appendix

List of Compulsory Standards Applicable to Medical Device Products

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| --- | --- | --- | --- | --- | --- | --- |
| **classification code** | | **product name** | **Applicable strong standard** | | | |
| 01-01 Ultrasonic surgery equipment and accessories | 02 High Intensity Ultrasound Therapy Equipment | Ultrasonic Therapy Apparatus, Ultrasound Therapy System, Focused Ultrasound Therapy System for Fat Reduction | YY 9706.262-2021 Medical Electrical Equipment Part 2-62: Special Requirements for Basic Safety and Essential Performance of High Intensity Ultrasound Therapy (HITU) Equipment (Implementation Date: May 1, 2023) |  |  |  |
| MRI-guided high-intensity focused ultrasound therapy system | YY 9706.262-2021 Medical Electrical Equipment Part 2-62: Special Requirements for Basic Safety and Essential Performance of High Intensity Ultrasound Therapy (HITU) Equipment (Implementation Date: May 1, 2023) | YY 9706.233-2021 Medical Electrical Equipment Part 2-33: Special Requirements for Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis (Implementation Date: May 1, 2023) | YY 0592-2016 High Intensity Focused Ultrasound (HIFU) Therapy System |  |
| Tumor Ablation Focused Ultrasound Therapy System, Tumor Focused Ultrasound Therapy System, Tumor High Intensity Focused Ultrasound Therapy System | YY 9706.262-2021 Medical Electrical Equipment Part 2-62: Special Requirements for Basic Safety and Essential Performance of High Intensity Ultrasound Therapy (HITU) Equipment (Implementation Date: May 1, 2023) | YY 0592-2016 High Intensity Focused Ultrasound (HIFU) Therapy System. |  |  |
| 01-02Laser surgery equipment and accessories | 01Laser surgery equipment | carbon dioxide laser therapy machine | GB 11748-2005 Carbon dioxide laser therapy machine | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024) | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements |  |
| Nd-doped yttrium aluminum garnet laser therapy machine | YY 0307-2011 Continuous wave neodymium-doped yttrium aluminum garnet laser treatment machine | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024) | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements | YY 1300-2016 Laser Therapy Equipment Pulse Nd-Doped Yttrium Aluminum Garnet Laser Therapy Machine |
| Holmium (Ho:YAG) laser therapy machine | YY 0846-2011 Laser treatment equipment Holmium-doped yttrium aluminum garnet laser treatment machine | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024 ) | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements |  |
| 01-03 High Frequency/RF Surgical Equipment and Accessories | 01High frequency surgical equipment | High Frequency Electrocautery Apparatus | GB9706.202-2021 Medical Electrical Equipment Part 2-2: Special Requirements for Basic Safety and Basic Performance of High-Frequency Surgical Equipment and High-Frequency Accessories (Implementation Date: May 1, 2023) |  |  |  |
| 02 Radiofrequency ablation equipment | Radiofrequency Therapy Apparatus, Radiofrequency Ablation Therapy Apparatus, Radiofrequency Thermocoagulator, Radiofrequency Ablation Generator, Radiofrequency Ablation System | YY 0897-2013 Ear, Nose and Throat Radiofrequency Ablation Equipment | GB9706.202-2021 Medical Electrical Equipment Part 2-2: Special Requirements for Basic Safety and Basic Performance of High-Frequency Surgical Equipment and High-Frequency Accessories (Implementation Date: May 1, 2023) |  |  |
| Cardiac Ablation System | GB9706.202-2021 Medical Electrical Equipment Part 2-2: Special Requirements for Basic Safety and Basic Performance of High-Frequency Surgical Equipment and High-Frequency Accessories (Implementation Date: May 1, 2023) |  |  |  |
| 03 Argon protection gas condensation equipment | 01-03-03 is applicable under all categories | GB9706.202-2021 Medical Electrical Equipment Part 2-2: Special Requirements for Basic Safety and Basic Performance of High-Frequency Surgical Equipment and High-Frequency Accessories (Implementation Date: May 1, 2023) |  |  |  |
| 04 Electrodes and catheters for high frequency/radio frequency | laparoscopic scissors | GB9706.202-2021 Medical Electrical Equipment Part 2-2: Special Requirements for Basic Safety and Basic Performance of High-Frequency Surgical Equipment and High-Frequency Accessories (Implementation Date: May 1, 2023) |  |  |  |
| Radiofrequency Ablation Catheter | YY 0778-2018 Radiofrequency Ablation Catheter | GB9706.202-2021 Medical Electrical Equipment Part 2-2: Special Requirements for Basic Safety and Basic Performance of High-Frequency Surgical Equipment and High-Frequency Accessories (Implementation Date: May 1, 2023) | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1: General Requirements |  |
| 05 Irrigation pump for radiofrequency ablation equipment | 01-03-05 applies under all categories | GB9706.202-2021 Medical Electrical Equipment Part 2-2: Special Requirements for Basic Safety and Basic Performance of High-Frequency Surgical Equipment and High-Frequency Accessories (Implementation Date: May 1, 2023) |  |  |  |
