and injection equipment	2008-10-17	2010-01-01	SAC/TC106
757	YY/T 0242-2007	Polypropylene special materials for medical infusion, blood transfusion and injection equipment	2007-07-02	2008-03-01	SAC/TC106
758	YY/T 1628-2019	Polyvinyl chloride pellets for medical infusion and blood transfusion equipment	2019-05-31	2019-09-01	SAC/TC106
759	YY/T 0770.1-2009	Filter materials for medical infusion and infusion equipment. Part 1: Medical liquid filter materials	2009-12-30	2011-06-01	SAC/TC106
760	YY/T 0770.2-2009	Filter materials for medical infusion and infusion equipment. Part 2: Air filter materials	2009-12-30	2011-06-01	SAC/TC106
761	YY/T 0806-2010	Polycarbonate special materials for medical infusion, blood transfusion, injection and other medical equipment	2010-12-27	2012-06-01	SAC/TC106
762	YY/T 0818.1-2010	Standard Guide for Medical Silicone Rubber Elastomers, Gels, Foams Part 1:	2010-12-27	2012-06-01	Shandong Center

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		Composition and Uncured Materials			
763	YY/T 0818.2-2010	Standard Guide for Medical Silicone Rubber Elastomers, Gels and Foams Part 2 : Crosslinking and Fabrication	2010-12-27	2012-06-01	Shandong Center
764	YY/T 1288-2015	Nylon blood filter for disposable blood transfusion equipment	2015-03-02	2016-01-01	SAC/TC106
765	YY/T 1617-2018	Polyvinyl chloride calendered film for blood bag	2018-11-07	2019-11-01	SAC/TC106
766	YY/T 0916.1-2014	Small aperture connectors for medical liquids and gases. Part 1 : General requirements	2014-06-17	2015-07-01	SAC/TC106
767	YY/T 0916.20-2019	Small-aperture connectors for medical liquids and gases. Part 20 : General test methods	2019-07-24	2020-08-01	SAC/TC106
768	YY/T 1557-2017	Special thermoplastic polyurethane materials for medical infusion, blood transfusion and injection equipment	2017-03-28	2018-04-01	SAC/TC106
<b>(2) Infusion apparatus</b>					
769	GB 8368-2018	Gravity infusion type of disposable infusion set	2018-03-15	2021-04-01	SAC/TC106
770	GB 18671-2009	Disposable intravenous infusion needle	2009-05-06	2010-03-01	SAC/TC106
771	YY 0286.1-2019	Dedicated infusion set Part 1 : Disposable microporous filter infusion set	2019-05-31	2020-12-01	SAC/TC106
772	YY 0286.2-2006	Special infusion set. Part 2 : Burette type infusion set for single use. Gravity infusion set	2006-04-19	2007-04-01	SAC/TC106
773	YY 0286.3-2017	Dedicated infusion set Part 3 : Disposable light-proof infusion set	2017-07-17	2019-01-01	SAC/TC106
774	YY/T 0286.4-2020	Special infusion sets. Part 4 : Infusion sets for single-use pressure infusion equipment	2020-06-30	2021-06-01	SAC/TC106
775	YY/T 0286.5-2021	Special infusion sets. Part 5 : Disposable bottle and bag infusion sets	2021-03-09	2022-04-01	SAC/TC106

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
776	YY/T 0286.6-2020	Special infusion set. Part 6 : One-time use scale flow-regulated infusion set	2020-03-31	2021-04-01	SAC/TC106
777	YY 0332-2011	Implantable drug delivery device	2011-12-31	2013-06-01	SAC/TC106
778	YY 0451-2010	Non-electrically driven portable infusion pump for single use	2010-12-27	2012-06-01	SAC/TC106
779	YY 0581.1-2011	Infusion connector part 1 : piercing connector (heparin cap)	2011-12-31	2013-06-01	SAC/TC106
780	YY 0581.2-2011	Infusion connector part 2 : Needleless connector	2011-12-31	2013-06-01	SAC/TC106
781	YY 0585.1-2019	Disposable fluid circuits and accessories for pressure infusion equipment. Part 1 : Fluid circuits	2019-05-31	2020-12-01	SAC/TC106
782	YY 0585.2-2019	Disposable fluid circuits and accessories for pressure infusion equipment. Part 2 : Accessories	2019-05-31	2020-12-01	SAC/TC106
783	YY 0585.3-2018	Disposable fluid circuits and accessories for pressure infusion equipment. Part 3 : Filters	2018-11-07	2020-05-01	SAC/TC106
784	YY 0585.4-2009	Disposable fluid circuits and accessories for pressure infusion devices. Part 4 : Backflow prevention valve	2009-12-30	2011-06-01	SAC/TC106
785	YY 0881-2013	Dedicated needle for disposable implantable drug delivery device	2013-10-21	2014-10-01	SAC/TC106
786	YY 1282-2016	Disposable intravenous indwelling needle	2016-03-23	2018-01-01	SAC/TC106
787	YY/T 0582.1-2005	Infusion bottle suspension device. Part 1 : Disposable suspension device	2005-12-07	2006-12-01	SAC/TC106
788	YY/T 0582.2-2005	Infusion bottle suspension device. Part 2 : Multi-purpose suspension device	2005-12-07	2006-12-01	SAC/TC106
789	YY/T 0611-2020	One-time use intravenous nutrition infusion bag	2020-09-27	2021-09-01	SAC/TC106
790	YY/T 0614-2017	Single-use high-pressure radiography syringe and accessories	2017-02-28	2018-01-01	SAC/TC106
791	YY/T 1291-2016	Subcutaneous infusion set for disposable insulin pump	2016-03-23	2017-01-01	SAC/TC106



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
792	YY 0804-2010	Infusion transfer device requirements and experimental methods	2010-12-27	2012-06-01	SAC/TC106
793	YY/T 0918-2014	Test method for bacterial retention of liquid medicine filter membrane and liquid medicine filter	2014-06-17	2015-07-01	SAC/TC106
794	YY/T 0923-2014	Microbial invasion test method for needleless interface of liquid circuit and blood circuit	2014-06-17	2015-07-01	SAC/TC106
795	YY/T 0929.1-2014	Sterile filter for infusion. Part 1: Integrity test of medical liquid filter	2014-06-17	2015-07-01	SAC/TC106
796	YY/T 0929.2-2018	Infusion liquid filter of 2 parts: a nominal pore size of 1.2 [ $\mu$ ] m Test Method trapped liquid filter Candida albicans	2018-12-20	2020-01-01	SAC/TC106
797	YY/T 1551.1-2017	Air filters for transfusion and blood transfusion apparatus. Part 1: Test method for aerosol bacteria retention	2017-02-28	2018-01-01	SAC/TC106
798	YY/T 1551.2-2017	Air filters for transfusion and blood transfusion equipment. Part 2: Test method for liquid bacteria retention	2017-02-28	2018-01-01	SAC/TC106
799	YY/T 1551.3-2017	Air filters for infusion and blood transfusion apparatus. Part 3: Integrity test method	2017-02-28	2018-01-01	SAC/TC106
800	YY/T 1648-2019	Correlation method between bubble point pressure and bacteria retention ability of filter for infusion equipment	2019-05-31	2020-06-01	SAC/TC106
<b>(3) Blood transfusion and blood collection equipment</b>					
801	GB 19335-2003	General technical conditions for single-use blood circuit products	2003-10-20	2004-04-01	SAC/TC106
802	GB 8369.1-2019	Blood transfusion set for single use. Part 1: Gravity blood transfusion	2019-10-14	2021-05-01	SAC/TC106
803	GB 8369.2-2020	Blood transfusion set for single use. Part 2:	2020-11-17	2022-06-01	SAC/TC106

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		Pressure blood transfusion equipment			
804	GB 14232.1-2020	Human blood and blood components bag-type plastic containers. Part 1 : Traditional blood bags	2020-07-23	2022-02-01	SAC/TC106
805	GB/T 14232.2-2015	Human blood and blood components bag-type plastic containers. Part 2 : Graphical symbols for labels and instructions for use	2015-12-10	2016-09-01	SAC/TC106
806	GB 14232.3-2011	Bag-type plastic containers for human blood and blood components. Part 3 : Blood bag system with special components	2011-12-30	2012-12-01	SAC/TC106
807	YY 0327-2002	Disposable blood container for ultraviolet radiation therapy	2002-01-07	2002-04-01	SAC/TC106
808	YY 0329-2009	Single-use leukocyte-removing filter	2009-06-16	2010-12-01	SAC/TC106
809	YY 0584-2005	Disposable centrifugal cup type blood component separator	2005-12-07	2006-12-01	SAC/TC106
810	YY 0613-2007	Single use centrifugal bag type blood component separator	2007-07-02	2008-08-01	SAC/TC106
811	YY 0765.1-2009	Disposable blood and blood component virus inactivation equipment. Part 1 : Methylene blue virus inactivation equipment	2009-12-30	2011-06-01	SAC/TC106
812	YY 0612-2007	Disposable human arterial blood sample collector (arterial blood gas needle)	2007-07-02	2008-08-01	SAC/TC106
813	YY/T 0326-2017	Single-use centrifugal plasma separator	2017-05-02	2018-04-01	SAC/TC106
814	YY/T 0328-2015	Single-use arteriovenous puncture	2015-03-02	2016-01-01	SAC/TC106
815	YY/T 1510-2017	Medical plasma virus inactivation box	2017-03-28	2018-04-01	SAC/TC106
816	YY/T 1566.1-2017	Disposable autologous blood processing equipment. Part 1 : Centrifuge cup type blood cell recovery device	2017-07-17	2018-07-01	SAC/TC106
817	YY/T 0289-1996	One-time use micro blood collection pipette	1996-08-12	1997-02-01	SAC/TC106

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
818	YY/T 0314-2007	Disposable human venous blood sample collection container	2007-07-02	2008-08-01	SAC/TC106
819	YY/T 0617-2007	Disposable human peripheral blood sample collection container	2007-07-02	2008-03-01	SAC/TC106
820	YY/T 1618-2018	Disposable human venous blood sample collection needle	2018-09-28	2019-10-01	SAC/TC95
821	YY/T 1286.1-2015	Performance of platelet storage bags. Part 1 : Determination of air permeability of membrane materials. Differential pressure method	2015-03-02	2016-01-01	SAC/TC106
822	YY/T 1286.2-2016	Platelet storage bag performance. Part 2 : Guidelines for evaluating platelet storage performance	2016-01-26	2017-01-01	SAC/TC106
823	YY/T 1631.1-2018	Determination of compatibility between blood transfusion set and blood components. Part 1 : Evaluation of residual blood components	2018-12-20	2020-01-01	SAC/TC106
824	YY/T 1631.2-2020	Determination of compatibility between blood transfusion set and blood components. Part 2 : Evaluation of blood component damage	2020-09-27	2021-09-01	SAC/TC106
825	YY/T 1416.1-2016	The method for determining the dosage in the disposable human venous blood sample collection container. Part 1 : Ethylenediaminetetraacetic acid ( EDTA ) salt	2016-03-23	2017-01-01	SAC/TC106
826	YY/T 1416.2-2016	Method for determination of additive dose in disposable human venous blood sample collection container. Part 2 : Sodium citrate	2016-01-26	2017-01-01	SAC/TC106
827	YY/T 1416.3-2016	The method of measuring the additive dose in the disposable human venous blood sample collection container. Part 3 : Heparin	2016-07-29	2017-06-01	SAC/TC106

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
828	YY/T 1416.4-2016	Method for determination of additive dose in disposable human venous blood sample collection container. Part 4 : Fluoride	2016-07-29	2017-06-01	SAC/TC106
829	YY/T 1416.5-2021	Method for determination of additive dose in disposable human venous blood sample collection container. Part 5 : Glycine	2021-03-09	2022-04-01	SAC/TC106
830	YY/T 1416.6-2021	Method for determination of additive dose in disposable human venous blood sample collection container. Part 6 : Imidazolidinyl urea	2021-03-09	2022-04-01	SAC/TC106
<b>(4) Drainage equipment</b>					
831	YY/T 0583.1-2015	One-time use thoracic drainage device Part 1 : Water-sealed type	2015-03-02	2016-01-01	SAC/TC106
832	YY/T 0583.2-2016	One-time use thoracic drainage device Part 2 : Dry seal valve type	2016-03-23	2017-01-01	SAC/TC106
833	YY/T 1287.1-2016	Extracranial drainage system Part 1 : Craniocentesis external drainage collection device	2016-03-23	2017-01-01	SAC/TC106
834	YY/T 1287.2-2016	Extracranial drainage system Part 2 : Lumbar puncture and external drainage collection device for cerebrospinal fluid	2016-01-26	2017-01-01	SAC/TC106
835	YY/T 1287.3-2016	Extracranial drainage system. Part 3 : Extracranial drainage catheter	2016-01-26	2017-01-01	SAC/TC106

## 8. Biological evaluation of nanomaterials

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
836	YY/T 0993-2015	Nanomaterials for biological evaluation of medical devices: in vitro cytotoxicity test ( MTT test and LDH test)	2015-03-02	2016-01-01	Central Procuratorate

837	YY/T 1295-2015	Biological Evaluation of Medical Devices Nanomaterials: Bacterial Endotoxin Test	2015-03-02	2016-01-01	Central Procuratorate
838	YY/T 1532-2017	Hemolysis test of nanomaterials in biological evaluation of medical devices	2017-03-28	2018-04-01	Central Procuratorate

## 9. Assisted reproductive medical equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
839	YY/T 0995-2015	Terms and definitions of medical devices used in human assisted reproductive technology	2015-03-02	2016-01-01	Central Procuratorate
840	YY/T 1434-2016	In Vitro Mouse Embryo Test of Medical Devices for Human In Vitro Assisted Reproductive Technology	2016-01-26	2017-01-01	Central Procuratorate
841	YY/T 1535-2017	Biological Evaluation of Human Sperm Survival Test for Medical Devices Used in Human In vitro Assisted Reproductive Technology	2017-03-28	2018-04-01	Central Procuratorate
842	YY/T 1688-2021	Methods for staining and counting blastocysts of medical devices for human assisted reproductive technology	2021-03-09	2022-04-01	Central Procuratorate
843	YY/T 1698-2020	Needle for assisted reproductive puncture and egg retrieval	2020-06-30	2021-06-01	Central Procuratorate
844	YY/T 1718-2020	Embryo transfer catheters for medical devices used in human external assisted reproductive technology	2020-03-31	2021-04-01	Central Procuratorate
845	YY/T 1695-2020	Detection method of amino acid in culture liquid of medical device for human assisted reproductive technology	2020-03-31	2021-04-01	Central Procuratorate

## 10. Medical additive manufacturing technology and medical equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
---------------	-----------------	---------------	--------------	---------------------	-------------

846	YY/T 1701-2020	Medical Ti-6Al-4V/Ti-6Al-4V ELI powder for additive manufacturing	2020-06-30	2021-06-01	Central Procuratorate
-----	----------------	---	------------	------------	-----------------------

## 11. Medical biological protection

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Medical masks</b>					
847	GB 19083-2010	Technical requirements for medical protective masks	2010-09-02	2011-08-01	Beijing Office
848	YY 0469-2011	Medical surgical mask	2011-12-31	2013-06-01	Beijing Office
849	YY/T 0969-2013	Disposable medical mask	2013-10-21	2014-10-01	Beijing Office
850	YY/T 0691-2008	Infectious pathogen protective equipment medical mask anti-synthetic blood penetration test method (fixed volume, horizontal jet)	2008-10-17	2010-01-01	Beijing Office
851	YY/T 0866-2011	Test method for total leakage rate of medical protective masks	2011-12-31	2013-06-01	Beijing Office
852	YY/T 1497-2016	Medical protective mask material virus filtration efficiency evaluation test method Phi-X174 bacteriophage test method	2016-07-29	2017-06-01	Beijing Office
<b>(2) Medical protective clothing</b>					
853	GB 19082-2009	Technical requirements for medical disposable protective clothing	2009-05-06	2010-03-01	Beijing Office
854	YY/T 1799-2020	Technical requirements for reusable medical protective clothing	2020-12-22	2021-01-01	Beijing Office
855	YY/T 1499-2016	Liquid barrier performance and classification of medical protective clothing	2016-07-29	2017-06-01	Beijing Office
856	YY/T 0689-2008	Blood and experience protective equipment, protective clothing materials, anti-blood-borne pathogen penetration performance test Phi-X174 bacteriophage test method	2008-10-17	2010-01-01	Beijing Office
857	YY/T 0699-2008	Liquid chemical protective equipment and protective clothing material resistance	2008-10-17	2010-01-01	Beijing Office

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		to pressurized liquid penetration test method			
858	YY/T 0700-2008	Blood and experience protective equipment, protective clothing materials, anti-penetration performance of blood and body fluids, synthetic blood test method	2008-10-17	2010-01-01	Beijing Office
859	YY/T 0867-2011	Test method for static decay time of nonwoven fabric	2011-12-31	2013-06-01	Beijing Office
860	YY/T 1425-2016	Test method for anti-injection needle puncture performance of protective clothing materials	2016-01-26	2017-01-01	Beijing Office
861	YY/T 1498-2016	Guidelines for the selection and evaluation of medical protective clothing	2016-07-29	2017-06-01	Beijing Office
862	YY/T 1632-2018	Water resistance of medical protective clothing materials: impact penetration test method	2018-12-20	2019-06-01	Beijing Office
<b>(3) Surgical gowns, surgical drapes</b>					
863	YY/T 0506.1-2005	Surgical drapes, surgical gowns and clean clothes for patients, medical staff and instruments. Part 1: General requirements for manufacturers, treatment plants and products	2005-04-05	2006-01-01	Shandong Center
864	YY/T 0506.2-2016	Surgical drapes, surgical gowns and clean clothes for patients, medical staff and instruments. Part 2: Performance requirements and performance levels	2016-01-26	2017-01-01	Shandong Center
865	YY/T 0506.4-2016	Surgical drapes, surgical gowns and clean clothes for patients, medical staff and instruments. Part 4: Dry flocculation test method	2016-07-29	2017-06-01	Shandong Center
866	YY/T 0506.5-2009	Surgical drapes, surgical gowns and clean clothes for patients, medical staff and instruments. Part 5: Test method for preventing the penetration of dry microorganisms	2009-06-16	2010-12-01	Shandong Center

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
867	YY/T 0506.6-2009	Surgical drapes, surgical gowns and clean clothes for patients, medical staff and instruments. Part 6 : Test method for moisture barrier microbial penetration	2009-06-16	2010-12-01	Shandong Center
868	YY/T 0506.7-2014	Surgical drapes, surgical gowns and clean clothes for patients, medical staff and instruments. Part 7 : Cleanliness - Microbiological test methods	2014-06-17	2015-07-01	Shandong Center
869	YY/T 0506.8-2019	Surgical drapes, surgical gowns and clean clothes for patients, medical staff and instruments. Part 8 : Product-specific requirements	2019-07-24	2020-08-01	Shandong Center
870	YY 0852-2011	Sterile surgical film for single use	2011-12-31	2013-06-01	Shandong Center
871	YY/T 0720-2009	One-time delivery package for natural childbirth	2009-06-16	2010-12-01	Shandong Center
872	YY/T 0855.1-2011	Test method and classification of laser resistance of patient protective coverings on surgical drapes. Part 1 : Primary ignition and penetration	2011-12-31	2013-06-01	Shandong Center
873	YY/T 0855.2-2011	Test method and classification of laser resistance of patient protective coverings on surgical drapes. Part 2 : Secondary ignition	2011-12-31	2013-06-01	Shandong Center
<b>(4) Medical gloves</b>					
874	YY/T 0616.1-2016	Disposable medical gloves. Part 1 : Biological evaluation requirements and test methods	2016-01-26	2017-01-01	Shandong Center
875	YY/T 0616.2-2016	Disposable medical gloves. Part 2 : Requirements and test methods for determining shelf life	2016-01-26	2017-01-01	Shandong Center
876	YY/T 0616.3-2018	Disposable medical gloves. Part 3 : Method for determining real-time expiration date with finished gloves in storage	2018-11-07	2019-11-01	Shandong Center



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
877	YY/T 0616.4-2018	Disposable medical gloves. Part 4 : Puncture resistance test method	2018-12-20	2020-01-01	Shandong Center
878	YY/T 0616.5-2019	Medical gloves for single use. Part 5 : Test method for resistance to chemical penetration and continuous exposure	2019-10-23	2020-10-01	Shandong Center
879	YY/T 0616.7-2020	Medical gloves for single use. Part 7 : Immunological determination method of antigenic protein content	2020-09-27	2021-09-01	Shandong Center
<b>(5) Medical protective shoe covers and caps</b>					
880	YY/T 1633-2019	Disposable medical protective shoe covers	2019-07-24	2021-02-01	Beijing Office
881	YY/T 1642-2019	Disposable medical protective cap	2019-07-24	2021-02-01	Beijing Office
<b>(6) Biological safety cabinet</b>					
882	YY 0569-2011	Class II biological safety cabinet	2011-12-31	2013-06-01	Beijing Office
883	YY/T 1540-2017	Guidelines for Verification of Medical Class II Biological Safety Cabinets	2017-05-02	2018-04-01	Beijing Office
884	YY/T 1539-2017	Medical clean workbench	2017-05-02	2018-04-01	Beijing Office