| 01-04 Microwave surgery equipment | 01Microwave surgery equipment | Microwave scalpel, microwave ablation device, microwave ablation therapy device | GB 9706.206-2020 Medical Electrical Equipment Part 2-6: Special Requirements for Basic Safety and Essential Performance of Microwave Therapy Equipment | YY 0838-2021 Microwave thermal coagulation equipment (implementation time: 2023/5/1) | YY 0899-2020 General requirements for accessories of medical microwave equipment |  |
| 01-06Shock wave surgery equipment | 01Shock wave lithotripter | extracorporeal lithotripsy device | GB9706.236-2021 Medical Electrical Equipment Part 2-36: Special Requirements for Basic Safety and Basic Performance of In vitro Lithotripsy Equipment (Implementation Date: May 1, 2023) |  |  |  |
| 01-08 Surgical lighting equipment | 01 Surgical shadowless lamp | Surgical shadowless lamp, mobile surgical shadowless lamp, emergency surgery shadowless lamp | YY 9706.241-2020 Medical Electrical Equipment Part 2-41:  Particular Requirements for Basic Safety and Essential Performance of Surgical Shadowless Lamps and Diagnostic Lighting Lamps |  |  |  |
| 01-10 Other surgical equipment | 03Electric stapler | Applicable products under 01-10-03 are applicable | YY 0876-2013 Linear cutting stapler and components | YY 0875-2013 Linear staplers and components |  |  |
| 02-01 Surgical instruments - knife | 01 Scalpel | Scalpel blade, disposable sterile surgical blade, disposable sterile dermatome | GB 8662-2006 Matching dimensions of surgical blades and surgical knife handles |  |  |  |
| 02-13 Surgical instruments - kiss (suture) instruments and materials | 01 stapler (with nails) | Stapler | YY 0875-2013 Linear staplers and components |  |  |  |
| 02 stapler (without nails) | cutting stapler | YY 0876-2013 Linear cutting stapler and components |  |  |  |
| 06 absorbable suture | synthetic absorbable suture, polyglycolic acid absorbable suture, polylactic acid absorbable suture, needled synthetic absorbable suture, needled polyglycolic acid absorbable suture, needled polylactic acid absorbable suture, absorbable Sexual surgical suture  animal source absorbable suture, needled animal source absorbable suture, sheep intestine suture, collagen suture, sheep intestine suture with needle, collagen suture with needle | YY 1116-2020 Absorbable surgical sutures |  |  |  |
| 07 Non-absorbable sutures | Natural nonabsorbable suture, silk suture, silk suture, needled natural nonabsorbable suture, needled silk suture, needled silk suture synthetic nonabsorbable suture, needled synthetic nonabsorbable suture,  polybutylene Sutures, stainless steel sutures, polypropylene sutures, nylon sutures, titanium sutures, polyester sutures, polyamide sutures | YY 0167-2020 Non-absorbable surgical sutures |  |  |  |
| 02-15 Surgical instruments - other instruments | 09 handle | scalpel handle | GB 8662-2006 Matching dimensions of surgical blades and surgical knife handles |  |  |  |
| 03-13 Nerve and Cardiovascular Surgical Devices - Cardiovascular Interventional Devices | 01 contrast catheter | Angiography Catheters, Angiography Catheters, Angiography Catheters for Peripheral Vascular | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1: General Requirements |  |  |  |
| 02 guide catheter | Guide catheters, guide catheters, support catheters, guide catheters for peripheral blood vessels | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1: General Requirements |  |  |  |
| 03Central venous catheter | Central venous catheters, medicated central venous catheters | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1: General Requirements | YY 0285.3-2017 Intravascular Catheters Disposable Sterile Catheters Part 3: Central Venous Catheters |  |  |
| 05 perfusion catheter | perfusion catheter | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1: General Requirements |  |  |  |
| 06 Balloon Dilation Catheter | Coronary Balloon Dilation Catheters, PTCA Catheters, PTA Catheters, PTCA Balloon Dilation Catheters, Non-compliant PTCA Balloon Dilation Catheters, Intraaortic Balloon Catheters, Rapid Exchange Balloon Dilation Catheters, Medicated Balloon Dilation Catheters | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1: General Requirements | YY 0285.4-2017 Intravascular Catheters Disposable Sterile Catheters Part 4: Balloon Dilatation Catheters |  |  |
| 07 cutting balloon | Cutting Balloon, Peripheral Cutting Balloon | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1: General Requirements |  |  |  |
| 08 contrast balloon | venography balloon catheter | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1: General Requirements |  |  |  |
| 09 Blocking Balloon | occluded balloon catheter, occluded balloon catheter | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1: General Requirements |  |  |  |
| 10 thrombus aspiration catheter | thrombus aspiration catheter | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1: General Requirements |  |  |  |