## 12. Sanitary materials

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Non-absorbable surgical dressing</b>					
885	YY 0594-2006	General requirements for surgical gauze dressings	2006-04-19	2007-04-01	Shandong Center
886	YY/T 0921-2015	Medical absorbent viscose fiber	2015-03-02	2016-01-01	Shandong Center
887	YY/T 0330-2015	Medical absorbent cotton	2015-03-02	2016-01-01	Shandong Center
888	YY/T 0331-2006	Performance requirements and test methods of absorbent cotton gauze and de-finger cotton viscose blended gauze	2006-04-19	2007-04-01	Shandong Center
889	YY/T 0854.1-2011	Performance requirements of cotton nonwoven surgical dressings. Part 1 : Nonwovens for dressing production	2011-12-31	2013-06-01	Shandong Center

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
890	YY/T 0854.2-2011	Performance requirements of cotton nonwoven surgical dressings. Part 2 : Finished dressings	2011-12-31	2013-06-01	Shandong Center
891	YY/T 0472.1-2004	Test methods for medical non-woven compresses. Part 1 : Non-woven fabrics for the production of compresses	2004-03-23	2005-01-01	Shandong Center
892	YY/T 0472.2-2004	Medical nonwoven compresses. Test methods. Part 2 : Finished compresses	2004-03-23	2005-01-01	Shandong Center
893	YY/T 1117-2001	Plaster bandage powder type	2011-11-09	2002-03-01	Shanghai Center
894	YY/T 1118-2001	Plaster bandage viscose type	2011-11-09	2002-03-01	Shanghai Center
<b>(2) Absorbable surgical dressing</b>					
895	YY/T 1283-2016	Absorbable gelatin sponge	2016-03-23	2017-01-01	Shandong Center
896	YY/T 1511-2017	Collagen sponge	2017-05-02	2018-04-01	Shandong Center
<b>(3) Contact wound dressing</b>					
897	YY/T 1293.1-2016	Contact wound dressings. Part 1 : Vaseline gauze	2016-03-23	2017-01-01	Shandong Center
898	YY/T 1293.2-2016	Contact wound dressings. Part 2 : Polyurethane foam dressings	2016-03-23	2017-01-01	Shandong Center
899	YY/T 1293.4-2016	Contact wound dressings. Part 4 : Hydrocolloid dressings	2016-07-29	2017-06-01	Shandong Center
900	YY/T 1293.5-2017	Contact wound dressings. Part 5 : Alginate dressings	2017-05-02	2018-04-01	Shandong Center
901	YY/T 1293.6-2020	Contact wound dressing. Part 6 : Mussel mucin dressing	2020-09-27	2021-09-01	Shandong Center
902	YY/T 1627-2018	General requirements for acute wound application and bandage	2018-11-07	2019-11-01	Shandong Center
903	YY/T 0471.1-2004	Test methods of contact wound dressings. Part 1 : Liquid absorption	2004-03-23	2005-01-01	Shandong Center
904	YY/T 0471.2-2004	Test methods for contact wound dressings. Part 2 : Water vapor transmission rate of breathable membrane dressings	2004-03-23	2005-01-01	Shandong Center

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
905	YY/T 0471.3-2004	Test method of contact wound dressing. Part 3 : Water resistance	2004-03-23	2005-01-01	Shandong Center
906	YY/T 0471.4-2004	Test method of contact wound dressing. Part 4 : Comfort	2004-03-23	2005-01-01	Shandong Center
907	YY/T 0471.5-2017	Test method of contact wound dressing. Part 5 : Bacteriostatic	2017-02-28	2018-01-01	Shandong Center
908	YY/T 0471.6-2004	Test method of contact wound dressing. Part 6 : Odor control	2004-03-23	2005-01-01	Shandong Center
909	YY/T 1477.1-2016	Standard test model for evaluating the performance of contact wound dressings. Part 1 : In vitro wound model for evaluating antibacterial activity	2016-01-26	2017-01-01	Shandong Center
910	YY/T 1477.2-2016	Standard test model for evaluating the performance of contact wound dressings. Part 2 : Animal scald model for evaluating the performance of promoting wound healing	2016-07-29	2017-06-01	Shandong Center
911	YY/T 1477.3-2016	Standard test model for evaluating the performance of contact wound dressings. Part 3 : In vitro model for evaluating fluid control performance	2016-07-29	2017-06-01	Shandong Center
912	YY/T 1477.4-2017	Standard test model for evaluating the performance of contact wound dressings. Part 4 : In vitro model for evaluating the adhesion potential of wound dressings	2017-02-28	2018-01-01	Shandong Center
913	YY/T 1477.5-2020	Standard test model for evaluating the performance of contact wound dressings. Part 5 : In vitro model for evaluating hemostatic properties	2020-03-31	2021-04-01	Shandong Center
914	YY/T 1477.6-2020	Standard test model for evaluating the performance of contact wound dressings. Part 6 : Animal model of difficult-to-heal type II diabetes wounds for	2020-09-27	2021-09-01	Shandong Center

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		evaluating the properties of promoting wound healing			
<b>(4) Bandaging and fixing products</b>					
915	YY/T 0148-2006	General requirements for medical tape	2006-04-19	2007-04-01	Shandong Center
916	YY/T 1467-2016	Medical bandaging dressing	2016-01-26	2017-01-01	Shandong Center
917	YY/T 0507-2009	Characterization and test methods of basic performance parameters of medical elastic bandages	2009-12-30	2011-06-01	Shandong Center
918	YY/T 1697-2020	Test method for determination of strength and curing time of synthetic water-activated polyurethane glass fiber orthopedic bandage	2020-02-21	2021-01-01	Shandong Center
<b>(5) Other</b>					
919	YY/T 0308-2015	Medical Sodium Hyaluronate Gel	2015-03-02	2016-01-01	Shandong Center
920	YY/T 0729.1-2009	Test method for bonding performance of tissue adhesives. Part 1: Lap - shear tensile strength	2009-06-16	2010-12-01	Shandong Center
921	YY/T 0729.2-2009	Test method for adhesive performance of tissue adhesives. Part 2: T-peel tensile strength	2009-06-16	2010-12-01	Shandong Center
922	YY/T 0729.3-2009	Test method for bonding performance of tissue adhesives. Part 3: Tensile strength	2009-06-16	2010-12-01	Shandong Center
923	YY/T 0729.4-2009	Test method for adhesive performance of tissue adhesives. Part 4: Wound closure strength	2009-06-16	2010-12-01	Shandong Center
924	YY/T 1436-2016	Requirements and test methods for lavage devices for ostomy and incontinence aids	2016-01-26	2017-01-01	Shandong Center

### 13. Disinfection and sterilization equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
925	GB 4793.4-2019	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 4: Special requirements for sterilizers and washer-disinfectors used to process medical materials	2019-12-17	2021-01-01	SAC/TC200
926	GB 8599-2008	Large-scale steam sterilizer technology requires automatic control type	2008-12-31	2009-12-01	SAC/TC200
927	GB/T 32309-2015	Hydrogen peroxide low temperature plasma sterilizer	2015-12-10	2016-09-01	SAC/TC200
928	GB/T 35267-2017	Endoscope washer-disinfectors	2017-12-29	2019-07-01	SAC/TC200
929	YY 0992-2016	Endoscope cleaning workstation	2016-03-23	2018-01-01	SAC/TC200
930	YY 0154-2013	Spring full lift safety valve for pressure steam sterilization equipment	2013-10-21	2014-10-01	SAC/TC200
931	YY 0504-2016	Portable steam sterilizer	2016-03-23	2018-01-01	SAC/TC200
932	YY 0731-2009	Large steam sterilizer manual control type	2009-06-16	2010-12-01	SAC/TC200
933	YY/T 1007-2018	Vertical steam sterilizer	2018-09-28	2019-10-01	SAC/TC200
934	YY 1277-2016	Biosafety performance requirements for steam sterilizers	2016-03-23	2018-01-01	SAC/TC200
935	YY 0503-2016	Ethylene oxide sterilizer	2016-03-23	2018-01-01	SAC/TC200
936	YY 1275-2016	Hot air dry heat sterilizer	2016-03-23	2018-01-01	SAC/TC200
937	YY/T 0791-2018	Medical steam generator	2018-09-28	2019-10-01	SAC/TC200
938	YY/T 0084.1-2009	Calculation of the strength of the main pressure components of the circular pressure steam sterilizer and related regulations	2009-06-16	2010-12-01	SAC/TC200
939	YY/T 0084.2-2009	Strength calculation of main pressure components of rectangular pressure steam sterilizer and related regulations	2009-06-16	2010-12-01	SAC/TC200
940	YY/T 0157-2013	Spring type steam release valve for pressure steam sterilization equipment	2013-10-21	2014-10-01	SAC/TC200

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
941	YY/T 0158-2013	Sealing gasket for pressure steam sterilization equipment	2013-10-21	2014-10-01	SAC/TC200
942	YY/T 0159-2005	Steam trap for pressure steam sterilization equipment	2005-04-05	2006-01-01	SAC/TC200
943	YY/T 0646-2015	Automatic control type for small steam sterilizer	2015-03-02	2016-01-01	SAC/TC200
944	YY/T 0679-2016	Medical low-temperature steam formaldehyde sterilizer	2016-07-29	2017-06-01	SAC/TC200
945	YY/T 1609-2018	Cassette steam sterilizer	2018-06-26	2019-07-01	SAC/TC200
946	YY/T 0215-2016	Medical ozone disinfection equipment	2016-07-29	2017-06-01	SAC/TC200
947	YY/T 0734.1-2018	Washer-disinfector Part 1 : General requirements and tests	2018-11-07	2019-11-01	SAC/TC200
948	YY/T 0734.2-2018	Washer-disinfector Part 2 : Requirements and tests for washer-disinfector for damp-heat disinfection of surgical and anesthesia instruments	2018-12-20	2020-01-01	SAC/TC200
949	YY/T 0734.3-2018	Washer-disinfector Part 3 : Requirements and tests for washer-disinfector for damp-heat disinfection of human waste containers	2018-12-20	2020-01-01	SAC/TC200
950	YY/T 0734.4-2016	Washer-disinfector Part 4 : Requirements and tests for washer-disinfector for damp-heat disinfection of non-invasive medical devices	2016-01-26	2017-01-01	SAC/TC200
951	YY/T 0734.5-2020	Washer-disinfector Part 5 : Requirements and tests for washer-disinfector for chemical disinfection of non-invasive medical devices that are not resistant to high temperature	2020-02-21	2021-01-01	SAC/TC200
952	YY/T 1309-2016	Requirements and tests for ultrasonic cleaning of washer-disinfectors	2016-03-23	2017-01-01	SAC/TC200
953	YY/T 1687-2019	Boiling sterilizer	2019-10-23	2020-10-01	SAC/TC200
954	YY/T 0822-2011	Ethylene oxide liquefied gas for sterilization	2011-12-31	2013-06-01	SAC/TC200

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
955	YY/T 0883-2013	Technical requirements for process challenge device and indicator system for steam penetration test	2013-10-21	2014-10-01	SAC/TC200
956	YY/T 1495-2016	Microbiological verification method of cleaning and disinfection effect	2016-07-29	2017-06-01	SAC/TC200

#### 14. Medical X-ray equipment and appliances

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Professional and general fields</b>					
957	GB 9706.14-1997	Medical electrical equipment Part 2 : Special requirements for the safety of auxiliary equipment of X-ray equipment	1997-09-30	1998-10-01	SAC/TC10/SC1
958	GB 9706.228-2020	Medical electrical equipment-Part 2-28 : Specific requirements for the basic safety and basic performance of medical diagnostic X-ray tube components	2020-12-24	2023-05-01	State Food and Drug Administration
959	GB/T 10149-1988	Terms and symbols for medical X-ray equipment	1988-12-22	1989-07-01	SAC/TC10/SC1
960	GB/T 17006.1-2000	Evaluation and routine testing of medical imaging department. Part 1 : General	2000-07-17	2000-12-01	SAC/TC10/SC1
961	GB/T 17006.2-2000	Evaluation and Routine Tests in Medical Imaging Department Part 2-1 : Stability Test of Film Processor	2000-07-17	2000-12-01	SAC/TC10/SC1
962	GB/T 17006.4-2000	Evaluation and routine test of medical imaging department Part 2-3 : Stability test of safe lighting state in darkroom	2000-07-17	2000-12-01	SAC/TC10/SC1
963	GB/T 17006.5-2000	Evaluation and routine test of medical imaging department Part 2-5 : Stability test of image display device	2000-07-17	2000-12-01	SAC/TC10/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
964	YY/T 0291-2016	Environmental requirements and test methods for medical X-ray equipment	2016-03-23	2017-01-01	SAC/TC10/SC1
965	YY/T 1099-2007	Packaging, transportation and storage of medical X-ray equipment	2007-01-31	2008-01-01	SAC/TC10/SC1
966	YY/T 0910.1-2013	Medical electrical equipment medical image display system. Part 1: Evaluation method	2013-10-21	2014-10-01	SAC/TC10/SC1
<b>(2) X-ray machine</b>					
967	GB 9706.3-2000	Medical electrical equipment Part 2: Special requirements for the safety of high-voltage generators for diagnostic X-ray generators	2000-07-12	2000-12-01	SAC/TC10/SC1
968	GB 9706.254-2020	Medical electrical equipment-Part 2-54: Specific requirements for the basic safety and basic performance of X-ray photography and fluoroscopy equipment	2020-12-24	2023-05-01	State Food and Drug Administration
969	GB 9706.243-2021	Medical electrical equipment Part 2-43: Specific requirements for the basic safety and basic performance of interventional X-ray equipment	2021-02-20	2023-05-01	State Food and Drug Administration
970	GB 9706.245-2020	Medical electrical equipment - 2-45 parts: breast X basic safety and essential performance ray equipment and stereotactic mammographic apparatus	2020-12-24	2023-05-01	State Food and Drug Administration
971	GB 9706.263-2020	Medical electrical equipment-Part 2-63: Special requirements for the basic safety and basic performance of extraoral imaging dental X-ray machines	2020-11-17	2023-05-01	State Food and Drug Administration
972	GB 9706.265-2021	Medical electrical equipment-Part 2-65: Specific requirements	2021-02-20	2023-05-01	State Food and Drug Administration