| 11 Trocar Peripheral Catheters | trocar peripheral catheter | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1: General Requirements |  |  |  |
| 12 puncture needles | Vascular puncture needle | YY 0450.1-2020 Disposable sterile intravascular catheter accessories Part 1: Guiding device |  |  |  |
| 13 guide cannula | Guide cannula | YY 0450.1-2020 Disposable sterile intravascular catheter accessories Part 1: Guiding device |  |  |  |
| 14 introducer sheath | Introducer sheath, introducer sheath, arterial sheath, venous vascular sheath, micropuncture vascular sheath, tear-away vascular sheath | YY 0450.1-2020 Disposable sterile intravascular catheter accessories Part 1: Guiding device |  |  |  |
| 15 dilators | dilator | YY 0450.1-2020 Disposable sterile intravascular catheter accessories Part 1: Guiding device |  |  |  |
| 16 guide wire | Hard guide wire, soft tip guide wire, renal artery guide wire, micro guide wire, push guide wire, super smooth guide wire, guiding guide wire, contrast guide wire | YY 0450.1-2020 Disposable sterile intravascular catheter accessories Part 1: Guiding device |  |  |  |
| 26 microcatheters | Microcatheters, Peripheral Intervention Microcatheters, Delivery Microcatheters, Floating Microcatheters, Disposable Microcatheters | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1: General Requirements |  |  |  |
| 05-01 Radiation therapy equipment | 01Medical electron accelerator | Medical electron linear accelerator, medical electron cyclotron, helical tomotherapy system, X-ray stereotactic radiosurgery system, mobile electron beam intraoperative radiotherapy system | GB 15213-2016 Performance and test methods of medical electron accelerators | YY 1650-2019 X-ray image-guided radiotherapy equipment performance and test methods | GB 9706.201-2020 Medical Electrical Equipment Part 2-1: Particular Requirements for Basic Safety and Essential Performance of Electron Accelerators with Energy from 1 MeV to 50 MeV (2023-05-01) | YY 0637-2013 Safety requirements for radiotherapy planning systems for medical electrical equipment (applicable to radiotherapy planning systems) |
| YY 0721-2009 Safety of radiotherapy record and verification system for medical electrical equipment (applicable to radiotherapy record and verification system) | YY 9706.268-2022 Part 2-68 of medical electrical equipment: Particular requirements for basic safety and essential performance of X-ray image-guided radiotherapy equipment for electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment (2025-06 -01) |  |  |
| 02Medical light ion therapy system | Medical light ion therapy system | YY 1650-2019 X-ray image-guided radiotherapy equipment performance and test methods | YY 9706.264-2022 Medical Electrical Equipment Part 2-64: Special Requirements for Basic Safety and Essential Performance of Light Ion Beam Medical Electrical Equipment (2025-06-01) | YY 9706.268-2022 Part 2-68 of medical electrical equipment: Particular requirements for basic safety and essential performance of X-ray image-guided radiotherapy equipment for electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment (2025-06 -01) |  |
| 03Medical X-ray therapy equipment | All products under 05-01-03 are applicable | YY 9706.208-2021 Medical electrical equipment Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment with energy from 10 kV to 1 MV (2023-05-01) | YY 0637-2013 Safety requirements for radiotherapy planning systems for medical electrical equipment (applicable to radiotherapy planning systems) | YY 0721-2009 Safety of radiotherapy record and verification system for medical electrical equipment (applicable to radiotherapy record and verification system) | YY 1650-2019 X-ray image-guided radiotherapy equipment performance and test methods |
| 04 Gamma beam teletherapy machine | Cobalt-60 teletherapy machine | YY 0096-2019 Cobalt-60 teletherapy machine | GB 9706.211-2020 Medical Electrical Equipment Part 2-11: Special Requirements for Basic Safety and Essential Performance of Gamma Beam Therapy Equipment (2023-05-01) | YY 0637-2013 Safety requirements for radiotherapy planning systems for medical electrical equipment (applicable to radiotherapy planning systems) | YY 0721-2009 Safety of radiotherapy record and verification system for medical electrical equipment (applicable to radiotherapy record and verification system) |
| YY 0775-2010 High-energy X(γ) beam dose calculation accuracy requirements and test methods for teletherapy planning system (if applicable) | YY 0831.1-2011 Gamma Beam Stereotactic Radiotherapy System Part 1: Head Multi-source Gamma Beam Stereotactic Radiotherapy System (if applicable) | YY 0831.2-2015 Gamma Beam Stereotactic Radiotherapy System Part 2: Body Multi-source Gamma Beam Stereotactic Radiotherapy System (if applicable) |  |