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		for the basic safety and basic performance of intraoral imaging dental X-ray machines			
973	GB/T 17006.7-2003	Evaluation and routine test of medical imaging department Part 2-7 : Stability test Intraoral dental X-ray photography equipment does not include dental panoramic equipment	2003-06-24	2003-12-01	SAC/TC10/SC1
974	GB/T 17006.8-2003	Evaluation and routine testing of medical imaging department Part 2-9 : Indirect fluoroscopy and indirect photography X-ray equipment for stability test	2003-06-24	2003-12-01	SAC/TC10/SC1
975	GB/T 17006.9-2003	Evaluation of medical imaging departments and routine testing 2-10 parts: Stability test of breast X-ray imaging apparatus	2003-06-24	2003-12-01	SAC/TC10/SC1
976	GB/T 17006.10-2003	Evaluation and routine test of medical imaging department Part 2-11 : Stability test Ordinary direct radiography X-ray equipment	2003-06-24	2003-12-01	SAC/TC10/SC1
977	GB/T 19042.1-2003	Evaluation and routine tests in medical imaging departments. Part 3-1 : Acceptance test of imaging performance of X-ray equipment for X-ray photography and fluoroscopy systems	2003-01-27	2003-07-01	SAC/TC10/SC1
978	GB/T 19042.2-2005	Evaluation and routine test of medical imaging department. Part 3-2 : Acceptance test of imaging performance of mammography X-ray equipment	2005-01-27	2005-08-01	SAC/TC10/SC1
979	GB/T 19042.3-2005	Evaluation and routine test of medical imaging department Part 3-3 : Digital subtraction	2005-01-27	2005-08-01	SAC/TC10/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		angiography ( DSA ) X-ray equipment imaging performance acceptance test			
980	GB/T 19042.4-2005	Evaluation and routine test of medical imaging department. Part 3-4: Acceptance test of imaging performance of dental X-ray equipment	2005-01-27	2005-08-01	SAC/TC10/SC1
981	YY/T 0106-2008	General technical requirements for medical diagnostic X-ray machines	2008-10-17	2010-01-01	SAC/TC10/SC1
982	YY/T 0796.1-2010	Exposure index of digital X-ray imaging system for medical electrical equipment . Part 1: Definition and requirements of general X-ray photography	2010-12-27	2012-06-01	SAC/TC10/SC1
983	YY/T 1708.1-2020	Basic requirements for connectivity of medical diagnostic X-ray imaging equipment. Part 1: General requirements	2020-06-30	2021-06-01	SAC/TC10/SC1
984	YY/T 0010-2020	Special technical requirements for intraoral imaging dental X-ray machine	2020-06-30	2021-06-01	SAC/TC10/SC1
985	YY/T 0202-2009	Technical requirements for medical diagnostic X-ray tomography equipment	2009-06-16	2010-12-01	SAC/TC10/SC1
986	YY/T 0347-2009	Special technical requirements for miniature medical diagnostic X-ray machine	2009-06-16	2010-12-01	SAC/TC10/SC1
987	YY/T 0706-2017	Special technical conditions for breast X-ray machine	2017-03-28	2018-04-01	SAC/TC10/SC1
988	YY/T 0707-2020	Special technical requirements for mobile X-ray machines	2020-09-27	2021-09-01	SAC/TC10/SC1
989	YY/T 0724-2021	Special technical conditions for dual-energy X-ray bone densitometer	2021-03-09	2022-04-01	SAC/TC10/SC1
990	YY/T 0740-2009	Special technical conditions for medical angiography X-ray machines	2009-11-15	2010-12-01	SAC/TC10/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
991	YY/T 0741-2018	Special technical conditions for digital photography X-ray machines	2018-09-28	2019-10-01	SAC/TC10/SC1
992	YY/T 0742-2021	Special technical conditions for gastrointestinal X-ray machine	2021-03-09	2022-04-01	SAC/TC10/SC1
993	YY/T 0744-2018	Special technical requirements for mobile C-arm X-ray machine	2018-01-19	2019-01-01	SAC/TC10/SC1
994	YY/T 0745-2009	Special technical requirements for remote X-ray machine	2009-11-15	2010-12-01	SAC/TC10/SC1
995	YY/T 0746-2021	Special technical conditions for vehicle-mounted medical X-ray diagnostic equipment	2021-03-09	2022-04-01	SAC/TC10/SC1
996	YY/T 0795-2010	Special technical requirements for oral X-ray digital tomography equipment	2010-12-27	2012-06-01	SAC/TC10/SC1
997	YY/T 0936-2014	Special technical conditions for urinary X-ray machine	2014-06-17	2015-07-01	SAC/TC10/SC1
998	YY/T 1732-2020	Special technical conditions for oral curved body X-ray machine	2020-06-30	2021-06-01	SAC/TC10/SC1
999	YY/T 1466-2016	Oral X-ray digital tomography equipment bone density measurement and evaluation method	2016-01-26	2017-01-01	SAC/TC10/SC1
1000	YY/T 1542-2017	Evaluation method for automatic exposure control of digital medical X-ray equipment	2017-05-02	2018-04-01	SAC/TC10/SC1
<b>(3) X-ray computerized tomography equipment ( CT )</b>					
1001	GB 9706.244-2020	Medical electrical equipment Part 2-44 : Specific requirements for the basic safety and basic performance of X-ray computed tomography equipment	2020-12-24	2023-05-01	State Food and Drug Administration
1002	GB/T 17006.11-2015	Evaluation and routine test of medical imaging department. Part 2-6 : X-ray computed tomography	2015-12-10	2016-09-01	SAC/TC10/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		equipment imaging performance stability test			
1003	GB/T 19042.5-2006	Evaluation and routine test of medical imaging department. Part 3-5 : X-ray computed tomography equipment imaging performance acceptance test	2006-10-17	2007-07-01	SAC/TC10/SC1
1004	YY/T 0310-2015	General technical requirements for X-ray computed tomography equipment	2015-03-02	2016-01-01	SAC/TC10/SC1
1005	YY/T 1708.2-2020	Basic requirements for connectivity of medical diagnostic X-ray imaging equipment. Part 2 : X-ray computed tomography equipment	2020-09-27	2021-09-01	SAC/TC10/SC1
1006	YY/T 1417-2016	Technical requirements for 64-layer spiral X-ray computerized tomography equipment	2016-07-29	2017-06-01	SAC/TC10/SC1
1007	YY/T 1625-2018	Special technical requirements for mobile X-ray computed tomography equipment	2018-12-20	2020-01-01	SAC/TC10/SC1
1008	YY/T 1766.1-2021	Image quality evaluation method of X-ray computed tomography equipment. Part 1 : Modulation transfer function evaluation	2021-03-09	2022-04-01	SAC/TC10/SC1
1009	YY/T 1766.2-2021	Image quality evaluation method of X-ray computed tomography equipment. Part 2 : Evaluation of low-contrast resolution	2021-03-09	2022-04-01	SAC/TC10/SC1
<b>(4) Medical X-ray equipment components and appliances</b>					
1010	GB/T 10151-2008	Technical requirements for high-voltage cable plugs and sockets for medical diagnostic X-ray equipment	2008-11-03	2009-10-01	SAC/TC10/SC1
1011	GB/T 13797-2009	General technical conditions for medical X-ray tubes	2009-09-30	2010-02-01	SAC/TC10/SC1
1012	GB/T 17006.3-2000	Evaluation and routine tests in medical imaging departments. Part 2-2 : X-ray radiography cassette	2000-07-17	2000-12-01	SAC/TC10/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		and film changer screen - film contact and screen - cassette assembly relative sensitivity stability test			
1013	GB/T 17006.6-2003	Evaluation and Routine Tests in Medical Imaging Department Part 2-4 : Stability Test of Hard Copy Camera	2003-01-27	2003-07-01	SAC/TC10/SC1
1014	YY/T 0011-2007	X-ray photography cassette	2007-01-31	2008-01-01	SAC/TC10/SC1
1015	YY/T 0093-2013	Medical diagnostic X-ray image intensifier	2013-10-21	2014-10-01	SAC/TC10/SC1
1016	YY/T 0094-2013	Medical diagnostic X-ray fluoroscopy screen	2013-10-21	2014-10-01	SAC/TC10/SC1
1017	YY/T 0095-2013	Calcium tungstate medium- speed medical intensifying screen	2013-10-21	2014-10-01	SAC/TC10/SC1
1018	YY/T 0129-2007	General technical conditions of medical diagnostic X-ray variable beam limiter	2007-01-31	2008-01-01	SAC/TC10/SC1
1019	YY/T 0197.1-2007	Medical diagnostic X-ray tube XD1-3/100 fixed anode X-ray tube	2007-01-31	2008-01-01	SAC/TC10/SC1
1020	YY/T 0197.2-2007	Medical diagnostic X-ray tube XD2-1/85 fixed anode X-ray tube	2007-01-31	2008-01-01	SAC/TC10/SC1
1021	YY/T 0197.3-2007	Medical diagnostic X-ray tube XD3-3.5/100 fixed anode X-ray tube	2007-01-31	2008-01-01	SAC/TC10/SC1
1022	YY/T 0197.4-2007	Medical diagnostic X-ray tube XD4-2, 9/100 fixed anode X-ray tube	2007-01-31	2008-01-01	SAC/TC10/SC1
1023	YY/T 0197.5-2007	Medical diagnostic X-ray tubes XD51- 20, 40/100 and XD51- 20, 40/125 rotating anode X-ray tubes	2007-01-31	2008-01-01	SAC/TC10/SC1
1024	YY/T 0608-2013	General technical requirements for TV systems of medical X-ray image intensifiers	2013-10-21	2014-10-01	SAC/TC10/SC1
1025	YY/T 0609-2018	General technical requirements for medical diagnostic X-ray tube components	2018-11-07	2019-11-01	SAC/TC10/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1026	YY/T 0610-2007	General technical conditions of medical imaging photo observation device	2007-01-31	2008-01-01	SAC/TC10/SC1
1027	YY/T 0737-2009	Special technical requirements for medical X-ray radiography bed	2009-11-15	2010-12-01	SAC/TC10/SC1
1028	YY/T 0738-2009	Special technical conditions for medical X-ray catheter bed	2009-11-15	2010-12-01	SAC/TC10/SC1
1029	YY/T 0739-2009	Special technical requirements for medical X-ray vertical photography racks	2009-11-15	2010-12-01	SAC/TC10/SC1
1030	YY/T 0743-2009	X-ray gastrointestinal diagnostic bed special technical conditions	2009-11-15	2010-12-01	SAC/TC10/SC1
1031	YY/T 0747-2009	XZ1-4/250 X-ray tube for treatment	2009-11-15	2010-12-01	SAC/TC10/SC1
1032	YY/T 0794-2010	Special technical requirements for image plate imaging device for X-ray photography	2010-12-27	2012-06-01	SAC/TC10/SC1
1033	YY/T 0891-2013	Special technical conditions for angiography high-pressure injection device	2013-10-21	2014-10-01	SAC/TC10/SC1
1034	YY/T 0933-2014	Digital X-ray image detector for general medical photography	2014-06-17	2015-07-01	SAC/TC10/SC1
1035	YY/T 0934-2014	Medical dynamic digital X-ray image detector	2014-06-17	2015-07-01	SAC/TC10/SC1
1036	YY/T 0935-2014	Special technical conditions for CT contrast injection device	2014-06-17	2015-07-01	SAC/TC10/SC1
1037	YY/T 1307-2016	Detector for medical breast digital X-ray photography	2016-03-23	2017-01-01	SAC/TC10/SC1
1038	YY/T 1541-2017	Technical requirements for high-voltage cable assemblies and sockets for mammary X-ray machines	2017-05-02	2018-04-01	SAC/TC10/SC1
1039	YY/T 0062-2004	Determination of inherent filtration of X-ray tube components	2004-11-08	2005-11-01	SAC/TC10/SC1
1040	YY/T 0063-2007	Focus characteristics of medical diagnostic X-ray tube components	2007-01-31	2008-01-01	SAC/TC10/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		of medical electrical equipment			
1041	YY/T 0064-2016	Electrical and load characteristics of medical diagnostic X-ray tube components	2016-03-23	2017-01-01	SAC/TC10/SC1
1042	YY/T 0457.1-2003	Characteristics of photoelectric X-ray image intensifiers for medical electrical equipment . Part 1 : Measurement of incident field size	2003-06-20	2004-01-01	SAC/TC10/SC1
1043	YY/T 0457.2-2003	Characteristics of photoelectric X-ray image intensifiers for medical electrical equipment . Part 2 : Determination of conversion factor	2003-06-20	2004-01-01	SAC/TC10/SC1
1044	YY/T 0457.3-2003	Characteristics of photoelectric X-ray image intensifiers for medical electrical equipment . Part 3 : Measurement of brightness distribution and non-uniformity	2003-06-20	2004-01-01	SAC/TC10/SC1
1045	YY/T 0457.4-2003	Characteristics of photoelectric X-ray image intensifiers for medical electrical equipment . Part 4 : Measurement of image distortion	2003-06-20	2004-01-01	SAC/TC10/SC1
1046	YY/T 0457.5-2003	Characteristics of photoelectric X-ray image intensifiers for medical electrical equipment . Part 5 : Measurement of detection quantum efficiency	2003-06-20	2004-01-01	SAC/TC10/SC1
1047	YY/T 0457.6-2003	Characteristics of photoelectric X-ray image intensifiers for medical electrical equipment . Part 6 : Determination of contrast and glare coefficient	2003-06-20	2004-01-01	SAC/TC10/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1048	YY/T 0457.7-2003	Characteristics of photoelectric X-ray image intensifiers for medical electrical equipment . Part 7 : Determination of modulation transfer function	2003-06-20	2004-01-01	SAC/TC10/SC1
1049	YY/T 0479-2004	Measurement of the Maximum Symmetrical Radiation Field of Rotating Anode X-ray Tubes for Medical Diagnostics	2004-03-23	2005-01-01	SAC/TC10/SC1
1050	YY/T 0480-2004	General purpose diagnostic X-ray imaging equipment and characteristics of anti-scatter grid for mammography	2004-03-23	2005-01-01	SAC/TC10/SC1
1051	YY/T 0590.1-2018	Characteristics of digital X-ray imaging devices for medical electrical equipment . Part 1-1 : Measurement of quantum detection efficiency. Detectors for general photography	2018-11-07	2019-11-01	SAC/TC10/SC1
1052	YY/T 0590.2-2010	Medical electrical equipment of digital X-ray imaging apparatus Characteristics of 1-2 parts: determination of the quantum detection efficiency of breast X-ray imaging detector with	2010-12-27	2012-06-01	SAC/TC10/SC1
1053	YY/T 0590.3-2011	Characteristics of digital X-ray imaging devices for medical electrical equipment . Part 1-3 : Measurement of quantum detection efficiency. Detectors for dynamic imaging	2011-12-31	2013-06-01	SAC/TC10/SC1
1054	YY/T 0892-2013	Leakage radiation test method for medical diagnostic X-ray tube assembly	2013-10-21	2014-10-01	SAC/TC10/SC1
<b>(5) Medical ray protection equipment</b>					



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1055	YY 0318-2000	Medical diagnostic X-ray radiation protection equipment. Part 3 : Protective clothing and gonadal protection equipment	2000-01-31	2000-07-01	SAC/TC10/SC1
1056	YY/T 0128-2004	Medical diagnostic X-ray radiation protection equipment and appliances	2004-11-08	2005-11-01	SAC/TC10/SC1
1057	YY/T 0292.1-2020	Medical diagnostic X-ray radiation protection equipment. Part 1 : Determination of material attenuation	2020-02-25	2021-03-01	SAC/TC10/SC1
1058	YY/T 0292.2-2020	Medical diagnostic X-ray radiation protection equipment. Part 2 : Transparent shields	2020-02-25	2021-03-01	SAC/TC10/SC1

## 15. Medical ultrasound equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Professional and general fields</b>					
1059	YY/T 0110-2009	Medical ultrasonic piezoelectric ceramic materials	2009-11-15	2010-12-01	SAC/TC10/SC2
1060	YY/T 0163-2005	Characteristics and calibration of medical ultrasonic measuring hydrophone	2005-12-07	2006-12-01	SAC/TC10/SC2
1061	YY/T 0458-2014	Technical requirements of ultrasound Doppler blood simulation fluid model	2014-06-17	2015-07-01	SAC/TC10/SC2
1062	YY/T 0642-2014	Ultrasonic sound field characteristics. Test method for determining the thermal and mechanical indices of medical diagnostic ultrasonic fields	2014-06-17	2015-07-01	SAC/TC10/SC2
1063	YY/T 0865.1-2011	Ultrasonic hydrophones. Part 1 : Measurement and characterization of medical ultrasonic fields below 40MHz	2011-12-31	2013-06-01	SAC/TC10/SC2
1064	YY/T 0865.2-2018	Ultrasonic hydrophones Part 2 : Calibration of	2018-12-20	2020-01-01	SAC/TC10/SC2

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		hydrophones for ultrasonic fields below 40MHz			
1065	YY/T 0865.3-2013	Ultrasonic hydrophones. Part 3 : Characteristics of ultrasonic field hydrophones below 40MHz	2013-10-21	2014-10-01	SAC/TC10/SC2
1066	YY/T 0937-2014	Technical requirements of ultrasound tissue phantom	2014-06-17	2015-07-01	SAC/TC10/SC2
1067	YY/T 1085-2007	Milliwatt ultrasonic source	2007-01-31	2008-01-01	SAC/TC10/SC2
1068	YY/T 1088-2007	In 0.5MHz to 15MHz using hydrophone measurements and characterization of medical ultrasound equipment sound field characteristic in the frequency range of the guide	2007-01-31	2008-01-01	SAC/TC10/SC2
1069	YY/T 1420-2016	Environmental requirements and test methods for medical ultrasound equipment	2016-01-26	2017-01-01	SAC/TC10/SC2
1070	YY/T 1521-2017	Technical requirements of ultrasonic elastic tissue phantom	2017-03-28	2018-04-01	SAC/TC10/SC2
<b>(2) Ultrasonic diagnostic equipment</b>					
1071	GB 9706.237-2020	Medical electrical equipment Part 2-37 : Specific requirements for the basic safety and basic performance of ultrasonic diagnostic and monitoring equipment	2020-04-09	2023-05-01	State Food and Drug Administration
1072	GB/T 16846-2008	Requirements for the announcement of acoustic output of medical ultrasonic diagnostic equipment	2008-03-24	2009-01-01	SAC/TC10/SC2
1073	GB 10152-2009	B-mode ultrasonic diagnostic equipment	2009-11-15	2010-12-01	SAC/TC10/SC2
1074	GB/T 15214-2008	Reliability test requirements and methods of ultrasonic diagnostic equipment	2008-11-03	2009-10-01	SAC/TC10/SC2
1075	GB/T 15261-2008	Measurement method of acoustic properties of ultrasonic tissue-like materials	2008-01-22	2008-09-01	SAC/TC10/SC2
1076	YY/T 0162.1-2009	The first part of the series of medical ultrasonic equipment grades: B-type ultrasonic diagnostic equipment	2009-11-15	2010-12-01	SAC/TC10/SC2
1077	YY 0773-2010	General technical conditions of ophthalmology B-mode	2010-12-27	2012-06-01	SAC/TC10/SC2

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		ultrasonic diagnostic equipment			
1078	YY 0767-2009	Ultrasound color blood flow imaging system	2009-12-30	2011-06-01	SAC/TC10/SC2
1079	YY 0849-2011	Ophthalmology High Frequency Ultrasound Diagnosis System	2011-12-31	2013-06-01	SAC/TC10/SC2
1080	YY/T 0107-2015	Ophthalmology Type A Ultrasonic Measuring Instrument	2015-03-02	2016-01-01	SAC/TC10/SC2
1081	YY/T 0593-2015	Ultrasound transcranial Doppler blood flow analyzer	2015-03-02	2016-01-01	SAC/TC10/SC2
1082	YY/T 0774-2019	Ultrasound bone densitometer	2019-07-24	2021-08-01	SAC/TC10/SC2
1083	YY/T 1476-2016	General technical conditions of ultrasound bladder scanner	2016-01-26	2017-01-01	SAC/TC10/SC2
1084	YY/T 1659-2019	General technical requirements for intravascular ultrasound diagnostic equipment	2019-07-24	2020-08-01	SAC/TC10/SC2
1085	YY/T 1676-2020	Ultrasound Endoscope	2020-03-31	2022-10-01	SAC/TC10/SC2
1086	YY/T 1749-2020	Ultrasonic elasticity measuring equipment of liver tissue based on external vibration	2020-09-27	2022-09-01	SAC/TC10/SC2
1087	YY/T 0108-2008	M-mode test method for ultrasonic diagnostic equipment	2008-04-25	2009-06-01	SAC/TC10/SC2
1088	YY/T 0643-2008	Ultrasonic pulse echo diagnosis equipment performance test method	2008-04-25	2009-06-01	SAC/TC10/SC2
1089	YY/T 0703-2008	Performance test method of ultrasonic real-time pulse echo system	2008-10-17	2010-01-01	SAC/TC10/SC2
1090	YY/T 0704-2008	Ultrasonic pulse Doppler diagnostic system performance test method	2008-10-17	2010-01-01	SAC/TC10/SC2
1091	YY/T 0705-2008	Ultrasonic continuous wave Doppler system test method	2008-10-17	2010-01-01	SAC/TC10/SC2
1092	YY/T 0748.1-2009	Ultrasonic pulse echo scanner. Part 1: Calibration space measurement system and the technical method of system point spread function response measurement	2009-11-15	2010-12-01	SAC/TC10/SC2
1093	YY/T 0850-2011	Guidelines for Evaluation of Uncertainty in Measurement of Acoustic Output Parameters of Ultrasonic Diagnostic and Monitoring Equipment	2011-12-31	2013-06-01	SAC/TC10/SC2

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1094	YY/T 0906-2013	B-type ultrasonic diagnostic equipment performance test method with intracavity probe	2013-10-21	2014-10-01	SAC/TC10/SC2
1095	YY/T 0938-2014	Guidelines for Verification of B-mode Ultrasonic Diagnostic Equipment	2014-06-17	2015-07-01	SAC/TC10/SC2
1096	YY/T 0939-2014	Ultrasonic bone densitometer broadband ultrasonic attenuation (BUA) test method	2014-06-17	2015-07-01	SAC/TC10/SC2
1097	YY/T 1084-2015	Measurement method of sound output power of medical ultrasonic diagnostic equipment	2015-03-02	2016-01-01	SAC/TC10/SC2
1098	YY/T 1279-2015	Three-dimensional ultrasound imaging performance test method	2015-03-02	2016-01-01	SAC/TC10/SC2
1099	YY/T 1419-2016	Ultrasonic quasi-static strain elastic performance test method	2016-01-26	2017-01-01	SAC/TC10/SC2
1100	YY/T 1480-2016	Performance test method of ultrasonic elastography equipment based on acoustic radiation force	2016-07-29	2017-06-01	SAC/TC10/SC2
<b>(3) Ultrasonic monitoring equipment</b>					
1101	YY/T 0448-2019	Ultrasound Doppler Fetal Heart Rate Monitor	2019-05-31	2020-06-01	SAC/TC10/SC2
1102	YY/T 0449-2018	Ultrasound Doppler Fetal Monitor	2018-11-07	2019-11-01	SAC/TC10/SC2
1103	YY/T 1481-2016	Guidelines for Verification of Doppler Ultrasound Fetal Monitor	2016-07-29	2017-06-01	SAC/TC10/SC2
1104	YY/T 0749-2009	Ultrasonic handheld probe Doppler fetal heart rate monitor performance requirements and measurement and reporting methods	2009-11-15	2010-12-01	SAC/TC10/SC2
<b>(4) Ultrasound treatment equipment</b>					
1105	GB 9706.205-2020	Medical electrical equipment- Part 2-5 : Specific requirements for the basic safety and basic performance of ultrasonic physical therapy equipment	2020-07-23	2023-05-01	State Food and Drug Administration
1106	YY 9706.262-2021	Medical electrical equipment Part 2-62 : Specific requirements for the basic	2021-03-09	2023-05-01	SAC/TC10/SC2

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		safety and basic performance of high-intensity ultrasound therapy ( HITU ) equipment			
1107	YY 0460-2009	Ultrasonic cleaning equipment	2009-11-15	2010-12-01	SAC/TC10/SC2
1108	YY 0592-2016	High-intensity focused ultrasound ( HIFU ) treatment system	2016-01-26	2018-01-01	SAC/TC10/SC2
1109	YY 0766-2009	Ultrasonic lens removal and vitrectomy equipment for ophthalmology	2009-12-30	2011-06-01	SAC/TC10/SC2
1110	YY 0830-2011	Superficial tissue ultrasound treatment equipment	2011-12-31	2013-06-01	SAC/TC10/SC2
1111	YY/T 1090-2018	Ultrasound physiotherapy equipment	2018-12-20	2020-01-01	SAC/TC10/SC2
1112	YY/T 1601-2018	Ultrasonic bone tissue surgery equipment	2018-01-19	2019-01-01	SAC/TC10/SC2
1113	YY/T 1750-2020	Ultrasonic soft tissue cutting hemostatic surgery equipment	2020-09-27	2022-09-01	SAC/TC10/SC2
1114	YY/T 0644-2008	Measurement and publication of the basic output characteristics of ultrasonic surgical systems	2008-04-25	2009-06-01	SAC/TC10/SC2
1115	YY/T 0750-2018	Ultrasonic physiotherapy equipment sound field requirements and measurement methods in the frequency range of 0.5MHZ ~ 5MHZ	2018-09-21	2019-09-26	SAC/TC10/SC2
1116	YY/T 0751-2009	Measurement and publication of the output characteristics of ultrasonic dental cleaning equipment	2009-11-15	2010-12-01	SAC/TC10/SC2
1117	YY/T 0797-2010	Ultrasonic output test ultrasound physiotherapy equipment maintenance guide	2010-12-27	2012-06-01	SAC/TC10/SC2
1118	YY/T 1767-2021	Ultrasonic power measurement high-intensity therapeutic ultrasound ( HITU ) transducer and system	2021-03-09	2022-04-01	SAC/TC10/SC2
<b>(5) Medical ultrasonic transducer and others</b>					
1119	YY/T 0111-2005	Technical requirements and test methods for ultrasonic Doppler transducers	2005-12-07	2006-12-01	SAC/TC10/SC2
1120	YY/T 1089-2007	Basic electroacoustic characteristics and measurement methods of unit type pulse echo ultrasonic transducer	2007-01-31	2008-01-01	SAC/TC10/SC2

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1121	YY/T 1142-2013	Medical ultrasonic equipment and probe frequency characteristics test method	2013-10-21	2014-10-01	SAC/TC10/SC2
1122	YY/T 1278-2015	Measurement method of acoustic beam area of transducer of medical ultrasonic equipment	2015-03-02	2016-01-01	SAC/TC10/SC2
1123	YY/T 1668-2019	Basic electroacoustic characteristics and measurement methods of array pulse echo ultrasonic transducer	2019-07-24	2021-08-01	SAC/TC10/SC2
1124	YY 0299-2016	Medical ultrasound gel	2016-01-26	2018-01-01	SAC/TC10/SC2
1125	YY/T 1671-2020	Ultrasound probe puncture frame	2020-02-25	2022-03-01	SAC/TC10/SC2

## 16. Diagnostic electronic equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1126	GB 9706.26-2005	Medical electrical equipment Part 2 : Special requirements for the safety of EEG machines	2005-10-10	2006-08-01	SAC/TC10/SC5
1127	GB 10793-2000	Medical electrical equipment. Part 2 : Special requirements for the safety of electrocardiographs	2000-07-17	2000-12-01	SAC/TC10/SC5
1128	GB/T 21416-2008	Medical electronic thermometer	2008-01-22	2008-09-01	SAC/TC10/SC5
1129	GB/T 21417.1-2008	Medical infrared thermometers. Part 1 : Ear cavity type	2008-01-22	2008-09-01	SAC/TC10/SC5
1130	YY 0670-2008	Non-invasive automatic measurement sphygmomanometer	2008-10-17	2010-06-01	SAC/TC10/SC5
1131	YY 0782-2010	Medical electrical equipment-Part 2-51 : Special requirements for the safety and basic performance of recording and analysis single-channel and multi-channel electrocardiographs	2010-12-27	2012-06-01	SAC/TC10/SC5
1132	YY 0885-2013	Medical electrical equipment Part 2 : Special requirements for the safety	2013-10-21	2014-10-01	SAC/TC10/SC5

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		and basic performance of Holter system			
1133	YY 1139-2013	ECG diagnostic equipment	2013-10-21	2014-10-01	SAC/TC10/SC5
1134	YY 0784-2010	Medical electrical equipment: basic safety and performance specific requirements for medical pulse oximeter equipment	2010-12-27	2012-06-01	SAC/TC10/SC5
1135	YY 9706.240-2021	Medical electrical equipment-Part 2-40 : Specific requirements for basic safety and basic performance of electromyography and evoked response equipment	2021-03-09	2023-05-01	SAC/TC10/SC5
1136	YY 9706.233-2021	Medical electrical equipment Part 2-33 : Special requirements for basic safety and basic performance of magnetic resonance equipment for medical diagnosis	2021-03-09	2023-05-01	SAC/TC10/SC5
1137	YY/T 0195-1994	Reliability test method of electrocardiograph	1994-12-19	1995-05-01	SAC/TC10/SC5
1138	YY/T 1519-2017	Electrophysiological Mapping Catheter	2017-03-28	2018-04-01	SAC/TC10/SC5
1139	YY/T 1635-2018	Multi-channel physiological recorder	2018-12-20	2020-01-01	SAC/TC10/SC5
1140	YY/T 0196-2005	Single use ECG electrodes	2005-12-07	2006-12-01	SAC/TC10/SC5
1141	YY/T 0324-2019	Infrared breast examination instrument	2019-05-31	2020-06-01	SAC/TC10/SC4
1142	YY/T 1078-2008	Direct impedance blood flow chart	2008-04-25	2009-06-01	SAC/TC10/SC5
1143	YY/T 1143-2008	Bridge-type impedance blood flow chart	2008-04-25	2009-06-01	SAC/TC10/SC5
114 4	YY/T 0482-2010	Measurement of main image quality parameters of medical imaging magnetic resonance equipment	2010-12-27	2012-06-01	SAC/TC10/SC5

## 17. Monitoring electronic equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
---------------	-----------------	---------------	--------------	---------------------	-------------

1145	GB 9706.25-2005	Medical electrical equipment-Part 2-27 : Special requirements for the safety of ECG monitoring equipment	2005-10-10	2006-08-01	SAC/TC10/SC5
1146	YY 1079-2008	ECG monitor	2008-04-25	2009-12-01	SAC/TC10/SC5
1147	YY 0828-2011	ECG monitor cable and lead wire	2011-12-31	2013-06-01	SAC/TC10/SC5
1148	YY 0667-2008	Medical electrical equipment Part 2-30 : Special requirements for the safety and basic performance of automatic circulation non-invasive blood pressure monitoring equipment	2008-10-17	2010-06-01	SAC/TC10/SC5
1149	YY 0668-2008	Medical electrical equipment-Part 2-49 : Special requirements for the safety of multi-parameter patient monitoring equipment	2008-10-17	2010-06-01	SAC/TC10/SC5
1150	YY 0783-2010	Medical electrical equipment Part 2-34 : Special requirements for the safety and basic performance of invasive blood pressure monitoring equipment	2010-12-27	2012-06-01	SAC/TC10/SC5
1151	YY 0781-2010	Blood pressure sensor	2010-12-27	2012-06-01	SAC/TC10/SC5
1152	YY 0785-2010	Clinical Thermometer - - Performance Requirements of Electronic Thermometer for Continuous Measurement	2010-12-27	2012-06-01	SAC/TC10/SC5
1153	YY/T 0754-2009	Special requirements for the safety and performance of blood pressure transmission pipelines for invasive blood pressure monitoring equipment	2009-11-15	2010-12-01	SAC/TC10/SC5

## 18. Surgery and treatment electronic equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1154	GB 9706.4-2009	Medical electrical equipment. Part 2 : Special requirements for the safety of high-frequency surgical equipment	2009-05-06	2010-03-01	SAC/TC10/SC5



1155	GB 9706.22-2003	Medical electrical equipment Part 2 : Special requirements for the safety of in vitro lithotripsy equipment	2003-06-24	2003-12-01	SAC/TC10/SC5
1156	GB 9706.27-2005	Medical electrical equipment-Part 2-24 : Particular requirements for the safety of infusion pumps and infusion controllers	2005-10-10	2006-08-01	SAC/TC10/SC5
1157	0001 YY - 2008	Technical requirements for in vitro lithotripsy equipment	2008-04-25	2009-12-01	SAC/TC10/SC5
1158	YY 0678-2008	Performance and safety of medical cryosurgery equipment	2008-10-17	2010-06-01	SAC/TC103/SC1
1159	YY 1105-2008	Electric gastric lavage machine	2008-04-25	2009-12-01	SAC/TC10/SC5
1160	YY/T 0677-2008	Liquid nitrogen cryosurgery treatment equipment	2008-10-17	2010-06-01	SAC/TC103/SC1
1161	YY/T 0752-2016	Electric bone tissue surgery equipment	2016-01-26	2017-01-01	SAC/TC10/SC5
1162	YY/T 0904-2013	Battery-powered bone tissue surgery equipment	2013-10-21	2014-10-01	SAC/TC10/SC4
1163	YY/T 1469-2016	Portable electric infusion pump	2016-01-26	2017-01-01	SAC/TC10/SC5
1164	YY/T 1629.1-2018	Electric bone tissue surgery equipment and knives. Part 1 : Grinding head	2018-09-21	2019-09-26	SAC/TC10/SC5
1165	YY/T 1629.2-2018	Electric bone tissue surgery equipment and knives. Part 2 : Skull drills	2018-11-07	2019-11-01	SAC/TC10/SC5
1166	YY/T 1629.4-2020	Electric bone tissue surgery equipment and knives. Part 4 : Milling cutters	2020-09-27	2021-09-01	SAC/TC10/SC5
1167	YY/T 1629.5-2020	Electric bone tissue surgery equipment and knives. Part 5 : Saw blades	2020-09-27	2021-09-01	SAC/TC10/SC5
1168	YY/T 1653-2020	Tubing for infusion pump	2020-02-21	2021-01-01	SAC/TC10/SC5
1169	YY/T 1712-2021	Auxiliary surgery equipment and auxiliary surgery system using robotics technology	2021-03-09	2022-10-01	SAC/TC10/SC5

## 19. Infant care equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1170	GB 11243-2008	Medical electrical equipment. Part 2 : Special requirements for the safety of infant incubators	2008-12-30	2010-03-01	SAC/TC10/SC5
1171	YY 0455-2011	Medical electrical equipment. Part 2 : Special requirements for the safety of infant radiant warmers	2011-12-31	2013-06-01	SAC/TC10/SC5
1172	YY 9706.220-2021	Medical electrical equipment Part 2-20 : Special requirements for the basic safety and basic performance of the infant transfer incubator	2021-03-09	2023-05-01	SAC/TC10/SC5

## Twenty, patient carrying equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1173	YY 0003-1990	Hospital bed	1990-10-16	1991-04-01	SAC/TC10/SC5
1174	YY 0045-2013	Ordinary delivery bed	2013-10-21	2014-10-01	SAC/TC169
1175	YY 0570-2013	Medical electrical equipment Part 2 : Special requirements for operating table safety	2013-10-21	2014-10-01	SAC/TC10/SC5
1176	YY 0571-2013	Medical electrical equipment. Part 2 : Special requirements for the safety of hospital electric beds	2013-10-21	2014-10-01	SAC/TC10/SC5
1177	YY/T 1106-2008	Electric operating table	2008-04-25	2009-06-01	SAC/TC10/SC5
1178	YY/T 1638.1-2019	Patient handling equipment Part 1 : Ambulance stretcher	2019-10-23	2020-10-01	SAC/TC10/SC5

## 21. Defibrillator, pacemaker

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1179	GB 9706.8-2009	Medical electrical equipment Part 2-4 : Particular requirements for the safety of cardiac defibrillators	2009-05-06	2010-03-01	SAC/TC10/SC5
1180	YY 0945.2-2015	Medical electrical equipment Part 2 : Particular requirements for the safety of external cardiac pacemakers with internal power supply	2015-03-02	2017-01-01	SAC/TC10/SC5

## 22. Radiotherapy, Nuclear Medicine and Radiation Dosimetry

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Professional and general fields</b>					
1181	GB/T 17857-1999	Medical radiology terms (radiotherapy, nuclear medicine and radiation dosimetry equipment)	1999-09-10	2000-01-01	SAC/TC10/SC3
<b>(2) Radiotherapy</b>					
1182	GB/T 18987-2015	Radiation therapy equipment coordinates, movement and scale	2015-12-10	2017-07-01	SAC/TC10/SC3
1183	GB 9706.10-1997	Medical electrical equipment Part 2 : Special requirements for the safety of therapeutic X-ray generators	1997-06-08	1998-09-01	SAC/TC10/SC3
1184	GB 9706.16-2015	Medical electrical equipment. Part 2 : Specific requirements for the safety of radiotherapy simulators	2015-12-10	2017-07-01	SAC/TC10/SC3
1185	GB 9706.201-2020	Medical electrical equipment Part 2-1 : Specific requirements for the basic safety and basic performance of electronic accelerators with an energy of 1MeV to 50MeV	2020-12-24	2023-05-01	State Food and Drug Administration
1186	GB 9706.211-2020	Medical electrical equipment-Part 2-11 : Specific requirements for	2020-12-24	2023-05-01	State Food and Drug Administration

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		basic safety and basic performance of gamma beam therapy equipment			
1187	GB 9706.217-2020	Medical electrical equipment Part 2-17 : Specific requirements for the basic safety and basic performance of automatic control brachytherapy after-installation equipment	2020-12-24	2023-05-01	State Food and Drug Administration
1188	GB 15213-2016	Performance and test methods of medical electron accelerator	2016-06-14	2018-01-01	SAC/TC10/SC3
1189	GB/T 17856-1999	Radiation therapy simulator performance and test methods	1999-09-10	2000-01-01	SAC/TC10/SC3
1190	GB/T 19046-2013	Acceptance Test and Periodic Inspection Regulations for Medical Electron Accelerator	2013-12-17	2014-08-01	SAC/TC10/SC3
1191	GB/T 17827-1999	Guidelines for the Design of Radiation Therapy Room	1999-08-11	2000-05-01	SAC/TC10/SC3
1192	YY 0096-2019	Cobalt- 60 long-distance therapy machine	2019-05-31	2020-12-01	SAC/TC10/SC3
1193	YY 0637-2013	Safety requirements of radiotherapy planning system for medical electrical equipment	2013-10-21	2014-10-01	SAC/TC10/SC3
1194	YY 0721-2009	Safety of Radiotherapy Record and Verification System for Medical Electrical Equipment	2009-06-16	2010-12-01	SAC/TC10/SC3
1195	YY 0775-2010	Accuracy requirements and test methods for calculation of high-energy X ( $\gamma$ ) beam dose of teletherapy planning system	2010-12-27	2012-06-01	SAC/TC10/SC3
1196	YY 0831.1-2011	Gamma beam stereotactic radiotherapy system. Part 1 : Multi-source gamma beam stereotactic radiotherapy system on the head	2011-12-31	2013-06-01	SAC/TC10/SC3
1197	YY 0831.2-2015	Gamma beam stereotactic radiotherapy system. Part 2 : Multi-source gamma beam stereotactic	2015-03-02	2017-01-01	SAC/TC10/SC3

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		radiotherapy system on the body			
1198	YY 0832.1-2011	X-ray radiotherapy stereotactic and planning system. Part 1: Head X-ray radiotherapy stereotactic and planning system	2011-12-31	2013-06-01	SAC/TC10/SC3
1199	YY 0832.2-2015	X-ray radiotherapy stereotactic and planning system. Part 2: Body X-ray radiotherapy stereotactic and planning system	2015-03-02	2017-01-01	SAC/TC10/SC3
1200	YY 1650-2019	X-ray image guided radiotherapy equipment performance and test methods	2019-05-31	2020-12-01	SAC/TC10/SC3
1201	YY/T 0317-2007	General technical conditions for medical therapeutic X-ray machines	2007-01-31	2008-01-01	SAC/TC10/SC3
1202	YY/T 0798-2010	Quality Assurance Guidelines for Radiation Therapy Planning System	2010-12-27	2012-06-01	SAC/TC10/SC3
1203	YY/T 0848-2011	Blood irradiator	2011-12-31	2013-06-01	SAC/TC10/SC3
1204	YY/T 0887-2013	Dose calculation requirements and test methods for radioactive seed implantation treatment planning system	2013-10-21	2014-10-01	SAC/TC10/SC3
1205	YY/T 0888-2013	Imaging dose of X-ray image guiding device in radiotherapy equipment	2013-10-21	2014-10-01	SAC/TC10/SC3
1206	YY/T 0889-2013	Performance and test methods of intensity-modulated radiotherapy planning system	2013-10-21	2014-10-01	SAC/TC10/SC3
1207	YY/T 0890-2013	The performance and test method of the electronic field imaging device in radiotherapy	2013-10-21	2014-10-01	SAC/TC10/SC3
1208	YY/T 0895-2013	Debugging of radiotherapy planning system Testing of typical external beam treatment techniques	2013-10-21	2014-10-01	SAC/TC10/SC3
1209	YY/T 0971-2016	Performance and test method of multi-element	2016-03-23	2017-01-01	SAC/TC10/SC3

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		beam limiting device for radiotherapy			
1210	YY/T 0973-2016	Performance and test method of radiotherapy planning system for automatic control brachytherapy after-loading equipment	2016-03-23	2017-01-01	SAC/TC10/SC3
1211	YY/T 1308-2016	Automatic control type brachytherapy after-loading equipment	2016-03-23	2017-01-01	SAC/TC10/SC3
1212	YY/T 1407-2016	Radiotherapy simulator imaging system performance and test methods	2016-03-23	2017-01-01	SAC/TC10/SC3
1213	YY/T 1537-2017	Performance and test method of laser positioning system for radiotherapy	2017-05-02	2018-04-01	SAC/TC10/SC3
1214	YY/T 1538-2017	Performance and test method of automatic scanning water phantom system for radiotherapy	2017-05-02	2018-04-01	SAC/TC10/SC3
1215	YY/T 1547.1-2017	Position fixation devices for radiotherapy. Part 1 : Thermoplastic film	2017-05-02	2018-04-01	SAC/TC10/SC3
1216	YY/T 1547.2-2017	Position fixation device for radiotherapy. Part 2 : Vacuum negative pressure pad	2017-05-02	2018-04-01	SAC/TC10/SC3
1217	YY/T 1548-2017	Film dose measurement method for radiotherapy	2017-05-02	2018-04-01	SAC/TC10/SC3
1218	YY/T 1694-2020	Performance and test methods of body surface optical positioning equipment for radiotherapy	2020-02-21	2021-06-01	SAC/TC10/SC3
1219	YY/T 1711-2020	Gated interface for radiotherapy	2020-06-30	2022-06-01	SAC/TC10/SC3
1220	YY/T 1763-2021	Medical electrical equipment performance characteristics of medical light ion beam equipment	2021-03-09	2022-10-01	SAC/TC10/SC3
1221	YY/T 0723-2009	Digital medical electrical equipment and medical imaging communications ( the DICOM ) - Radiotherapy objects	2009-06-16	2010-12-01	SAC/TC10/SC3
1222	YY/T 0736-2009	Guidelines for the application of medical	2009-11-25	2010-12-01	SAC/TC10/SC3

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		electrical equipment DICOM in radiotherapy			
<b>(3) Nuclear medicine</b>					
1223	GB/T 18988.1-2013	Radionuclide imaging equipment performance and test rules. Part 1: Positron emission tomography imaging device	2013-12-17	2014-08-01	SAC/TC10/SC3
1224	GB/T 18988.2-2013	Radionuclide imaging equipment performance and test rules. Part 2: Single-photon emission computed tomography device	2013-12-17	2014-08-01	SAC/TC10/SC3
1225	GB/T 18988.3-2013	Radionuclide imaging equipment performance and test rules. Part 3: Gamma camera whole body imaging system	2013-12-17	2014-08-01	SAC/TC10/SC3
1226	GB/T 18989-2013	Radionuclide imaging equipment performance and test rules Gamma camera	2013-12-17	2014-08-01	SAC/TC10/SC3
1227	GB/T 20013.1-2005	Routine tests of nuclear medicine instruments. Part 1: Radiation counting system	2005-10-10	2006-06-01	SAC/TC10/SC3
1228	GB/T 20013.2-2005	Routine tests of nuclear medicine instruments. Part 2: Scintillation cameras and single-photon emission computed tomography imaging devices	2005-10-10	2006-06-01	SAC/TC10/SC3
1229	GB/T 20013.3-2015	Routine test of nuclear medicine equipment. Part 3: Positron emission tomography imaging device	2015-12-10	2017-07-01	SAC/TC10/SC3
1230	GB/T 20013.4-2010	Routine tests of nuclear medicine instruments. Part 4: Radionuclide calibrators	2010-09-02	2011-02-01	SAC/TC10/SC3
1231	YY/T 0829-2011	Positron emission and X-ray computed tomography system performance and test methods	2011-12-31	2013-06-01	SAC/TC10/SC3
1232	YY/T 1408-2016	Single-photon emission and X-ray computed tomography system	2016-03-23	2017-01-01	SAC/TC10/SC3

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		performance and test methods			
1133	YY/T 1546-2017	Test method for CT attenuation correction of SPECT imaging	2017-05-02	2018-04-01	SAC/TC10/SC3
<b>(4) Radiation dosimetry</b>					
1234	GB 9706.21-2003	Medical electrical equipment Part 2 : Particular requirements for the safety of dosimeters used for radiotherapy in contact with patients and with electrically connected radiation detectors	2003-04-14	2003-12-01	SAC/TC10/SC3
1235	GB/T 19629-2005	Ionization chamber and/or semiconductor detector dosimeter used in X-ray diagnostic imaging of medical electrical equipment	2005-01-17	2005-06-01	SAC/TC10/SC3
1236	GB/T 20012-2005	Medical electrical equipment dose area product meter	2005-10-10	2006-06-01	SAC/TC10/SC3
1237	YY/T 0481-2016	Radiation conditions for measuring characteristics of medical diagnostic X-ray equipment	2016-03-23	2017-01-01	SAC/TC10/SC3
1238	YY/T 0722-2016	Medical electrical equipment used in diagnostic radiology for non-connected measurement of X-ray tube voltage dosimetry instrument	2016-07-29	2017-06-01	SAC/TC10/SC3
1239	YY/T 0840-2011	A special method for describing the performance of radionuclide calibrators for medical electrical equipment	2011-12-31	2013-06-01	SAC/TC10/SC3
1240	YY/T 0894-2013	Dosage instrument for brachytherapy of medical electrical equipment. Instrument based on well-type ionization chamber	2013-10-21	2014-10-01	SAC/TC10/SC3
1241	YY/T 0976-2016	Ionization chamber dosimeter for radiotherapy	2016-03-23	2017-01-01	SAC/TC10/SC3



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		of medical electrical equipment			

### 23. Medical extracorporeal circulation equipment and devices

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
(1) Professional and general fields					
1242	GB 9706.2-2003	Medical electrical equipment Part 2-16 : Particular requirements for the safety of hemodialysis, hemodiafiltration and hemofiltration equipment	2003-10-09	2004-06-01	SAC/TC158
1243	GB 9706.39-2008	Medical electrical equipment Part 2-39 : Particular requirements for the safety of peritoneal dialysis equipment	2008-12-31	2009-12-01	SAC/TC158
1244	GB/T 13074-2009	Blood purification terms	2009-05-06	2010-01-01	SAC/TC158
1245	YY/T 1145-2014	Cardiopulmonary bypass system terminology	2014-06-17	2015-07-01	SAC/TC158
1246	YY/T 1269-2015	Routine control requirements for hemodialysis and related treatment water treatment equipment	2015-03-02	2016-01-01	SAC/TC158
1247	YY/T 1414-2016	Technical requirements for solenoid valves used in the fluid circuit of hemodialysis equipment	2016-03-23	2017-01-01	SAC/TC158
1248	YY/T 1545-2017	Evaluation of the connection between hemodialysis concentrates and hemodialysis equipment	2017-05-02	2018-04-01	SAC/TC158
1249	YY/T 1492-2016	General requirements for surface coating products of cardiopulmonary bypass system	2016-07-29	2017-06-01	SAC/TC158
1250	YY/T 1620-2018	Evaluation method for red blood cell damage of continuous flow blood	2018-09-28	2019-10-01	SAC/TC158