| Body Multi-source Gamma (γ) Beam Stereotactic Radiotherapy System | YY 0831.2-2015 Gamma Beam Stereotactic Radiotherapy System Part 2: Body Multi-source Gamma Beam Stereotactic Radiotherapy System | GB 9706.211-2020 Medical Electrical Equipment Part 2-11: Special Requirements for Basic Safety and Essential Performance of Gamma Beam Therapy Equipment (2023-05-01) | YY 0637-2013 Safety requirements for radiotherapy planning systems for medical electrical equipment (applicable to radiotherapy planning systems) | YY 0721-2009 Safety of radiotherapy record and verification system for medical electrical equipment (applicable to radiotherapy record and verification system) |
| YY 0775-2010 High-energy X(γ) beam dose calculation accuracy requirements and test methods for teletherapy planning system (if applicable) | YY 0831.1-2011 Gamma Beam Stereotactic Radiotherapy System Part 1: Head Multi-source Gamma Beam Stereotactic Radiotherapy System (if applicable) |  |  |
| 05 Brachytherapy afterloading equipment | All products under 05-01-05 are applicable | GB 9706.217 Medical Electrical Equipment Part 2-17: Special Requirements for Basic Safety and Essential Performance of Automatically Controlled Brachytherapy Aftermarket Equipment (2023-05-01) | YY 0637-2013 Safety requirements for radiotherapy planning systems for medical electrical equipment (applicable to radiotherapy planning systems) | YY 0721-2009 Safety of radiotherapy record and verification system for medical electrical equipment (applicable to radiotherapy record and verification system) |  |
| 06Radioactive Seed Implantation Therapy System | Radioactive seed implant therapy system | YY 1650-2019 X-ray image-guided radiotherapy equipment performance and test methods | YY 0637-2013 Safety requirements for radiotherapy planning systems for medical electrical equipment (applicable to radiotherapy planning systems) | YY 0721-2009 Safety of radiotherapy record and verification system for medical electrical equipment (applicable to radiotherapy record and verification system) | YY 9706.268-2022 Part 2-68 of medical electrical equipment: Particular requirements for basic safety and essential performance of X-ray image-guided radiotherapy equipment for electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment (2025-06 -01) |
| 05-02 Radiation therapy simulation and image guidance equipment | 01Radiation therapy simulation system | All products under 05-02-01 are applicable | GB 9706.229-2021 Medical Electrical Equipment Part 2-29: Special Requirements for Basic Safety and Essential Performance of Radiotherapy Simulators (2023-05-01) |  |  |  |
| 02X-ray image guidance system for radiation therapy | All products under 05-02-02 are applicable | YY 1650-2019 X-ray image-guided radiotherapy equipment performance and test methods | YY 9706.268-2022 Part 2-68 of medical electrical equipment: Particular requirements for basic safety and essential performance of X-ray image-guided radiotherapy equipment for electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment (2025-06 -01) |  |  |
| 05-03 Radiation therapy collimation device | 01X radiation radiotherapy stereotaxic system | Stereotactic radiation therapy planning system | YY 0832.2-2015 Stereotactic and planning system for X-radiation radiotherapy Part 2: Stereotactic and planning system for body X-radiation radiotherapy | YY 0637-2013 Safety requirements for radiotherapy planning systems for medical electrical equipment (applicable to radiotherapy planning systems) | YY 0721-2009 Safety of radiotherapy record and verification system for medical electrical equipment (applicable to radiotherapy record and verification system) |  |
| Stereotactic system for X-radiation radiotherapy | YY 0832.1-2011 Stereotactic and planning system for X-ray radiotherapy Part 1: Stereotactic and planning system for head X-ray radiotherapy |  |  |  |
| 02 Collimation beam limiting device | — | YY 0637-2013 Safety requirements for radiotherapy planning systems for medical electrical equipment (applicable to radiotherapy planning systems) | YY 0721-2009 Safety of radiotherapy record and verification system for medical electrical equipment (applicable to radiotherapy record and verification system) |  |  |
| 06-01 Diagnostic X-ray machine | 01 Angiographic X-ray machine | — | GB 9706.243-2021 Medical Electrical Equipment Part 2-43: Special Requirements for Basic Safety and Essential Performance of X-ray Equipment for Interventional Operations (Implementation Date: May 1, 2023) | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.254-2020 Medical Electrical Equipment Part 2-54: Special Requirements for Basic Safety and Essential Performance of X-ray Photography and Fluoroscopy Equipment (Implementation Date: May 1, 2023) |
| 02 Urinary X-ray machine | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.254-2020 Medical Electrical Equipment Part 2-54: Special Requirements for Basic Safety and Essential Performance of X-ray Photography and Fluoroscopy Equipment (Implementation Date: May 1, 2023) |  |
| 03 Mammography machine | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.245-2020 Medical Electrical Equipment Part 2-45: Special Requirements for Basic Safety and Essential Performance of Mammography Equipment and Mammography Stereotaxic Devices (Implementation Date: May 1, 2023) |  |
| 04 Dental X-ray machine | — | GB 9706.263-2020 Medical Electrical Equipment Part 2-63: Special Requirements for Basic Safety and Basic Performance of Extraoral Imaging Dental X-ray Machines (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.265-2021 Medical Electrical Equipment Part 2-65: Special Requirements for Basic Safety and Basic Performance of Intraoral Imaging Dental X-ray Machines (Implementation Date: May 1, 2023) |
| 05 Perspective photography X-ray machine | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.254-2020 Medical Electrical Equipment Part 2-54: Special Requirements for Basic Safety and Essential Performance of X-ray Photography and Fluoroscopy Equipment (Implementation Date: May 1, 2023) | GB 9706.243 -2021 Medical Electrical Equipment Part 2-43: Special Requirements for Basic Safety and Essential Performance of X-ray Equipment for Interventional Operations (if applicable) (implementation date: May 1, 2023) |
| 06 Mobile C-arm X-ray machine | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.254-2020 Medical Electrical Equipment Part 2-54: Special Requirements for Basic Safety and Essential Performance of X-ray Photography and Fluoroscopy Equipment (Implementation Date: May 1, 2023) | GB 9706.243 -2021 Medical Electrical Equipment Part 2-43: Special Requirements for Basic Safety and Essential Performance of X-ray Equipment for Interventional Operations (if applicable) (implementation date: May 1, 2023) |
| 07 Photographic X-ray machine | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.254-2020 Medical Electrical Equipment Part 2-54: Special Requirements for Basic Safety and Essential Performance of X-ray Photography and Fluoroscopy Equipment (Implementation Date: May 1, 2023) |  |
| 08 Perspective X-ray machine | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.254-2020 Medical Electrical Equipment Part 2-54: Special Requirements for Basic Safety and Essential Performance of X-ray Photography and Fluoroscopy Equipment (Implementation Date: May 1, 2023) |  |
| 09 X-ray bone densitometer | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) |  |  |
| 10 Vehicle X-ray machine | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.254-2020 Medical Electrical Equipment Part 2-54: Special requirements for basic safety and essential performance of X-ray photography and fluoroscopy equipment (if applicable) (implementation time: May 1, 2023) | GB 9706.263-2020 Medical Electrical Equipment Part 2-63: Special Requirements for Basic Safety and Essential Performance of Extraoral Imaging Dental X-ray Machines (if applicable) (Implementation Date: May 1, 2023) |
| GB 9706.245-2020 Medical Electrical Equipment Part 2-45: Special Requirements for Basic Safety and Essential Performance of Mammography Equipment and Mammography Stereotaxic Devices (if applicable) (implementation date: May 1, 2023) | GB 9706.263-2020 Medical Electrical Equipment Part 2-63: Special Requirements for Basic Safety and Essential Performance of Extraoral Imaging Dental X-ray Machines (if applicable) (Implementation Date: May 1, 2023) | GB 9706.254-2020 Medical Electrical Equipment Part 2-54: Special requirements for basic safety and essential performance of X-ray photography and fluoroscopy equipment (if applicable) (implementation time: May 1, 2023) |  |
| 11 Portable X-ray machine | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.254-2020 Medical Electrical Equipment Part 2-54: Special Requirements for Basic Safety and Essential Performance of X-ray Photography and Fluoroscopy Equipment (Implementation Date: May 1, 2023) |  |
| 12 Limb digital tomography X-ray machine | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.254-2020 Medical Electrical Equipment Part 2-54: Special requirements for basic safety and essential performance of X-ray photography and fluoroscopy equipment (if applicable) (implementation time: May 1, 2023) |  |
| 06-02 X-ray computed tomography equipment (CT) | 01 X-ray computed tomography equipment (CT) | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.244 -2021 Medical Electrical Equipment Part 2-44: Special Requirements for Basic Safety and Essential Performance of X-ray Computed Tomography Equipment (Implementation Date: May 1, 2023) |  |
| 06-03 X-ray generating and beam limiting device | 01 X-ray high voltage generator | X-ray high voltage generator | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) |  |  |  |
| 02 X-ray tube | — | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) |  |  |  |
| 03 X-ray tube assembly | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228-2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) |  |  |
| 04 beam limiting device | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) |  |  |  |