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		pump in cardiopulmonary bypass system			
<b>(2) Hemodialysis and related treatment</b>					
1251	YY 0053-2016	Hemodialysis and related treatments	2016-03-23	2018-01-01	SAC/TC158
1252	YY 0054-2010	Hemodialysis equipment	2010-12-27	2012-06-01	SAC/TC158
1253	YY 0267-2016	Extracorporeal circulation blood circuit of hemodialysis and related therapeutic blood purification device	2016-03-23	2018-01-01	SAC/TC158
1254	YY 0572-2015	Hemodialysis and related treatment water	2015-03-02	2017-01-01	SAC/TC158
1255	YY 0598-2015	Concentrates for hemodialysis and related treatments	2015-03-02	2017-01-01	SAC/TC158
1256	YY 0645-2018	Continuous blood purification equipment	2018-01-19	2019-01-01	SAC/TC158
1257	YY 0793.1-2010	Technical requirements for water treatment equipment for hemodialysis and related treatments. Part 1 : Used for multi-bed dialysis	2010-12-27	2012-06-01	SAC/TC158
1258	YY 0793.2-2011	Technical requirements for water treatment equipment for hemodialysis and related treatment. Part 2 : Used for single bed dialysis	2011-12-31	2013-06-01	SAC/TC158
1259	YY 1272-2016	Dialysate filter	2016-03-23	2018-01-01	SAC/TC158
1260	YY 1273-2016	Roller pump for assisting blood purification	2016-03-23	2018-01-01	SAC/TC158
1261	YY/T 1494-2016	General requirements for packaging materials for hemodialysis and related treatment concentrates	2016-07-29	2017-06-01	SAC/TC158
1262	YY/T 1730-2020	Disposable hemodialysis catheter	2020-06-30	2021-06-01	SAC/TC158
<b>(Three) peritoneal dialysis</b>					
1263	YY 1274-2016	Pressure-controlled peritoneal dialysis equipment	2016-03-23	2018-01-01	SAC/TC158
1264	YY 1493-2016	Gravity-controlled peritoneal dialysis equipment	2016-07-29	2018-06-01	SAC/TC158

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1265	YY/T 1734-2020	Iodine solution protective cap for peritoneal dialysis	2020-06-30	2021-06-01	SAC/TC158
1266	YY/T 1773-2021	One-time use of peritoneal dialysis external tubing	2021-03-09	2022-10-01	SAC/TC158
<b>(4) External counterpulsation</b>					
1267	GB 10035-2017	Balloon type external counterpulsation device	2017-12-29	2019-07-01	SAC/TC158
<b>(5) Hemoperfusion and plasma separation and its auxiliary devices</b>					
1268	YY 0465-2019	Single-use hollow fiber plasma separator and plasma component separator	2019-05-31	2020-06-01	SAC/TC158
1269	YY 1413-2016	Centrifugal blood component separation equipment	2016-03-23	2018-01-01	SAC/TC158
1270	YY 0603-2015	Cardiovascular implants and artificial organ heart surgery hard-shell blood reservoir / venous blood reservoir system (with or without filter) and venous blood storage soft bag	2015-03-02	2017-01-01	SAC/TC158
1271	YY 0790-2010	Hemoperfusion equipment	2010-12-27	2012-06-01	SAC/TC158
1272	YY 1290-2016	Disposable bilirubin plasma adsorber	2016-03-23	2018-01-01	SAC/TC158
1273	YY/T 0464-2019	Single use hemoperfusion device	2019-10-23	2020-10-01	SAC/TC158
<b>(6) Cardiopulmonary bypass</b>					
1274	GB 12260-2017	Cardiopulmonary bypass system rolling blood pump	2017-12-29	2019-07-01	SAC/TC158
1275	GB 12263-2017	Cardiopulmonary bypass system heat exchange water tank	2017-12-29	2019-07-01	SAC/TC158
1276	YY 0604-2016	Cardiopulmonary bypass system blood gas exchanger (oxygenator)	2016-03-23	2018-01-01	SAC/TC158
1277	YY 0948-2015	Cardiopulmonary circulation system for one-time use of arteriovenous cannula	2015-03-02	2017-01-01	SAC/TC158
1278	YY 1048-2016	Cardiopulmonary bypass system extracorporeal circulation pipeline	2016-03-23	2018-01-01	SAC/TC158

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1279	YY 1271-2016	Cardiopulmonary circulation system disposable suction tube	2016-03-23	2018-01-01	SAC/TC158
1280	YY 1412-2016	Cardiopulmonary bypass system centrifugal pump	2016-03-23	2018-01-01	SAC/TC158
1281	YY 0485-2020	Cardioplegia perfusion device for single use	2020-06-30	2021-12-01	SAC/TC158
1282	YY 0580-2011	Cardiovascular implants and artificial organs cardiopulmonary bypass system arterial line blood filter	2011-12-31	2013-06-01	SAC/TC158
1283	YY/T 1270-2015	Cardiopulmonary bypass system blood circuit connector (connector)	2015-03-02	2016-01-01	SAC/TC158
1284	YY/T 1739-2020	Cardiopulmonary bypass system centrifugal pump pump head	2020-06-30	2021-12-01	SAC/TC158
1285	YY/T 0730-2009	Cardiovascular surgical implants and artificial organs cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO) requirements for single-use tubing kits	2009-06-16	2010-12-01	SAC/TC158

## 24. Respiratory anesthesia equipment and devices

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Professional and general fields</b>					
1286	GB/T 4999-2003	Terminology for anesthesia breathing equipment	2003-06-09	2003-12-01	SAC/TC116
1287	YY 0601-2009	Special requirements for basic safety and main performance of respiratory gas monitors for medical electrical equipment	2009-12-30	2011-06-01	SAC/TC116
1288	YY/T 0882-2013	Anesthesia and breathing equipment and oxygen compatibility	2013-10-21	2014-10-01	SAC/TC116
1289	YY/T 1040.1-2015	Cone connectors for anesthesia and respiratory equipment. Part 1: Cone head and sleeve	2015-03-02	2016-01-01	SAC/TC116

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1290	YY/T 1040.2-2008	Cone joints for anesthesia and respiratory equipment. Part 2 : Threaded load-bearing joints	2008-10-17	2010-06-01	SAC/TC116
<b>(2) Anesthesia machine and related accessories</b>					
1291	GB 9706.29-2006	Medical electrical equipment Part 2 : Special requirements for the safety and basic performance of anesthesia systems	2006-07-25	2007-05-01	SAC/TC116
1292	YY 0635.1-2013	Inhalation Anesthesia System Part 1 : Anesthesia Respiratory System	2013-10-21	2014-10-01	SAC/TC116
1293	YY 0635.2-2009	Inhalation Anesthesia System Part 2 : Anesthetic Gas Purification System Delivery and Collection System	2009-06-16	2010-12-01	SAC/TC116
1294	YY 0635.3-2009	Inhalation anesthesia system. Part 3 : Anesthetic gas delivery device	2009-06-16	2010-12-01	SAC/TC116
1295	YY 0635.4-2009	Inhalation Anesthesia System Part 4 : Anesthesia Ventilator	2009-06-16	2010-12-01	SAC/TC116
1296	YY/T 0755-2009	Anesthetic filling system for anesthesia vaporizer	2009-11-15	2010-12-01	SAC/TC116
1297	YY/T 0975-2016	Anesthesia and respiratory equipment The color, pattern and characteristics of the label used to display the drug-containing syringe during anesthesia	2016-03-23	2017-01-01	SAC/TC116
<b>(3) Ventilator and related equipment</b>					
1298	GB 9706.212-2020	Medical electrical equipment Part 2-12 : Specific requirements for the basic safety and basic performance of intensive care ventilators	2020-04-09	2023-05-01	SAC/TC116
1299	YY 0042-2018	High-frequency jet ventilator	2018-12-20	2020-06-01	SAC/TC116
1300	YY 0600.1-2007	Special requirements for basic safety and main performance of medical ventilators. Part 1 : Household respiratory support equipment	2007-01-31	2008-02-01	SAC/TC116

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1301	YY 0600.2-2007	Part 2 of the special requirements for the basic safety and main performance of medical ventilators	2007-01-31	2008-02-01	SAC/TC116
1302	YY 0600.3-2007	Special requirements for basic safety and main performance of medical ventilators. Part 3 : First aid and transfer to ventilators	2007-01-31	2008-02-01	SAC/TC116
1303	YY 0600.4-2013	Special requirements for basic safety and main performance of medical ventilators. Part 4 : Manual resuscitator	2013-10-21	2014-10-01	SAC/TC116
1304	YY 0600.5-2011	Special requirements for basic safety and main performance of medical ventilators. Part 5 : Pneumatic emergency resuscitator	2011-12-31	2013-06-01	SAC/TC116
1305	YY 0671.1-2009	Sleep apnea treatment Part 1 : Sleep apnea treatment equipment	2009-06-16	2010-12-01	SAC/TC116
1306	YY 0786-2010	Special requirements for respiratory humidification system of medical respiratory tract humidifier	2010-12-27	2012-06-01	SAC/TC116
1307	YY/T 0735.1-2009	Anesthetic and respiratory equipment body humidified respiratory gas heat and moisture exchanger ( HME ) of 1 parts: the minimum tidal volume of 250mL of HME	2009-11-15	2010-12-01	SAC/TC116
1308	YY/T 0735.2-2010	Anesthesia and respiratory equipment Heat and moisture exchangers ( HMEs ) used to humidify human breathing gas. Part 2 : 250mL minimum tidal volume HMEs for tracheostomy patients	2010-12-27	2012-06-01	SAC/TC116
1309	YY/T 1438-2016	Peak expiratory flow meter for anesthesia and respiratory equipment to evaluate lung function of spontaneous breathing	2016-01-26	2017-01-01	SAC/TC116

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1310	YY/T 1610-2018	Anesthesia and respiratory equipment medical oxygen humidifier	2018-01-19	2019-01-01	SAC/TC116
<b>(4) Medical gas system</b>					
1311	YY 9706.269-2021	Medical electrical equipment Part 2-69 : Specific requirements for the basic safety and basic performance of oxygen concentrators	2021-03-09	2023-05-01	SAC/TC116
1312	YY 0893-2013	Independent gas mixer for medical gas mixer	2013-10-21	2014-10-01	SAC/TC116
1313	YY 1107-2003	Buoy type oxygen inhaler	2003-06-20	2004-01-01	SAC/TC116
1314	YY 1468-2016	Oxygen concentrator gas supply system for medical gas pipeline system	2016-01-26	2018-01-01	SAC/TC116
1315	YY/T 0186-1994	General technical conditions of medical center suction system	1994-12-19	1995-05-01	SAC/TC116
1316	YY/T 0187-1994	General technical requirements for oxygen supply system in medical center	1994-12-19	1995-05-01	SAC/TC116
1317	YY/T 0298-1998	General technical specifications for medical molecular sieve oxygen production equipment	1998-04-08	1998-10-01	SAC/TC116
1318	YY/T 0799-2010	Medical gas low pressure hose assembly	2010-12-27	2012-06-01	SAC/TC116
1319	YY/T 0801.1-2010	Medical gas pipeline system terminal. Part 1 : Terminals for compressed medical gas and vacuum	2010-12-27	2012-06-01	SAC/TC116
1320	YY/T 0801.2-2010	Medical gas pipeline system terminal. Part 2 : Terminal for anesthetic gas purification system	2010-12-27	2012-06-01	SAC/TC116
1321	YY/T 1439.2-2016	Pressure regulators used with medical gases. Part 2 : Busbar pressure regulators and pipeline pressure	2016-01-26	2017-01-01	SAC/TC116
1322	YY/T 1440-2016	High-pressure flexible connection for use with medical gas systems	2016-01-26	2017-01-01	SAC/TC116

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1323	YY/T 1522-2017	Flow measuring device connected to terminal of medical gas pipeline system	2017-03-28	2018-04-01	SAC/TC116
<b>(5) Suction device for emergency nursing in hospital</b>					
1324	YY/T 0636.1-2021	Medical suction equipment Part 1: Electric suction equipment	2021-03-09	2023-05-01	SAC/TC116
1325	YY/T 0636.2-2021	Medical suction equipment Part 2: Manually driven suction equipment	2021-03-09	2022-04-01	SAC/TC116
1326	YY/T 0636.3-2021	Medical suction equipment. Part 3: Suction equipment powered by vacuum or positive pressure source	2021-03-09	2023-05-01	SAC/TC116
<b>(6) Atomization equipment / atomization device</b>					
1327	YY 0109-2013	Medical ultrasonic nebulizer	2013-10-02	2014-10-01	SAC/TC10/SC2
1328	YY/T 1743-2021	Nebulization systems and components for anesthesia and respiratory equipment	2021-03-09	2023-05-01	SAC/TC116
<b>(7) Tracheal tube and others</b>					
1329	YY 0337.1-2002	Tracheal intubation part 1: common intubation and joints	2002-09-24	2003-04-01	Shandong Center
1330	YY 0337.2-2002	Intubation of 2 parts: Cole (Cole) type cannula	2002-09-24	2003-04-01	Shandong Center
1331	YY 0338.1-2002	Intubation for tracheotomy. Part 1: Intubation and connector for adults	2002-09-24	2003-04-01	Shandong Center
1332	YY 0338.2-2002	Tracheotomy and intubation Part 2: Tracheotomy and intubation in children	2002-09-24	2003-04-01	Shandong Center
1333	YY 0498.1-2004	Laryngoscope connector part 1: Conventional hook-type handle - sight blade connector	2004-11-08	2005-11-01	SAC/TC116
1334	YY 0498.2-2004	Laryngoscope connector part 2: Miniature electric lamp thread and lamp holder with conventional sight piece	2004-11-08	2005-11-01	SAC/TC116
1335	YY 0499-2004	General technical requirements for anesthesia laryngoscope	2004-11-08	2005-11-01	SAC/TC116



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1336	YY 0671.2-2011	Sleep apnea treatment part 2 : mask and application accessories	2011-12-31	2013-06-01	SAC/TC116
1337	YY 0461-2003	Breathing circuit for anesthesia machine and ventilator	2003-06-20	2004-01-01	Shandong Center
1338	YY 91123-1999	Anesthesia laryngoscopy (connection part is void)	1999-01-01	2000-06-15	SAC/TC116
1339	YY 91136-1999	Neonatal Laryngoscope	1999-01-01	2000-06-15	SAC/TC116
1340	YY/T 0339-2019	Suction catheter for respiratory tract	2019-05-31	2020-06-01	SAC/TC116
1341	YY/T 0490-2017	Tracheobronchial intubation specifications and markings	2017-05-02	2018-04-01	SAC/TC116
1342	YY/T 0486-2016	Requirements for marking and random information of tracheal catheters for laser surgery	2016-01-26	2017-01-01	SAC/TC116
1343	YY/T 0977-2016	Anesthesia and respiratory equipment oropharyngeal airway	2016-03-23	2017-01-01	SAC/TC116
1344	YY/T 0978-2016	Anesthesia storage balloon	2016-03-23	2017-01-01	Shandong Center
1345	YY/T 0985-2016	Throat airway and joints on anesthesia and breathing equipment	2016-03-23	2017-01-01	SAC/TC116
1346	YY/T 1543-2017	Nasal Oxygen Tube	2017-05-02	2018-04-01	SAC/TC116
1347	YY/T 0753.1-2009	Respiratory system filters for anesthesia and respiratory use. Part 1 : Salt test method for evaluating filter characteristics	2009-11-15	2010-12-01	SAC/TC116
1348	YY/T 0753.2-2009	Respiratory system filters for anesthesia and breathing. Part 2 : Non-filtering characteristics	2009-11-15	2010-12-01	SAC/TC116