| 06-04X-ray image receiving and processing device | 01 X-ray image intensifier, X-ray image intensifier TV system | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) |  |  |  |
| 02 X-ray detector, X-ray detector and its imaging system | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) |  |  |  |
| 06-05 X-ray accessories and auxiliary equipment | 01 Perspective photography bed | Fluoroscopy bed, X-ray gastrointestinal diagnosis bed | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) |  |  |  |
| 02 catheter bed | Cath bed, interventional operating table | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) |  |  |  |
| 03 X-ray photography patient support device | Electric photography flat bed, photography flat bed, X-ray photography bed, mobile X-ray inspection stand | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) |  |  |  |
| 12 Puncture positioning guide | Stereotaxic positioning device for mammography, breast biopsy positioning device, numerical control puncture guide, automatic puncture guide, percutaneous puncture angle locator, one-time use puncture import fixer, one-time use guide, one-time use CT positioning puncture angle guide Devices, medical image in vitro positioning stickers, X-ray film nipple positioning stickers, one-time use image positioning materials | GB 9706.245-2020 Medical Electrical Equipment Part 2-45: Particular Requirements for Basic Safety and Essential Performance of Mammography Equipment and Mammography Stereotaxic Devices |  |  |  |
| 06-06 Medical radiation protection equipment | 01 Medical radiation protection equipment | — | YY 0318-2000 Medical diagnostic X-ray radiation protection equipment Part 3: Protective clothing and gonad protection equipment |  |  |  |
| 06-07 Ultrasonic imaging diagnostic equipment | 01 Ultrasonic pulse echo imaging equipment | Ultrasonic diagnostic system, ultrasonic diagnostic instrument, endoscopic ultrasonic diagnostic instrument, intravascular ultrasonic diagnostic system, intravascular ultrasonic diagnostic instrument ultrasonic diagnostic system,  ultrasonic diagnostic instrument, sinus ultrasonic diagnostic instrument, portable ultrasonic diagnostic instrument, ultrasonic bladder scanner, skin ultrasound Diagnostic system, full digital ultrasonic diagnostic system, full digital ultrasonic diagnostic instrument, trolley type ultrasonic diagnostic instrument, medical ultrasonic image processor, handheld ultrasonic diagnostic instrument | GB 9706.237-2020 Medical Electrical Equipment Part 2-37: Special Requirements for Basic Safety and Basic Performance of Ultrasonic Diagnostic and Monitoring Equipment (Implementation Date: 2023/5/1) | GB 10152-2009 B-type ultrasonic diagnostic equipment |  |  |
| 02 Ultrasonic echo Doppler imaging equipment | Color Ultrasound Diagnostic Instrument, Color Doppler Ultrasound Diagnostic Instrument | GB 10152-2009 B-type ultrasonic diagnostic equipment | GB 9706.237-2020 Medical Electrical Equipment Part 2-37: Special Requirements for Basic Safety and Basic Performance of Ultrasonic Diagnostic and Monitoring Equipment (Implementation Date: 2023/5/1) |  |  |
| 06-08 Auxiliary equipment for ultrasonic imaging diagnosis | 01 Ultrasonic Couplant | Medical Ultrasonic Couplant | YY 0299-2016 Medical Ultrasonic Couplant |  |  |  |
| 04 Ultrasound probe | All products under 06-08-04 are applicable | GB 9706.237-2020 Medical Electrical Equipment Part 2-37: Special Requirements for Basic Safety and Basic Performance of Ultrasonic Diagnostic and Monitoring Equipment (Implementation Date: 2023/5/1) |  |  |  |
| 06-09 Magnetic resonance imaging equipment (MRI) | 01Permanent magnetic resonance imaging system | Permanent magnetic magnetic resonance imaging system, medical magnetic resonance imaging system | YY 9706.233-2021 Medical Electrical Equipment Part 2-33: Special Requirements for Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis (Implementation Date: 5/1/2023) |  |  |  |
| 02Continuous conduction magnetic resonance imaging system | Normally Conductive Magnetic Resonance Imaging System, Medical Magnetic Resonance Imaging System |  |  |  |
| 03Superconducting magnetic resonance imaging system | Superconducting magnetic resonance imaging system, medical magnetic resonance imaging system |  |  |  |
| 06-13 Optical imaging diagnostic equipment | 01 Infrared thermal imaging camera | All products under 06-13-01 are applicable | YY 9706.257-2021 Medical Electrical Equipment Part 2-57: Special Requirements for Basic Safety and Basic Performance of Non-laser Light Source Equipment Used in Treatment, Diagnosis, Monitoring and Plastic Surgery/Medical Aesthetics (Implementation Date: 5/1/2023) |  |  |  |
| 02 Infrared breast diagnostic instrument | All products under 06-13-02 are applicable | YY 9706.257-2021 Medical Electrical Equipment Part 2-57: Special Requirements for Basic Safety and Basic Performance of Non-laser Light Source Equipment Used in Treatment, Diagnosis, Monitoring and Plastic Surgery/Medical Aesthetics (Implementation Date: 5/1/2023) |  |  |  |
| 03 Optical coherence tomography system (non-ophthalmology) | All products under 06-13-03 are applicable | YY 9706.257-2021 Medical Electrical Equipment Part 2-57: Special Requirements for Basic Safety and Basic Performance of Non-laser Light Source Equipment Used in Treatment, Diagnosis, Monitoring and Plastic Surgery/Medical Aesthetics (Implementation Date: 5/1/2023) |  |  |  |
| 04 Operating microscopes (non-ophthalmological) | All products under 06-13-04 are applicable | GB 11239.1-2005 Surgical Microscope Part 1: Requirements and Test Methods |  |  |  |
| 06-14 Medical endoscope | 01 Optical endoscope | knee arthroscopy | YY 0068.1-2008 Medical Endoscope Rigid Endoscope Part 1: Optical Properties and Test Methods | YY 0068.4-2009 Medical Endoscope Rigid Endoscope Part 4: Basic Requirements |  |  |
| 02 Electrocoagulation cutting endoscope | Bladder resection endoscope, prostate resection endoscope | YY 0068.1-2008 Medical Endoscope Rigid Endoscope Part 1: Optical Properties and Test Methods | YY 0068.4-2009 Medical Endoscope Rigid Endoscope Part 4: Basic Requirements |  |  |
| 03Electronic endoscope | Electronic laparoscope, electronic laryngoscope, electronic nasopharyngoscope, electronic anorectoscope, electronic enteroscopy system, electronic cystoscope, electronic bladder pyeloscope, electronic colonoscope, electronic choledochoscope, electronic colonoscope, electronic tracheal intubation scope , electronic duodenoscope, electronic gastroscope, electronic thoraco-laparoscopy |  |  |  |  |
| 04Capsule endoscope system | All products under 06-14-04 are applicable |  |  |  |  |
| 06-15 Endoscope function supply device | 04 Endoscope air supply device | Endoscopic carbon dioxide insufflation machine | YY 0843-2011 Medical endoscope endoscope function supply device insufflation machine |  |  |  |
| 06-17 Combination function fusion imaging device | 01Single photon emission and X-ray computed tomography system | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228 -2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.244-2020 Medical Electrical Equipment Part 2-44: Special Requirements for Basic Safety and Essential Performance of X-ray Computed Tomography Equipment (Implementation Date: May 1, 2023) |  |
| 02Positron emission and X-ray computed tomography system | — | GB 9706.103-2020 Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance Collateral Standard: Radiation Protection for Diagnostic X-ray Equipment (Implementation Date: May 1, 2023) | GB 9706.228 -2020 Medical Electrical Equipment Part 2-28: Particular Requirements for Basic Safety and Essential Performance of Medical Diagnostic X-ray Tube Components (Implementation Date: May 1, 2023) | GB 9706.244-2020 Medical Electrical Equipment Part 2-44: Special Requirements for Basic Safety and Essential Performance of X-ray Computed Tomography Equipment (Implementation Date: May 1, 2023) |  |
| 07-01 Diagnostic aids | 03 ENT examination mirror | laryngoscope | YY 91136-1999 neonatal laryngoscope |  |  |  |
| 05Surface Inspection Light | Medical examination light, pediatric examination light, reflector light, head-worn examination light, spotlight | YY 9706.241-2020 Medical Electrical Equipment Part 2-41:  Special Requirements for Basic Safety and Basic Performance of Surgical Shadowless Lamps and Diagnostic Lighting Lamps (Implementation Date: 5/1/2023) |  |  |  |
| 06 Reflective appliances | Forehead mirror | YY 9706.241-2020 Medical Electrical Equipment Part 2-41:  Special Requirements for Basic Safety and Basic Performance of Surgical Shadowless Lamps and Diagnostic Lighting Lamps (Implementation Date: 5/1/2023) |  |  |  |
| 07-03 Physiological parameter analysis and measurement equipment | 01 ECG measurement and analysis equipment | Single-channel ECG, multi-channel ECG, ECG, ECG, ECG analysis system | YY 1139-2013 ECG diagnostic equipment | GB 9706.225-2021 Medical Electrical Equipment Part 2-25: Special Requirements for Basic Safety and Basic Performance of Electrocardiographs (Implementation Date: 2023.05.01) | GB 9706.247-2021 Medical Electrical Equipment Part 2-47: Special Requirements for Basic Safety and Basic Performance of Dynamic Electrocardiography System (Implementation Date: May 1, 2024) |  |
| 02 Cardiac electrophysiological mapping equipment | Electrophysiological mapper, multi-channel electrophysiological recorder |  | YY 0285.1-2017 Intravascular Catheter Disposable Sterile Catheter Part 1 | GB 9706.227-2021 Medical Electrical Equipment Part 2-27: Special Requirements for Basic Safety and Basic Performance of ECG Monitoring Equipment (2023.05.01) |  |
| 03Non-invasive blood pressure measurement equipment | Sphygmomanometer, mechanical sphygmomanometer, mercury sphygmomanometer | GB 3053-1993 Sphygmomanometer and Sphygmomanometer |  |  |  |
| Blood Pressure Monitor | YY 0670-2008 Non-invasive automatic measuring blood pressure monitor |  |  |  |