## 25. Medical Optics and Instruments

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Optical radiation safety</b>					
1349	GB 9706.20-2000	Medical electrical equipment Part 2 : Special requirements for the safety of diagnostic	2000-12-13	2001-05-01	SAC/TC103/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		and therapeutic laser equipment			
1350	YY 9706.257-2021	Medical electrical equipment Part 2-57 : Special requirements for the basic safety and basic performance of non-laser light source equipment used in treatment, diagnosis, monitoring and plastic surgery /medical cosmetics	2021-03-09	2023-05-01	SAC/TC103/SC1
1351	YY/T 0756-2009	Optical and optical instruments Laser and laser-related equipment laser beam power (energy) density distribution test method	2009-12-30	2011-06-01	SAC/TC103/SC1
1352	YY/T 0757-2009	Guidelines for the safe use of laser beams by the human body	2009-11-15	2010-12-01	SAC/TC103/SC1
1353	YY/T 1534-2017	Detection method of optical radiation safety classification of medical LED equipment	2017-03-28	2018-04-01	SAC/TC103/SC1
<b>(2) Ophthalmic optics and instruments</b>					
1354	GB 23719-2009	Ophthalmic optics and instrument optical visual aids	2009-05-06	2010-03-01	SAC/TC103/SC1
1355	GB 38455-2019	Ophthalmic instrument keratometer	2019-12-31	2022-01-01	State Food and Drug Administration
1356	GB/T 11417.1-2012	Ophthalmic optical contact lenses. Part 1 : Vocabulary, classification and recommended marking specifications	2012-12-31	2013-06-01	SAC/TC103/SC1
1357	GB 11417.2-2012	Optical contact lenses for ophthalmology. Part 2 : Rigid contact lenses	2012-12-31	2013-12-01	SAC/TC103/SC1
1358	GB 11417.3-2012	Optical contact lenses for ophthalmology. Part 3 : Soft contact lenses	2012-12-31	2013-12-01	SAC/TC103/SC1
1359	GB/T 11417.4-2012	Ophthalmic optical contact lenses. Part 4 : Standard salt solution for testing	2012-12-31	2013-06-01	SAC/TC103/SC1
1360	GB/T 11417.5-2012	Ophthalmic optical contact lenses. Part 5 : Optical performance test methods	2012-12-31	2013-06-01	SAC/TC103/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1361	GB/T 11417.6-2012	Optical contact lenses for ophthalmology. Part 6 : Test methods for mechanical properties	2012-12-31	2013-06-01	SAC/TC103/SC1
1362	GB/T 11417.7-2012	Optical contact lenses for ophthalmology. Part 7 : Test methods for physical and chemical properties	2012-12-31	2013-06-01	SAC/TC103/SC1
1363	GB/T 11417.8-2012	Optical contact lenses for ophthalmology. Part 8 : Determination of expiry date	2012-12-31	2013-06-01	SAC/TC103/SC1
1364	GB/T 11417.9-2012	Ophthalmic optical contact lenses. Part 9 : UV and visible radiation aging test (in vitro method)	2012-12-31	2013-06-01	SAC/TC103/SC1
1365	GB/T 28538-2012	Study on compatibility of ophthalmic optical contact lenses and contact lens care products in rabbit eyes	2012-06-29	2012-11-01	SAC/TC103/SC1
1366	GB/T 28539-2012	Guidelines for the determination of the intake and release of preservatives in ophthalmic optical contact lenses and contact lens care products	2012-06-29	2012-11-01	SAC/TC103/SC1
1367	YY 0065-2016	Ophthalmology instrument slit lamp microscope	2016-01-26	2018-01-01	SAC/TC103/SC1
1368	YY/T 0290.1-2008	Ophthalmology optical intraocular lens. Part 1 : Terminology	2008-10-17	2010-06-01	SAC/TC103/SC1
1369	YY 0290.2-2021	Ophthalmology optical intraocular lens. Part 2 : Optical properties and test methods	2021-03-09	2023-04-01	SAC/TC103/SC1
1370	YY 0290.3-2018	Ophthalmology optical intraocular lens. Part 3 : Mechanical properties and test methods	2018-12-20	2020-06-01	SAC/TC103/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1371	YY/T 0290.4-2008	Ophthalmic optical intraocular lens. Part 4 : Labels and information	2008-10-17	2010-06-01	SAC/TC103/SC1
1372	YY 0290.5-2008	Ophthalmic optical intraocular lens. Part 5 : Biocompatibility	2008-10-17	2010-06-01	SAC/TC103/SC1
1373	YY/T 0290.6-2009	Ophthalmic optical intraocular lens. Part 6 : Expiry date and stability of transportation	2009-06-16	2010-12-01	SAC/TC103/SC1
1374	YY 0290.8-2008	Ophthalmology optical intraocular lens. Part 8 : Basic requirements	2008-10-17	2010-06-01	SAC/TC103/SC1
1375	YY 0290.9-2010	Ophthalmology optical intraocular lens. Part 9 : Multifocal intraocular lens	2010-12-27	2012-06-01	SAC/TC103/SC1
1376	YY 0290.10-2009	Ophthalmology optical intraocular lens. Part 10 : phakic intraocular lens	2009-06-16	2010-12-01	SAC/TC103/SC1
1377	YY 0477-2016	Rigid breathable contact lens for orthokeratology	2016-03-23	2018-01-01	SAC/TC103/SC1
1378	YY 0633-2008	Ophthalmological instrument indirect ophthalmoscope	2008-04-25	2009-12-01	SAC/TC103/SC1
1379	YY 0634-2008	Ophthalmology instrument fundus camera	2008-04-25	2009-12-01	SAC/TC103/SC1
1380	YY 0673-2008	Ophthalmic instruments	2008-10-17	2010-06-01	SAC/TC103/SC1
1381	YY 0674-2008	Optometry head for ophthalmic instruments	2008-10-17	2010-06-01	SAC/TC103/SC1
1382	YY 0675-2008	Ophthalmological equipment	2008-10-17	2010-06-01	SAC/TC103/SC1
1383	YY 0676-2008	Ophthalmic instruments	2008-10-17	2010-06-01	SAC/TC103/SC1
1384	YY 0762-2017	Ophthalmic optical capsular bag tension ring	2017-07-17	2018-07-01	SAC/TC103/SC1
1385	YY 0787-2010	Corneal topography	2010-12-27	2012-06-01	SAC/TC103/SC1
1386	YY 0788-2010	Microkeratome for ophthalmology instruments	2010-12-27	2012-06-01	SAC/TC103/SC1
1387	YY 0792.1-2016	Ophthalmic instruments. Intraocular illuminators. Part 1 : Requirements and test methods	2016-03-23	2018-01-01	SAC/TC103/SC1
1388	YY 0792.2-2010	Ophthalmic instruments. Intraocular illuminators. Part 2 : Basic requirements and test methods for optical radiation safety	2010-12-27	2012-06-01	SAC/TC103/SC1
1389	YY 0861-2011	Ophthalmic optics ophthalmic viscoelastic agent	2011-12-31	2013-06-01	SAC/TC103/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1390	YY 0862-2011	Ophthalmology Optical Intraocular Filler	2011-12-31	2013-06-01	SAC/TC103/SC1
1391	YY 1080-2009	Ophthalmic instruments direct ophthalmoscope	2009-12-30	2011-06-01	SAC/TC103/SC1
1392	YY/T 0066-2015	Terminology of ophthalmic instruments	2015-03-02	2016-01-01	SAC/TC103/SC1
1393	YY/T 0718-2009	Ophthalmological instrument retinoscope	2009-06-16	2010-12-01	SAC/TC103/SC1
1394	YY/T 0719.1-2009	Ophthalmic optical contact lens care products. Part 1 : Terminology	2009-06-16	2010-12-01	SAC/TC103/SC1
1395	YY 0719.2-2009	Ophthalmic optical contact lens care products Part 2 : Basic requirements	2009-06-16	2010-12-01	SAC/TC103/SC1
1396	YY/T 0719.3-2009	Ophthalmic optical contact lens care products Part 3 : Microbiological requirements and test methods and contact lens care system	2009-06-16	2010-12-01	SAC/TC103/SC1
1397	YY/T 0719.4-2009	Ophthalmic optical contact lens care products. Part 4 : Antimicrobial antiseptic effectiveness test and guidelines for determining the date of disposal	2009-06-16	2010-12-01	SAC/TC103/SC1
1398	YY/T 0719.5-2009	Ophthalmic optical contact lens care products-Part 5 : Determination of physical compatibility of contact lenses and contact lens care products	2009-06-16	2010-12-01	SAC/TC103/SC1
1399	YY/T 0719.6-2020	Ophthalmic optical contact lens care products. Part 6 : Guidelines for determining the expiry date	2020-06-30	2021-06-01	SAC/TC103/SC1
1400	YY/T 0719.7-2011	Ophthalmic optical contact lenses and contact lens care products. Part 7 : Biological evaluation test methods	2011-12-31	2013-06-01	SAC/TC103/SC1
1401	YY/T 0719.8-2019	Ophthalmic optical contact lens care products. Part 8 : Detergent determination method	2019-10-23	2020-10-1	SAC/TC103/SC1
1402	YY/T 0764-2009	Ophthalmology instrument eye chart projector	2009-12-30	2011-06-01	SAC/TC103/SC1
1403	YY/T 0871-2013	Hygienic treatment of ophthalmology optical contact lenses try-on	2013-10-21	2014-10-01	SAC/TC103/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		contact lenses for many patients			
1404	YY/T 0942-2014	Ophthalmic optical intraocular lens implantation system	2014-06-17	2015-07-01	SAC/TC103/SC1
1405	YY/T 0984-2016	Lacrimal plug	2016-03-23	2017-01-01	SAC/TC103/SC1
1406	YY/T 0968.1-2014	Evaluation method of medical optical radiation protective glasses. Part 1 : Reduction degree of optical radiation hazard	2014-06-17	2015-07-01	SAC/TC103/SC1
1407	YY/T 0968.2-2014	Evaluation method of medical optical radiation protective glasses. Part 2 : Visual and color vision	2014-06-17	2015-07-01	SAC/TC103/SC1
1408	YY/T 1036-2004	Indentation tonometer	2004-03-23	2005-01-01	SAC/TC103/SC1
1409	YY/T 1418-2016	Ophthalmic optics and instrumental human eye aberration expression	2016-01-26	2017-01-01	SAC/TC103/SC1
1410	YY/T 1484-2016	Ophthalmology instrument ocular axis length measuring instrument	2016-07-29	2017-06-01	SAC/TC103/SC1
<b>(3) Minimally invasive endoscope system and equipment</b>					
1411	GB 9706.19-2000	Medical electrical equipment. Part 2 : Particular requirements for the safety of endoscopic equipment	2000-07-12	2000-12-01	SAC/TC103/SC1
1412	YY 0068.1-2008	Rigid endoscopes for medical endoscopes-Part 1 : Optical performance and test methods	2008-04-25	2009-12-01	SAC/TC103/SC1
1413	YY 0068.2-2008	Rigid endoscopes for medical endoscopes-Part 2 : Mechanical properties and test methods	2008-10-17	2010-06-01	SAC/TC103/SC1
1414	YY/T 0068.3-2008	Medical Endoscope Rigid Endoscope Part 3 : Labels and accompanying materials	2008-10-17	2010-06-01	SAC/TC103/SC1
1415	YY 0068.4-2009	Medical endoscope. Rigid endoscope. Part 4 : Basic requirements	2009-12-30	2011-06-01	SAC/TC103/SC1
1416	YY 0069-2009	Special requirements for rigid endoscopy	2009-12-30	2011-06-01	SAC/TC103/SC1
1417	YY 1028-2008	Fiber upper gastrointestinal endoscope	2008-10-17	2010-06-01	SAC/TC103/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1418	YY 1075-2007	Rigid endoscope	2007-07-02	2008-03-01	SAC/TC103/SC1
1419	YY 1082-2007	Rigid arthroscopy	2007-07-02	2008-03-01	SAC/TC103/SC1
1420	YY 1298-2016	Medical endoscope capsule endoscope	2016-03-23	2018-01-01	SAC/TC103/SC1
1421	YY 91083-1999	Fiber-guided cystoscope	1989-05-15	1989-05-15	SAC/TC103/SC1
1422	YY 0843-2011	Pneumoperitoneum machine for medical endoscope endoscopic function supply device	2011-12-31	2013-06-01	SAC/TC103/SC1
1423	YY 0847-2011	Medical endoscope endoscopic instrument stone-retrieving mesh basket	2011-12-31	2013-06-01	SAC/TC103/SC1
1424	YY 1081-2011	Cold light source for medical endoscope endoscopic function supply device	2011-12-31	2013-06-01	SAC/TC103/SC1
1425	YY/T 0070-2018	Rectal and sigmoid colonoscope	2018-09-21	2019-09-26	SAC/TC103/SC1
1426	YY/T 0071-2018	Rigid coagulation cutting endoscope	2018-09-21	2019-09-26	SAC/TC103/SC1
1427	YY/T 0283-2007	Fiber colonoscope	2007-07-02	2008-03-01	SAC/TC103/SC1
1428	YY/T 0619-2017	Rigid coagulation cutting endoscope	2017-02-28	2018-01-01	SAC/TC103/SC1
1429	YY/T 1587-2018	Medical Endoscope Electronic Endoscope	2018-06-26	2019-07-01	SAC/TC103/SC1
1430	YY/T 0763-2009	Optical cable for medical endoscope lighting	2009-12-30	2011-06-01	SAC/TC103/SC1
1431	YY/T 0842-2011	Medical Endoscope Endoscope Accessory Scope Sheath	2011-12-31	2013-06-01	SAC/TC103/SC1
1432	YY/T 0863-2011	Medical endoscope Endoscope function supply device rolling type flushing suction device	2011-12-31	2013-06-01	SAC/TC103/SC1
1433	YY/T 0864-2011	Medical endoscope endoscopic function supply device liquid dilatation pump	2011-12-31	2013-06-01	SAC/TC103/SC1
1434	YY/T 0922-2014	Medical Endoscope Endoscope Accessory Mirror Bridge	2014-06-17	2015-07-01	SAC/TC103/SC1
1435	YY/T 0930-2014	Medical Endoscope Endoscope Instrument Cell Brush	2014-06-17	2015-07-01	SAC/TC103/SC1
1436	YY/T 0931-2014	Medical endoscope endoscopic instrument loop ligation device	2014-06-17	2015-07-01	SAC/TC103/SC1
1437	YY/T 0940-2014	Medical endoscope endoscopic instrument grasping forceps	2014-06-17	2015-07-01	SAC/TC103/SC1

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1438	YY/T 0941-2014	Medical endoscope Endoscope instrument biting-cutting forceps	2014-06-17	2015-07-01	SAC/TC103/SC1
1439	YY/T 0943-2014	Medical Endoscope Endoscope Instrument Needle Holder	2014-06-17	2015-07-01	SAC/TC103/SC1
1440	YY/T 0944-2014	Medical endoscope endoscope instrument separation forceps	2014-06-17	2015-07-01	SAC/TC103/SC1
1441	YY/T 1297-2015	Medical endoscope endoscopic instrument curette	2015-03-02	2016-01-01	SAC/TC103/SC1
1442	YY/T 1446-2016	Medical Endoscope Endoscopic Instruments Palm-type Instruments	2016-01-26	2017-01-01	SAC/TC103/SC1
1443	YY/T 0955-2014	Medical endoscope endoscopic surgery equipment planer	2014-06-17	2015-07-01	SAC/TC103/SC1
1444	YY/T 1603-2018	Medical endoscope Endoscope function supply device camera system	2018-01-19	2019-01-01	SAC/TC103/SC1
<b>(4) Medical microscope</b>					
1445	GB 11239.1-2005	Operating microscope Part 1 : Requirements and test methods	2005-01-24	2005-07-01	SAC/TC103/SC1
1446	YY 1296-2016	Optical and photonics operating microscopes optical hazards of ophthalmic operating microscopes	2016-03-23	2018-01-01	SAC/TC103/SC1
1447	YY/T 0067-2007	Microcirculation microscope	2007-01-31	2008-02-01	SAC/TC103/SC1
<b>(5) Medical lighting equipment</b>					
1448	YY 9706.241-2020	Medical electrical equipment Part 2-41 : Specific requirements for basic safety and basic performance of surgical shadowless lamps and diagnostic lamps	2020-09-27	2023-05-01	SAC/TC103/SC1
1449	YY/T 0932-2014	Medical lighting source	2014-06-17	2015-07-01	SAC/TC103/SC1
1450	YY/T 1146-2016	Illumination test method for medical optical instruments	2016-03-23	2017-01-01	SAC/TC103/SC1
<b>(6) Laser surgery equipment</b>					
1451	GB 11748-2005	CO2 laser treatment machine	2005-01-24	2005-07-01	State Food and Drug Administration
1452	YY 0846-2011	Laser treatment equipment Holmium-doped yttrium	2011-12-31	2013-06-01	SAC/TC103/SC1



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		aluminum garnet laser treatment machine			
1453	YY 0599-2015	Laser treatment equipment Excimer laser corneal refractive treatment machine	2015-03-02	2017-01-01	SAC/TC103/SC1
1454	YY 1289-2016	Laser treatment equipment ophthalmic semiconductor laser photocoagulator	2016-03-23	2018-01-01	SAC/TC103/SC1
1455	YY/T 0758-2009	General requirements for laser fiber for treatment	2009-11-15	2010-12-01	SAC/TC103/SC1
<b>(7) Laser treatment equipment</b>					
1456	GB 12257-2000	General technical conditions of helium-neon laser treatment machine	2000-07-12	2000-12-01	State Food and Drug Administration
1457	YY 0307-2011	Continuous wave neodymium-doped yttrium aluminum garnet laser treatment machine	2011-12-31	2013-06-01	SAC/TC103/SC1
1458	YY 0789-2010	Q switch Nd : YAG laser eye treatment machine	2010-12-27	2012-06-01	SAC/TC103/SC1
1459	YY 0844-2011	Laser treatment equipment Pulse carbon dioxide laser treatment machine	2011-12-31	2013-06-01	SAC/TC103/SC1
1460	YY 0845-2011	Laser treatment equipment Semiconductor laser photodynamic treatment machine	2011-12-31	2013-06-01	SAC/TC103/SC1
1461	YY 0983-2016	Laser treatment equipment Ruby laser treatment machine	2016-03-23	2018-01-01	SAC/TC103/SC1
1462	YY 1301-2016	Laser treatment equipment Erbium laser treatment machine	2016-03-23	2018-01-01	SAC/TC103/SC1
1463	YY 1300-2016	Laser treatment equipment Pulse neodymium-doped yttrium aluminum garnet laser treatment machine	2016-03-23	2018-01-01	SAC/TC103/SC1
1464	YY 1475-2016	Laser treatment equipment Q- switched neodymium-doped yttrium aluminum garnet laser treatment machine	2016-01-26	2018-01-01	SAC/TC103/SC1
1465	YY/T 1751-2020	Laser treatment equipment semiconductor laser nasal cavity irradiation treatment instrument	2020-09-27	2021-09-01	SAC/TC103/SC1

## 26. Physiotherapy equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Electrotherapy equipment</b>					
1466	GB 9706.203-2020	Medical electrical equipment Part 2-3 : Specific requirements for basic safety and basic performance of short-wave treatment equipment	2020-05-29	2023-05-01	State Food and Drug Administration
1467	GB 9706.206-2020	Medical electrical equipment Part 2-6 : Specific requirements for the basic safety and basic performance of microwave therapy equipment	2020-07-23	2023-05-01	State Food and Drug Administration
1468	YY 9706.210-2021	Medical electrical equipment-Part 2-10 : Specific requirements for the basic safety and basic performance of nerve and muscle stimulators	2021-03-09	2023-05-01	SAC/TC10/SC4
1469	YY 0778-2018	Radiofrequency ablation catheter	2018-12-20	2020-06-01	SAC/TC10/SC4
1470	YY 9706.235-2021	Medical electrical equipment Part 2-35 : Specific requirements for the basic safety and basic performance of medical blanket, pad or mattress heating equipment	2021-03-09	2023-05-01	SAC/TC10/SC4
1471	YY 0899-2020	General requirements for medical microwave equipment accessories	2020-06-30	2022-06-01	SAC/TC10/SC4
1472	YY 91086-1999	Technical conditions of ultrashort wave treatment equipment	1999-01-01	2013-06-15	SAC/TC10/SC4
1473	YY 91087-1999	Special safety requirements for ultrashort wave treatment equipment	1999-01-01	2013-06-15	SAC/TC10/SC4
1474	YY 0322-2018	High frequency electrocautery treatment instrument	2018-09-28	2020-04-01	SAC/TC10/SC4

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1475	YY 0649-2016	Potential therapy equipment	2016-07-29	2018-06-01	SAC/TC10/SC4
1476	YY 0650-2008	Gynecological Radio Frequency Therapy Apparatus	2008-04-25	2009-12-01	SAC/TC10/SC4
1477	YY 0776-2010	Liver radiofrequency ablation treatment equipment	2010-12-27	2012-06-01	SAC/TC10/SC4
1478	YY 0777-2010	RF hyperthermia equipment	2010-12-27	2012-06-01	SAC/TC10/SC4
1479	YY 0838-2021	Microwave thermocoagulation equipment	2021-03-09	2023-05-01	SAC/TC10/SC4
1480	YY 0839-2011	Microwave hyperthermia equipment	2011-12-31	2013-06-01	SAC/TC10/SC4
1481	YY 0860-2011	Cardiac radiofrequency ablation treatment equipment	2011-12-31	2013-06-01	SAC/TC10/SC4
1482	YY 0897-2013	ENT radiofrequency ablation equipment	2013-10-21	2014-10-01	SAC/TC10/SC4
1483	YY 0898-2013	Millimeter wave treatment equipment	2013-10-21	2014-10-01	SAC/TC10/SC4
1484	YY 0951-2015	Interference electric therapy equipment	2015-03-02	2017-01-01	SAC/TC10/SC4
1485	YY/T 0868-2021	Electrodes for nerve and muscle stimulators	2021-03-09	2023-05-01	SAC/TC10/SC4
1486	YY/T 1409-2016	Plasma surgery equipment	2016-03-23	2017-01-01	SAC/TC10/SC4
1487	YY/T 0696-2021	Measurement of output characteristics of nerve and muscle stimulators	2021-03-09	2023-05-01	SAC/TC10/SC4
<b>(2) Thermotherapy equipment</b>					
1488	YY 0306-2018	Special requirements for the safety of thermal radiation therapy equipment	2018-12-20	2020-06-01	SAC/TC10/SC4
1489	YY 0323-2018	Special requirements for the safety of infrared treatment equipment	2018-09-28	2020-04-01	SAC/TC10/SC4
1490	YY 0060-2018	Hot compress (bag)	2018-11-07	2020-05-01	SAC/TC10/SC4
1491	YY 0952-2015	Medical temperature control blanket	2015-03-02	2017-01-01	SAC/TC10/SC4
1492	YY/T 0061-2021	Specific electromagnetic wave therapy device	2021-03-09	2023-05-01	SAC/TC10/SC4

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1493	YY/T 0165-2016	Thermal pad type therapeutic apparatus	2016-07-29	2017-06-01	SAC/TC10/SC4
1494	YY/T 0982-2016	Thermal magnetic vibrator treatment equipment	2016-03-23	2017-01-01	SAC/TC10/SC4
1495	YY/T 0998-2015	Semiconductor heating and cooling treatment equipment	2015-03-02	2016-01-01	SAC/TC10/SC4
<b>(3) Light therapy equipment</b>					
1496	YY 9706.250-2021	Medical electrical equipment-Part 2-50 : Specific requirements for the basic safety and basic performance of infant phototherapy equipment	2021-03-09	2023-05-01	SAC/TC103/SC1
1497	YY 0901-2013	UV treatment equipment	2013-10-21	2014-10-01	SAC/TC10/SC4
1498	YY/T 0902-2013	Contact far infrared physiotherapy equipment	2013-10-21	2014-10-01	SAC/TC10/SC4
1499	YY/T 1496-2016	Red light treatment equipment	2016-07-29	2017-06-01	SAC/TC10/SC4
<b>(4) Strength therapy equipment</b>					
1500	YY 0833-2020	General technical requirements for limb compression physiotherapy equipment	2020-02-21	2022-01-01	SAC/TC10/SC4
1501	YY 0950-2015	Pneumatic ballistic extracorporeal pressure wave treatment equipment	2015-03-02	2017-01-01	SAC/TC10/SC4
1502	YY/T 0697-2016	Electric cervical and lumbar traction treatment equipment	2016-07-29	2017-06-01	SAC/TC10/SC4
1503	YY/T 0851-2011	Medical anti-embolism stockings	2011-12-31	2013-06-01	Shandong Center
1504	YY/T 0853-2011	Medical varicose vein compression stockings	2011-12-31	2013-06-01	Shandong Center
1505	YY/T 1491-2016	Electric cervical and lumbar traction bed, chair and accessories	2016-07-29	2017-06-01	SAC/TC10/SC4
1506	YY/T 1665-2019	Vibration percussion expectoration machine	2019-07-24	2020-08-01	SAC/TC10/SC4
1507	YY/T 1685-2020	Pneumatic pulse oscillation expectoration equipment	2020-02-21	2021-01-01	SAC/TC10/SC4
<b>(5) Magnetic therapy equipment</b>					

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1508	YY/T 0994-2015	Magnetic stimulation equipment	2015-03-02	2016-01-01	SAC/TC10/SC4

## 27. Bioelectric signal feedback equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1509	YY/T 0903-2013	EEG Biofeedback Apparatus	2013-10-21	2014-10-01	SAC/TC10/SC4
1510	YY/T 1095-2015	EMG biofeedback instrument	2015-03-02	2016-01-01	SAC/TC10/SC4
1511	YY/T 1096-2007	Temperature biofeedback meter	2007-01-31	2008-01-01	SAC/TC10/SC4

## 28. Medical rehabilitation equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1512	YY 0900-2013	Weight loss walking training platform	2013-10-21	2014-10-01	SAC/TC10/SC4
1513	YY/T 0997-2015	Passive exercise equipment for elbow and knee joints	2015-03-02	2016-01-01	SAC/TC10/SC4
1514	YY/T 1410-2016	Balance test training system	2016-03-23	2017-01-01	SAC/TC10/SC4
1515	YY/T 1626-2019	Electric upper and lower limb circular motion training equipment	2019-05-31	2020-06-01	SAC/TC10/SC4

## Twenty-nine. Traditional Chinese Medicine Equipment

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) TCM diagnostic equipment</b>					
1516	YY/T 1488-2016	Tongue information collection equipment	2016-07-29	2017-06-01	SAC/TC10/SC4
1517	YY/T 1489-2016	Traditional Chinese Medicine Pulse Map Collection Equipment	2016-07-29	2017-06-01	SAC/TC10/SC4
1518	YY/T 1661-2019	Acupoint impedance testing equipment	2019-07-24	2020-08-01	SAC/TC10/SC4
<b>(2) TCM treatment equipment</b>					
1519	YY 0780-2018	Electroacupuncture treatment instrument	2018-06-26	2019-07-01	SAC/TC10/SC4

1520	YY/T 1306-2016	Fumigation Therapeutic Apparatus	2016-03-23	2017-01-01	SAC/TC10/SC4
1521	YY/T 1490-2016	Electronic heating moxibustion equipment	2016-07-29	2017-06-01	SAC/TC10/SC4
1522	YY/T 1666-2019	Meridian Stimulator	2019-07-24	2020-08-01	SAC/TC10/SC4
<b>(3) TCM equipment</b>					
1523	GB 2024-2016	Acupuncture needles	2016-06-14	2018-07-01	SAC/TC95
1524	YY 0104-2018	Triangular Needle	2018-06-26	2019-07-01	SAC/TC10/SC4
1525	YY/T 0105-2020	Intradermal needle	2020-09-27	2021-09-01	SAC/TC10/SC4
1526	YY/T 1624-2019	Manual negative pressure cupping device	2019-10-23	2020-10-01	SAC/TC10/SC4

### Thirty, stethoscope

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1527	YY/T 1035-2021	Stethoscope	2021-03-09	2022-04-01	Jiangsu Institute

## 31. Medical laboratories and in vitro diagnostic equipment and reagents

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Quality and capability of medical laboratories</b>					
1528	GB/T 22576.1-2018	Requirements for the quality and competence of medical laboratories . Part 1 : General requirements	2018-12-28	2019-07-01	SAC/TC136
1529	GB/Z 30154-2013	Medical Laboratory GB/T 22576-2008 Laboratory Implementation Guide	2013-12-17	2014-08-01	SAC/TC136
1530	GB/T 29790-2020	Instant inspection of quality and ability requirements	2020-11-19	2021-12-01	SAC/TC136
1531	YY/T 1172-2010	Medical laboratory quality management terminology	2010-12-27	2012-06-01	SAC/TC136
<b>(2) Reference measurement system</b>					
1532	GB/T 19702-2021	Requirements for the expression and content of reference measurement procedures for the measurement of quantities in biological samples of in vitro diagnostic medical devices	2021-03-09	2022-04-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1533	GB/T 19703-2020	Requirements for the content of certified reference materials and supporting documents for the measurement of quantities in biological samples of in vitro diagnostic medical devices	2020-11-19	2021-12-01	SAC/TC136
1534	GB/T 21919-2008	Requirements for laboratory medicine reference measurement laboratories	2008-05-28	2009-01-01	SAC/TC136
1535	YY/T 0638-2008	Metrological traceability of the measurement of calibrators and control substances in biological samples of in vitro diagnostic medical devices	2008-04-25	2009-06-01	SAC/TC136
1536	YY/T 1195-2011	Serum total protein reference measurement procedure	2010-12-27	2012-06-01	SAC/TC136
1537	YY/T 1455-2016	Guidelines for Assigning Values and Uncertainty Evaluation of Enzyme Catalytic Activity Concentrations Using Reference Measurement Procedures	2016-01-26	2017-01-01	SAC/TC136
1538	YY/T 1675-2019	Serum electrolyte (potassium, sodium, calcium, magnesium) reference measurement procedure (ion chromatography)	2019-10-23	2020-10-01	SAC/TC136
1539	YY/T 1728-2021	Reference method for in vitro activity detection of yeast-like fungal antibacterial agents related to infectious diseases in clinical laboratory testing and in vitro diagnostic systems	2021-03-09	2022-04-01	SAC/TC136

**(3) General standards in the field of in vitro diagnostics**

1540	GB/T 21415-2008	Metrology traceability of measurement calibrators and control substance assignments in biological samples of in vitro diagnostic medical devices	2008-01-22	2008-09-01	SAC/TC136
1541	YY 0648-2008	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	2008-04-25	2009-12-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1542	GB/T 29791.1-2013	Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part 1: Terms, definitions and general requirements	2013-10-10	2014-02-01	SAC/TC136
1543	GB/T 29791.2-2013	Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part 2: In vitro diagnostic reagents for professional use	2013-10-10	2014-02-01	SAC/TC136
1544	GB/T 29791.3-2013	Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part 3: In vitro diagnostic devices for professional use	2013-10-10	2014-02-01	SAC/TC136
1545	GB/T 29791.4-2013	Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part 4: In vitro diagnostic reagents for self-testing	2013-10-10	2014-02-01	SAC/TC136
1546	GB/T 29791.5-2013	Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part 5: In vitro diagnostic devices for self-testing	2013-10-10	2014-02-01	SAC/TC136
1547	YY/T 0639-2019	Information provided by manufacturers of in vitro diagnostic medical devices for in vitro diagnostic reagents for biological staining	2019-07-24	2020-08-01	SAC/TC136
1548	YY/T 0692-2008	Basic terminology of biochips	2008-10-17	2010-01-01	SAC/TC136
1549	YY/T 1152-2009	Aldehyde-based substrates for biochips	2009-12-30	2011-06-01	SAC/TC136
1550	YY/T 1244-2014	Purified water for in vitro diagnostic reagents	2014-06-17	2015-07-01	SAC/TC136
1551	YY/T 1441-2016	General requirements for performance evaluation of in vitro diagnostic medical devices	2016-01-26	2017-01-01	SAC/TC136
1552	YY/T 1454-2016	Basic requirements for in vitro diagnostic medical devices for self-testing	2016-01-26	2017-01-01	SAC/TC136



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1553	YY/T 1579-2018	Evaluation of the stability of in vitro diagnostic reagents for in vitro diagnostic medical devices	2018-02-24	2019-03-01	SAC/TC136
1554	YY/T 1652-2019	General technical requirements for quality control materials for in vitro diagnostic reagents	2019-05-31	2020-06-01	SAC/TC136
1555	YY/T 1709-2020	Evaluation of Uncertainty in Measurement of Calibrators for In Vitro Diagnostic Reagents	2020-06-30	2021-12-01	SAC/TC136
<b>(4) Product Standards of In Vitro Diagnostic System</b>					
1556	GB/T 19634-2005	General technical requirements for blood glucose monitoring systems for self-testing in vitro diagnostic testing systems	2005-01-24	2005-05-01	SAC/TC136
1557	YY/T 0688.1-2008	Clinical laboratory testing and in vitro diagnostic system infection pathogen susceptibility test and performance evaluation of antibacterial agent susceptibility test equipment. Part 1: Reference method for in vitro activity detection of antibacterial agents against rapidly growing aerobic bacteria related to infectious diseases	2008-10-17	2010-01-01	SAC/TC136
1558	YY/T 0688.2-2010	Clinical laboratory testing and in-vitro diagnostic system - Infectious pathogen susceptibility test and antimicrobial agent susceptibility test equipment performance evaluation Part 2: Antimicrobial agent susceptibility test equipment performance evaluation	2010-12-27	2012-06-01	SAC/TC136
1559	YY/T 0690-2008	Requirements for self-test in vitro monitoring system for clinical laboratory testing and in vitro medical device oral anticoagulant therapy	2008-10-17	2010-01-01	SAC/TC136
1560	YY/T 1150-2009	General technical requirements for hemoglobin dry chemical detection system	2009-12-30	2011-06-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(5) Medical laboratory equipment</b>					
1561	YY 1621-2018	Medical carbon dioxide incubator	2018-09-28	2020-04-01	SAC/TC338/SC1
1562	YY/T 0086-2020	Medical refrigerator	2020-02-21	2022-01-01	SAC/TC338/SC1
1563	YY/T 0657-2017	Medical centrifuge	2017-03-28	2018-04-01	SAC/TC136
1564	YY/T 1641-2018	Medical biochemical incubator	2018-12-20	2020-01-01	SAC/TC338/SC1
1565	YY/T 1757-2021	Medical cryopreservation box	2021-03-09	2023-04-01	SAC/TC338/SC1
<b>(6) Instruments and equipment for clinical testing</b>					
1566	YY/T 0014-2005	Semi-automatic biochemical analyzer	2005-12-07	2006-12-01	SAC/TC136
1567	YY/T 0032-2004	Hemoglobin meter	2004-11-08	2005-11-01	SAC/TC136
1568	YY/T 0087-2004	Electrophoresis device	2004-11-08	2005-11-01	SAC/TC136
1569	YY/T 0475-2011	Dry chemical urine analyzer	2011-12-31	2013-06-01	SAC/TC136
1570	YY/T 0588-2017	Flow cytometer	2017-12-05	2018-12-01	SAC/TC136
1571	YY/T 0589-2016	Electrolyte Analyzer	2016-03-23	2017-01-01	SAC/TC136
1572	YY/T 0653-2017	Blood analyzer	2017-03-28	2018-04-01	SAC/TC136
1573	YY/T 0654-2017	Automatic biochemical analyzer	2017-03-28	2018-04-01	SAC/TC136
1574	YY/T 0655-2008	Dry chemical analyzer	2008-04-25	2009-06-01	SAC/TC136
1575	YY/T 0656-2008	Automated blood culture system	2008-04-25	2009-06-01	SAC/TC136
1576	YY/T 0659-2017	Coagulation Analyzer	2017-03-28	2018-04-01	SAC/TC136
1577	YY/T 0996-2015	Urine formed element analyzer (digital imaging automatic recognition)	2015-03-02	2016-01-01	SAC/TC136
1578	YY/T 1154-2009	Confocal Laser Scanner	2009-12-30	2011-06-01	SAC/TC136
1579	YY/T 1155-2019	Automatic luminescence immunoassay analyzer	2019-05-31	2020-06-01	SAC/TC136
1580	YY/T 1173-2010	Polymerase Chain Reaction Analyzer	2010-12-27	2012-06-01	SAC/TC136
1581	YY/T 1174-2010	Semi-automatic chemiluminescence immunoassay analyzer	2010-12-27	2012-06-01	SAC/TC136
1582	YY/T 1245-2014	Automatic blood group analyzer	2014-06-17	2015-07-01	SAC/TC136
1583	YY/T 1246-2014	Glycated hemoglobin analyzer	2014-06-17	2015-07-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1584	YY/T 1251-2014	Erythrocyte Sedimentation Rate Tester	2014-06-17	2015-07-01	SAC/TC136
1585	YY/T 1304.1-2015	Time-resolved fluorescence immunoassay system. Part 1: Semi-automatic time-resolved fluorescence immunoassay analyzer	2015-03-02	2016-01-01	SAC/TC136
1586	YY/T 1452-2016	Dry blood cell analyzer (centrifugal method)	2016-01-26	2017-01-01	SAC/TC136
1587	YY/T 1460-2016	Blood rheometer	2016-01-26	2017-01-01	SAC/TC136
1588	YY/T 1529-2017	Enzyme-linked immunoassay analyzer	2017-05-02	2018-04-01	SAC/TC136
1589	YY/T 1531-2017	Bacterial Biochemical Identification System	2017-03-28	2018-04-01	SAC/TC136
1590	YY/T 1533-2017	Automatic time-resolved fluorescence immunoassay analyzer	2017-03-28	2018-04-01	SAC/TC136
1591	YY/T 1582-2018	Colloidal gold immunochromatographic analyzer	2018-02-24	2019-03-01	SAC/TC136
1592	YY/T 1723-2020	High-throughput gene sequencer	2020-06-30	2021-12-01	SAC/TC136
1593	YY/T 1740.1-2021	Medical mass spectrometer part 1: liquid chromatography - mass spectrometer	2021-03-09	2022-10-01	SAC/TC136
<b>(7) Blood and body fluids reagents</b>					
1594	YY/T 0456.2-2014	Application reagents for blood cell analyzer Part 2: Hemolytic agent	2014-06-17	2015-07-01	SAC/TC136
1595	YY/T 0456.3-2014	Hematology Analyzer Application Reagent Part 3: Diluent	2014-06-17	2015-07-01	SAC/TC136
1596	YY/T 0456.4-2014	Reagents for Hematology Analyzer Part 4 Reagents for Detection of Nucleated Red Blood Cells	2014-06-17	2015-07-01	SAC/TC136
1597	YY/T 0456.5-2014	Reagents for blood analyzers. Part 5 Reticulocyte detection reagents	2014-06-17	2015-07-01	SAC/TC136
1598	YY/T 0701-2008	Calibrator (product) for blood cell analyzer	2008-10-17	2010-01-01	SAC/TC136
1599	YY/T 0702-2008	Quality control material for blood cell analyzer (product)	2008-10-17	2010-01-01	SAC/TC136
1600	YY/T 1156-2009	Thrombin time test kit (kit)	2009-12-30	2011-06-01	SAC/TC136
1601	YY/T 1157-2009	Activated partial thromboplastin time detection kit (kit)	2009-12-30	2011-06-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1602	YY/T 1158-2009	Prothrombin time detection kit (kit)	2009-12-30	2011-06-01	SAC/TC136
1603	YY/T 1159-2009	Fibrinogen detection kit (kit)	2009-12-30	2011-06-01	SAC/TC136
1604	YY 1741-2021	Antithrombin III determination kit	2021-03-09	2023-04-01	SAC/TC136
1605	YY/T 1238-2014	RhD ( IgM ) blood typing reagent (monoclonal antibody)	2014-06-17	2015-07-01	SAC/TC136
1606	YY/T 1240-2014	D-dimer quantitative detection reagent (kit)	2014-06-17	2015-07-01	SAC/TC136
1607	YY/T 1530-2017	Control substances for urine formed element analyzers	2017-03-28	2018-04-01	SAC/TC136
1608	YY/T 1592-2018	ABO positive type and RhD blood type test card (column agglutination method)	2018-02-24	2019-03-01	SAC/TC136
1609	YY/T 1669-2019	ABO reverse shaping test card (column agglutination method)	2019-07-24	2020-08-01	SAC/TC136
<b>(8) Clinical biochemical reagents</b>					
1610	GB/T 26124-2011	Clinical chemistry in vitro diagnostic reagents (kits)	2011-05-12	2011-11-01	SAC/TC136
1611	YY/T 1227-2014	Clinical chemistry in vitro diagnostic reagents (kits) naming	2014-06-17	2015-07-01	SAC/TC136
1612	YY/T 1255-2015	Immunoturbidimetric detection reagent (kit) (transmission method)	2015-03-02	2016-01-01	SAC/TC136
1613	YY/T 1549-2017	Calibrator for biochemical analyzer	2017-05-02	2018-04-01	SAC/TC136
1614	YY/T 1662-2019	Quality control material for biochemical analyzer	2019-05-31	2020-06-01	SAC/TC136
1615	YY/T 0478-2011	Urinalysis Test Strip	2011-12-31	2013-06-01	SAC/TC136
1616	YY/T 0501-2014	Urine dry chemical analysis quality control substance	2014-06-17	2015-07-01	SAC/TC136
1617	YY/T 1194-2011	Alpha - amylase determination reagent (kit) (continuous monitoring method)	2011-12-31	2013-06-01	SAC/TC136
1618	YY/T 1196-2013	Chlorine determination kit (enzymatic method)	2013-10-21	2014-10-01	SAC/TC136
1619	YY/T 1197-2013	Alanine aminotransferase ( ALT ) determination kit (continuous monitoring method)	2013-10-21	2014-10-01	SAC/TC136
1620	YY/T 1198-2013	Aspartate aminotransferase ( AST ) determination kit (continuous monitoring method)	2013-10-21	2014-10-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1621	YY/T 1199-2013	Triglyceride ( TG ) determination kit (enzymatic method)	2013-10-21	2014-10-01	SAC/TC136
1622	YY/T 1200-2013	Glucose determination kit (enzymatic method)	2013-10-21	2014-10-01	SAC/TC136
1623	YY/T 1201-2013	Urea determination kit (enzyme coupling monitoring method)	2013-10-21	2014-10-01	SAC/TC136
1624	YY/T 1202-2013	Potassium determination kit (enzymatic method)	2013-10-21	2014-10-01	SAC/TC136
1625	YY/T 1203-2013	Sodium determination kit (enzymatic method)	2013-10-21	2014-10-01	SAC/TC136
1626	YY/T 1204-2013	Kit for determination of total bile acid ( TBA ) (enzyme cycle method)	2013-10-21	2014-10-01	SAC/TC136
1627	YY/T 1205-2013	Kit for determination of total bilirubin (vanadate oxidation method)	2013-10-21	2014-10-01	SAC/TC136
1628	YY/T 1206-2013	Total cholesterol kit (oxidase method)	2013-10-21	2014-10-01	SAC/TC136
1629	YY/T 1207-2013	Uric Acid Determination Kit (Uricase Peroxidase Coupling Method)	2013-10-21	2014-10-01	SAC/TC136
1630	YY/T 1228-2014	Albumin determination reagent (kit)	2014-06-17	2015-07-01	SAC/TC136
1631	YY/T 1229-2014	Calcium determination reagent (kit)	2014-06-17	2015-07-01	SAC/TC136
1632	YY/T 1230-2014	Cystatin C determination reagent (kit)	2014-06-17	2015-07-01	SAC/TC136
1633	YY/T 1231-2014	Creatinine determination reagent (kit) (sarcosine oxidase method)	2014-06-17	2015-07-01	SAC/TC136
1634	YY/T 1232-2014	$\gamma$ - glutamyltransferase assay reagent (kit) ( GPNA substrate method)	2014-06-17	2015-07-01	SAC/TC136
1635	YY/T 1234-2014	Reagent for alkaline phosphatase determination (kit) ( NPP substrate- AMP buffer method)	2014-06-17	2015-07-01	SAC/TC136
1636	YY/T 1241-2014	Lactate dehydrogenase assay reagent (kit)	2014-06-17	2015-07-01	SAC/TC136
1637	YY/T 1242-2014	[alpha] - hydroxybutyrate dehydrogenase assay reagent (kit)	2014-06-17	2015-07-01	SAC/TC136
1638	YY/T 1243-2014	Creatine Kinase Determination Reagent (Box)	2014-06-17	2015-07-01	SAC/TC136
1639	YY/T 1253-2015	Low-density lipoprotein cholesterol determination kit (kit)	2015-03-02	2016-01-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1640	YY/T 1254-2015	High-density lipoprotein cholesterol determination kit (kit)	2015-03-02	2016-01-01	SAC/TC136
1641	YY/T 1258-2015	Homocysteine detection reagent (kit) (enzyme cycle method)	2015-03-02	2016-01-01	SAC/TC136
1642	YY/T 1421-2016	Apolipoprotein B Assay Kit	2016-01-26	2017-01-01	SAC/TC136
1643	YY/T 1444-2016	Total protein determination kit	2016-01-26	2017-01-01	SAC/TC136
1644	YY/T 1448-2016	Lipoprotein ( a ) determination kit	2016-01-26	2017-01-01	SAC/TC136
1645	YY/T 1450-2016	Apolipoprotein AI determination kit (kit)	2016-01-26	2017-01-01	SAC/TC136
1646	YY/T 1461-2016	Ischemia modified albumin determination kit (kit)	2016-01-26	2017-01-01	SAC/TC136
1647	YY/T 1523-2017	Carbon dioxide determination kit ( PEPC enzymatic method)	2017-03-28	2018-04-01	SAC/TC136
1648	YY/T 1524-2017	$\alpha$ -L- Fucosidase ( AFU ) Assay Kit ( CNPF Substrate Method)	2017-03-28	2018-04-01	SAC/TC136
1649	YY/T 1528-2017	Kit for determination of myoglobin (immunoturbidimetric method)	2017-03-28	2018-04-01	SAC/TC136
1650	YY/T 1578-2018	Glycated albumin determination kit (enzymatic method)	2018-02-24	2019-03-01	SAC/TC136
1651	YY/T 1580-2018	Creatine kinase MB isoenzyme assay kit (immunosuppressive method)	2018-02-24	2019-03-01	SAC/TC136
1652	YY/T 1742-2021	Adenosine Deaminase Assay Kit	2021-03-09	2022-10-01	SAC/TC136
1653	YY/T 1584-2018	Retinol binding protein determination kit (immunoturbidimetric method)	2018-02-24	2019-03-01	SAC/TC136
1654	YY/T 1590-2018	Heart-shaped fatty acid binding protein determination kit (immunoturbidimetric method)	2018-02-24	2019-03-01	SAC/TC136
1655	YY/T 1605-2018	Kit for determination of glycosylated hemoglobin (latex immunoturbidimetric method)	2018-02-24	2019-03-01	SAC/TC136
1656	YY/T 1722-2020	Prealbumin determination kit (immunoturbidimetric method)	2020-06-30	2021-12-01	SAC/TC136
<b>(9) Immunological reagents</b>					
1657	GB/T 18990-2008	Luteinizing hormone test paper (colloidal gold immunochromatographic method)	2008-11-03	2009-10-01	SAC/TC136
1658	YY/T 1151-2009	Protein microarray chip for in vitro diagnosis	2009-12-30	2011-06-01	SAC/TC136
1659	YY/T 1181-2010	Immunohistochemistry kit	2010-12-27	2012-06-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1660	YY/T 1183-2010	Enzyme-linked immunosorbent assay reagent (kit)	2010-12-27	2012-06-01	SAC/TC136
1661	YY/T 1184-2010	Monoclonal antibody reagents for flow cytometry	2010-12-27	2012-06-01	SAC/TC136
1662	YY/T 1304.2-2015	Time-resolved fluorescence immunoassay system. Part 2 : Time-resolved fluorescence immunoassay quantitative determination reagents (kits)	2015-03-02	2016-01-01	SAC/TC136
1663	YY/T 1713-2020	Colloidal gold immunochromatographic detection kit	2020-06-30	2022-06-01	SAC/TC136
1664	YY 1727-2020	Oral mucosal exudate human immunodeficiency virus antibody detection kit (colloidal gold immunochromatographic method)	2020-06-30	2022-06-01	SAC/TC136
1665	YY/T 1514-2017	Human Immunodeficiency Virus ( Type 1+2 ) Antibody Detection Kit (Western Blot Method)	2017-05-02	2018-04-01	SAC/TC136
1666	YY/T 1526-2017	Human immunodeficiency virus antigen antibody combined detection kit (luminescent type)	2017-05-02	2018-04-01	SAC/TC136
1667	YY/T 1611-2018	Human immunodeficiency virus antibody detection kit (immunochromatographic method)	2018-12-20	2020-01-01	SAC/TC136
1668	YY/T 1247-2014	Hepatitis B virus surface antigen test kit (kit) (chemiluminescence immunoassay)	2014-06-17	2015-07-01	SAC/TC136
1669	YY/T 1248-2014	Hepatitis B virus surface antibody determination kit (kit) (chemiluminescence immunoassay)	2014-06-17	2015-07-01	SAC/TC136
1670	YY/T 1215-2013	Hepatitis C virus ( HCV ) antibody detection kit (colloidal gold method)	2013-10-21	2014-10-01	SAC/TC136
1671	YY/T 1735-2021	Hepatitis C virus antibody detection kit (kit) (chemiluminescence immunoassay)	2021-03-09	2022-04-01	SAC/TC136
1672	YY/T 1259-2015	Hepatitis E virus IgG antibody detection kit (enzyme-linked immunosorbent assay)	2015-03-02	2016-01-01	SAC/TC136
1673	YY/T 1260-2015	Hepatitis E virus IgM antibody detection kit (enzyme-linked immunosorbent assay)	2015-03-02	2016-01-01	SAC/TC136
1674	YY/T 1443-2016	Influenza A virus antigen detection kit (immunochromatographic method)	2016-01-26	2017-01-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1675	YY/T 1517-2017	Epstein-Barr virus capsid antigen ( VCA ) IgA antibody detection kit	2017-05-02	2018-04-01	SAC/TC136
1676	YY/T 1235-2014	Rubella virus IgG/IgM antibody detection kit (kit)	2014-06-17	2015-07-01	SAC/TC136
1677	YY/T 1236-2014	Cytomegalovirus IgG/IgM antibody detection kit (kit)	2014-06-17	2015-07-01	SAC/TC136
1678	YY/T 1482-2016	Herpes simplex virus IgG antibody detection kit (kit)	2016-07-29	2017-06-01	SAC/TC136
1679	YY/T 1483-2016	Herpes simplex virus IgM antibody detection kit (kit)	2016-07-29	2017-06-01	SAC/TC136
1680	YY/T 1645-2019	Human Parvovirus B19 IgG Antibody Detection Kit	2019-05-31	2020-06-01	SAC/TC136
1681	YY/T 1423-2016	Helicobacter pylori antibody detection kit (colloidal gold method)	2016-01-26	2017-01-01	SAC/TC136
1682	YY/T 1237-2014	Toxoplasma IgG antibody detection kit (kit) (enzyme-linked immunoassay)	2014-06-17	2015-07-01	SAC/TC136
1683	YY/T 1225-2014	Mycoplasma pneumonia antibody detection kit	2014-06-17	2015-07-01	SAC/TC136
1684	YY/T 1667-2020	Chlamydia pneumoniae IgG antibody detection kit (enzyme-linked immunosorbent assay)	2020-03-31	2021-04-01	SAC/TC136
1685	YY/T 1597-2017	Newborn phenylalanine determination kit	2017-12-05	2018-12-01	SAC/TC136
1686	YY/T 1525-2017	Methamphetamine detection kit (colloidal gold method)	2017-05-02	2018-04-01	SAC/TC136
1687	YY/T 1595-2017	Ketamine test kit (colloidal gold method)	2017-12-05	2018-12-01	SAC/TC136
1688	YY/T 1656-2020	Morphine detection kit (colloidal gold method)	2020-02-25	2021-03-01	SAC/TC136
1689	YY/T 1673-2019	Amphetamine detection kit (colloidal gold method)	2019-10-23	2020-10-01	SAC/TC136
1690	YY/T 1175-2010	Reagents for quantitative determination of tumor markers (kit) (chemiluminescence immunoassay)	2010-12-27	2012-06-01	SAC/TC136
1691	YY/T 1160-2009	Carcinoembryonic antigen ( CEA ) quantitative determination kit (kit) (chemiluminescence immunoassay)	2009-12-30	2011-06-01	SAC/TC136
1692	YY/T 1161-2009	Tumor-associated antigen CA125 quantitative	2009-12-30	2011-06-01	SAC/TC136



Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
		determination reagent (kit) (chemiluminescence immunoassay)			
1693	YY/T 1162-2009	Reagent for quantitative determination of alpha-fetoprotein (kit) (chemiluminescence immunoassay)	2009-12-30	2011-06-01	SAC/TC136
1694	YY/T 1216-2020	Alpha-fetoprotein determination kit	2020-06-30	2021-06-01	SAC/TC136
1695	YY/T 1163-2009	Reagent (kit) for quantitative determination of total prostate specific antigen ( t-PSA ) (chemiluminescence immunoassay)	2009-12-30	2011-06-01	SAC/TC136
1696	YY/T 1249-2014	Free prostate specific antigen quantitative labeling immunoassay kit	2014-06-17	2015-07-01	SAC/TC136
1697	YY/T 1262-2015	Neuron-specific enolase quantitative labeling immunoassay kit	2015-03-02	2016-01-01	SAC/TC136
1698	YY/T 1176-2010	Reagent for quantitative determination of cancer antigen CA15-3 (kit) (chemiluminescence immunoassay)	2010-12-27	2012-06-01	SAC/TC136
1699	YY/T 1177-2010	Reagent for quantitative determination of cancer antigen CA72-4 (kit) (chemiluminescence immunoassay)	2010-12-27	2012-06-01	SAC/TC136
1700	YY/T 1178-2010	Reagent for quantitative determination of carbohydrate antigen CA19-9 (kit) (chemiluminescence immunoassay)	2010-12-27	2012-06-01	SAC/TC136
1701	YY/T 1179-2010	Carbohydrate antigen CA50 quantitative reagent (kit) (chemiluminescence immunoassay)	2010-12-27	2012-06-01	SAC/TC136
1702	YY/T 1456-2016	Ferritin quantitative detection reagent (kit)	2016-01-26	2017-01-01	SAC/TC136
1703	YY/T 1192-2011	Human chorionic gonadotropin ( HCG ) quantitative determination kit (chemiluminescence immunoassay)	2011-12-31	2013-06-01	SAC/TC136
1704	YY/T 1257-2015	Free human chorionic gonadotropin $\beta$ subunit quantitative labeling immunoassay kit	2015-03-02	2016-01-01	SAC/TC136
1705	YY/T 1214-2019	Human chorionic gonadotropin determination kit	2019-07-24	2020-08-01	SAC/TC136
1706	YY/T 1672-2019	Pepsinogen I/II Assay Kit	2019-10-23	2020-10-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1707	YY/T 1674-2019	Insulin-like growth factor I determination kit	2019-10-23	2020-10-01	SAC/TC136
1708	YY/T 1516-2017	Prolactin quantitative labeling immunoassay kit	2017-03-28	2018-04-01	SAC/TC136
1709	YY/T 1252-2015	Total IgE quantitative labeling immunoassay kit	2015-03-02	2016-01-01	SAC/TC136
1710	YY/T 1581-2018	Allergen-specific IgE antibody detection kit	2018-02-24	2019-03-01	SAC/TC136
1711	YY/T 1221-2013	Cardiac troponin I diagnostic kit (kit) (colloidal gold method)	2013-10-21	2014-10-01	SAC/TC136
1712	YY/T 1233-2014	Reagent for quantitative determination of cardiac troponin - I (kit) (chemiluminescence immunoassay)	2014-06-17	2015-07-01	SAC/TC136
1713	YY/T 1451-2016	Brain natriuretic peptide and N-terminal brain natriuretic peptide precursor detection kit (kit) (quantitative labeling immunoassay method)	2016-01-26	2017-01-01	SAC/TC136
1714	YY/T 1513-2017	C- reactive protein assay kit	2017-03-28	2018-04-01	SAC/TC136
1715	YY/T 1588-2018	Procalcitonin determination kit	2018-02-24	2019-03-01	SAC/TC136
1716	YY/T 1442-2016	$\beta$ 2-microglobulin quantitative detection reagent (kit)	2016-01-26	2017-01-01	SAC/TC136
1717	YY/T 1422-2016	Serum pregnancy-associated plasma protein A detection kit (kit) (quantitative labeling immunoassay method)	2016-07-29	2017-06-01	SAC/TC136
1718	YY/T 1217-2013	Luteinizing hormone quantitative labeling immunoassay kit	2013-10-21	2014-10-01	SAC/TC136
1719	YY/T 1213-2019	Follicle Stimulating Hormone Determination Kit	2019-5-31	2020-06-01	SAC/TC136
1720	YY/T 1164-2009	Human chorionic gonadotropin ( HCG ) test paper (colloidal gold immunochromatographic method)	2009-12-30	2011-06-01	SAC/TC136
1721	YY/T 1222-2014	Quantitative labeling immunoassay kit for total triiodothyronine	2014-06-17	2015-07-01	SAC/TC136
1722	YY/T 1223-2014	Total Thyroxine Quantitative Labeling Immunoassay Kit	2014-06-17	2015-07-01	SAC/TC136
1723	YY/T 1721-2020	Free thyroxine determination kit	2020-06-30	2021-12-01	SAC/TC136
1724	YY/T 1724-2020	Free Triiodothyronine Determination Kit	2020-06-30	2021-06-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1725	YY/T 1218-2013	Thyroid Stimulating Hormone Quantitative Labeling Immunoassay Kit	2013-10-21	2014-10-01	SAC/TC136
1726	YY/T 1664-2019	Parathyroid hormone determination kit	2019-07-24	2020-08-01	SAC/TC136
1727	YY/T 1589-2018	Estradiol determination kit (chemiluminescence immunoassay)	2018-04-11	2019-05-01	SAC/TC136
1728	YY/T 1663-2019	Progesterone determination kit	2019-05-31	2020-06-01	SAC/TC136
1729	YY/T 1250-2014	Insulin quantitative labeling immunoassay kit	2014-06-17	2015-07-01	SAC/TC136
1730	YY/T 1518-2017	C-Peptide ( CP ) Quantitative Labeling Immunoassay Kit	2017-03-28	2018-04-01	SAC/TC136
1731	YY/T 1593-2018	Growth hormone assay kit	2018-02-24	2019-03-01	SAC/TC136
1732	YY/T 1193-2011	Kit for quantitative determination of follicle-stimulating hormone ( FSH ) (chemiluminescence immunoassay)	2011-12-31	2013-06-01	SAC/TC136
1733	YY/T 1585-2017	Kit for determination of total 25 - hydroxyvitamin D (labeled immunoassay)	2017-12-05	2018-12-01	SAC/TC136
1734	YY/T 1677-2019	Vitamin B <sub>12</sub> determination kit (labeled immunoassay method)	2019-10-23	2020-10-01	SAC/TC136
1735	YY/T 1583-2018	Folic acid determination kit (chemiluminescence immunoassay)	2018-02-24	2019-03-01	SAC/TC136
1736	YY/T 1458-2016	Anti-thyroid peroxidase antibody quantitative detection kit (kit) (chemiluminescence immunoassay)	2016-01-26	2017-01-01	SAC/TC136
1737	YY/T 1594-2018	Human anti-thyroglobulin antibody determination kit	2018-04-11	2019-05-01	SAC/TC136
1738	YY/T 1220-2013	Creatine kinase isoenzyme ( CK-MB ) diagnostic kit (kit) (colloidal gold method)	2013-10-21	2014-10-01	SAC/TC136
<b>(10) Microbiology reagents</b>					
1739	YY/T 1191-2011	Antibacterial drug sensitive paper	2011-12-31	2013-06-01	SAC/TC136
1740	YY/T 1726-2020	Concentration gradient agar diffusion drug susceptibility strip	2020-06-30	2021-12-01	SAC/TC136
1741	YY/T 1682-2019	Ureaplasma /Mycoplasma hominis culture and drug sensitivity detection kit	2019-10-23	2021-10-01	SAC/TC136
1742	YY/T 1729-2020	Fungi ( 1-3 ) - beta] -D -glucan assay kit	2020-06-30	2021-06-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1743	YY/T 0576-2005	Columbia Blood Agar Basal Medium	2005-12-07	2006-12-01	SAC/TC136
1744	YY/T 0578-2005	Salmonella and Shigella agar medium	2005-12-07	2006-12-01	SAC/TC136
1745	YY/T 0665-2008	MH agar medium	2008-04-25	2009-06-01	SAC/TC136
1746	YY/T 1165-2009	Sabao weak agar medium	2009-12-30	2011-06-01	SAC/TC136
1747	YY/T 1166-2009	Neisseria gonorrhoeae agar basal medium	2009-12-30	2011-06-01	SAC/TC136
1748	YY/T 1167-2009	Anaerobic Blood Agar Basal Medium	2009-12-30	2011-06-01	SAC/TC136
1749	YY/T 1169-2009	MacConkey Agar	2009-12-30	2011-06-01	SAC/TC136
1750	YY/T 1171-2009	Modified Roche Basal Medium	2009-12-30	2011-06-01	SAC/TC136
1751	YY/T 1185-2010	Brain Heart Infusion Medium	2010-12-27	2012-06-01	SAC/TC136
1752	YY/T 1186-2010	MH broth medium	2010-12-27	2012-06-01	SAC/TC136
1753	YY/T 1188-2010	Eosin Methylene Blue Agar Medium	2010-12-27	2012-06-01	SAC/TC136
1754	YY/T 1189-2010	China Blue Agar Medium	2010-12-27	2012-06-01	SAC/TC136
1755	YY/T 1190-2010	Lactose bile salt fermentation medium	2010-12-27	2012-06-01	SAC/TC136
1756	YY/T 1208-2013	Thiosulfate - citrate - bile salt - sucrose ( TCBS ) agar medium	2013-10-21	2014-10-01	SAC/TC136
1757	YY/T 1209-2013	BCYE agar medium	2013-10-21	2014-10-01	SAC/TC136
1758	YY/T 1210-2013	Macconkey Sorbitol Agar	2013-10-21	2014-10-01	SAC/TC136
1759	YY/T 1211-2013	Mannitol High Salt Agar Medium	2013-10-21	2014-10-01	SAC/TC136
1760	YY/T 1212-2013	Gentamicin Agar Basal Medium	2013-10-21	2014-10-01	SAC/TC136
1761	YY/T 1239-2014	Agar plate medium	2014-06-17	2015-07-01	SAC/TC136
1762	YY/T 0575-2005	Thioglycollate fluid medium	2005-12-07	2006-12-01	SAC/TC136
1763	YY/T 0577-2005	Nutrient agar medium	2005-12-07	2006-12-01	SAC/TC136
1764	YY/T 1187-2010	Nutrient broth	2010-12-27	2012-06-01	SAC/TC136
1765	YY/T 1219-2013	Tryptone Soy Broth Medium	2013-10-21	2014-10-01	SAC/TC136
1766	YY/T 1170-2009	Basic Peptone Aqueous Medium	2009-12-30	2011-06-01	SAC/TC136
1767	YY/T 1168-2009	Chocolate Agar Basal Medium	2009-12-30	2011-06-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(11) Molecular biology reagents</b>					
1768	GB/T 39367.1-2020	In vitro diagnostic test system. Qualitative in vitro test procedures of nucleic acid for the detection and identification of pathogenic microorganisms. Part 1: General requirements, terms and definitions	2020-11-19	2022-06-01	SAC/TC136
1769	YY/T 1153-2009	DNA microarray chip for in vitro diagnosis	2009-12-30	2011-06-01	SAC/TC136
1770	YY/T 1182-2020	Reagents (kits) for nucleic acid amplification detection	2020-02-21	2021-01-01	SAC/TC136
1771	YY/T 1303-2015	Nucleic acid amplification reverse dot hybridization reagent (kit)	2015-03-02	2016-01-01	SAC/TC136
1772	YY/T 1725-2020	Bacterial and fungal infection multiple nucleic acid detection kit	2020-06-30	2021-12-01	SAC/TC136
1773	YY/T 1459-2016	Human gene in situ hybridization detection kit	2016-01-26	2017-01-01	SAC/TC136
1774	YY/T 1586-2018	Tumor personalized treatment-related gene mutation detection kit (fluorescence PCR method)	2018-02-24	2019-03-01	SAC/TC136
1775	YY/T 1731-2020	Human Gene Single Nucleotide Polymorphism ( SNP ) Detection Kit	2020-06-30	2021-06-01	SAC/TC136
1776	YY/T 1717-2020	Nucleic acid extraction kit (magnetic bead method)	2020-03-31	2021-04-01	SAC/TC136
1777	YY/T 1462-2016	A H1N1 influenza virus RNA detection kit (fluorescence PCR method)	2016-01-26	2017-01-01	SAC/TC136
1778	YY/T 1596-2017	Influenza A virus nucleic acid detection kit (fluorescence PCR method)	2017-12-05	2018-12-01	SAC/TC136
1779	YY/T 1226-2014	Human papillomavirus nucleic acid (typing) detection kit (kit)	2014-06-17	2015-07-01	SAC/TC136
1780	YY/T 1515-2017	Human Immunodeficiency Virus ( Type I ) Nucleic Acid Quantitative Detection Kit	2017-05-02	2018-04-01	SAC/TC136
1781	YY/T 1424-2016	Chlamydia trachomatis DNA detection kit (fluorescence PCR method)	2016-01-26	2017-01-01	SAC/TC136
1782	YY/T 1256-2015	Ureaplasma urealyticum nucleic acid amplification detection kit	2015-03-02	2016-01-01	SAC/TC136

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
1783	YY/T 1180-2010	Human Leukocyte Antigen ( HLA ) Genotyping Kit ( SSP Method)	2010-12-27	2012-06-01	SAC/TC136
1784	YY/T 1224-2014	Detection kit for chromosomal and gene abnormalities related to bladder cancer cells (fluorescence in situ hybridization)	2014-06-17	2015-07-01	SAC/TC136
1785	YY/T 1657-2019	Preimplantation chromosome aneuploidy detection kit (sequencing method)	2019-07-24	2020-08-01	SAC/TC136
1786	YY/T 1591-2017	Human EGFR gene mutation detection kit	2017-12-05	2018-12-01	SAC/TC136
1787	YY/T 1527-2017	$\alpha$ / $\beta$ -Thalassemia Genotyping Test Kit	2017-03-28	2018-04-01	SAC/TC136
1788	YY/T 1261-2015	HER2 gene detection kit (fluorescence in situ hybridization method)	2015-03-02	2016-01-01	SAC/TC136

## 32. Other

Serial number	Standard number	Standard name	Release date	Implementation date	Focal point
<b>(1) Facial flusher</b>					
1789	YY/T 0981-2016	Disposable facial features irrigator	2016-03-23	2017-01-01	SAC/TC95
<b>(2) Glass thermometer</b>					
1790	GB 1588-2001	Glass thermometer	2001-12-04	2002-04-01	State Food and Drug Administration
<b>(3) Sphygmomanometer and sphygmomanometer</b>					
1791	GB 3053-1993	Sphygmomanometer and sphygmomanometer	1993-10-16	1994-06-01	SAC/TC10/SC5