| Ambulatory blood pressure recorder, ambulatory blood pressure instrument | YY 0667-2008 Medical Electrical Equipment Part 2: Special Requirements for Safety and Basic Performance of Automatic Cycle Non-invasive Blood Pressure Monitoring Equipment |  |  |  |
| 04 Body temperature measuring equipment | glass thermometer | GB 1588-2001 glass thermometer |  |  |  |
| Digital Thermometer | YY 0785-2010 Clinical Thermometer--Performance Requirements for Continuous Measurement Electronic Thermometer |  |  |  |
| 05 Pulse oximetry equipment | pulse oximeter | YY 0784-2010 Special requirements for basic safety and main performance of medical electrical equipment and medical pulse oximeter equipment |  |  |  |
| 06 Physiological parameters induced diagnostic equipment | EEG machine | GB 9706.226-2021 Medical Electrical Equipment Part 2-26: Special Requirements for Basic Safety and Basic Performance of EEG Machines (Implementation Time 2023.05.01) | YY 9706.240-2021 Medical Electrical Equipment Part 2-40: Special Requirements for Basic Safety and Basic Performance of Myoelectric and Evoked Response Equipment (Implementation Date 2023.05.01) |  |  |
| 07-04 Monitoring equipment | 01Patient monitoring equipment | Respiratory Gas Monitor | YY 0601-2009 Special requirements for basic safety and main performance of respiratory gas monitors for medical electrical equipment | Patient monitors, multi-parameter monitors:  YY 0668-2008 Medical electrical equipment Part 2-49: Special requirements for safety of multi-parameter patient monitoring equipment YY 0667-2008 Medical electrical equipment Part 2-30: Automatic circulation non-invasive blood pressure monitoring equipment Special requirements for safety and basic performance GB 9706.237-2020 Medical electrical equipment Part 2-37: Special requirements for basic safety and basic performance of ultrasonic diagnostic and monitoring equipment (2023.05.01) GB 9706.227-2021 Medical electrical equipment Part 2-27: Special requirements for basic safety and basic performance of ECG monitoring equipment (2023.05.01) |  |  |
| 07-07 Ultrasonic measurement and analysis equipment | 01 Ultrasonic Doppler blood flow analysis equipment | All products under 07-17-01 are applicable | GB 9706.237-2020 Medical Electrical Equipment Part 2-37: Special Requirements for Basic Safety and Basic Performance of Ultrasonic Diagnostic and Monitoring Equipment (Implementation Date: 2023/5/1) |  |  |  |
| 02 Ultrasonic human tissue measurement equipment | All products under 07-17-02 are applicable | GB 9706.237-2020 Medical Electrical Equipment Part 2-37: Special Requirements for Basic Safety and Basic Performance of Ultrasonic Diagnostic and Monitoring Equipment (Implementation Date: 2023/5/1) |  |  |  |
| 07-10 Accessories, consumables | 01Invasive blood pressure sensor | Invasive Pressure Sensor | YY 0781-2010 Blood pressure sensor |  |  |  |
| 04 Pulse oximeter sensor | — | YY 0784-2010 Special requirements for basic safety and main performance of medical electrical equipment and medical pulse oximeter equipment |  |  |  |
| 07 ECG lead wire | ECG lead wire | YY 0828-2011 ECG monitor cables and lead wires |  |  |  |
| 08-01 Respiratory equipment | 01 Therapeutic ventilator (life support) | Ventilator | GB 9706.212-2020 Medical Electrical Equipment Part 2-12: Special Requirements for Basic Safety and Basic Performance of Intensive Care Ventilators (Implementation Date: May 1, 2023) | YY 0601-2009 Special requirements for basic safety and main performance of respiratory gas monitors for medical electrical equipment |  |  |
| 02 First aid and transfer ventilator | Emergency and transport ventilators, emergency ventilators | YY 0600.3-2007 Special requirements for basic safety and main performance of medical ventilators Part 3: Ventilators for first aid and transfer | YY 0601-2009 Special requirements for basic safety and main performance of respiratory gas monitors for medical electrical equipment |  |  |
| 03 High frequency ventilator | High frequency jet ventilator | YY 0042-2018 High Frequency Jet Ventilator | YY 0601-2009 Special requirements for basic safety and main performance of respiratory gas monitors for medical electrical equipment |  |  |
| 04 Household ventilator (life support) | Ventilator | YY 9706.272-2021 Medical Electrical Equipment Part 2-72: Special Requirements for Basic Safety and Essential Performance of Household Ventilators Used by Ventilator-Dependent Patients (Implementation Date: May 1, 2024) | YY 0601-2009 Special requirements for basic safety and main performance of respiratory gas monitors for medical electrical equipment |  |  |
| 05 Household respiratory support equipment (non-life support) | Ventilator, non-invasive ventilator for home use | YY 0600.1-2007 Special Requirements for Basic Safety and Main Performance of Medical Ventilators Part 1: Household Respiratory Support Equipment |  |  |  |
| 06Sleep apnea therapy equipment | positive pressure ventilation machine | YY 9706.270-2021 Medical Electrical Equipment Part 2-70: Special Requirements for Basic Safety and Basic Performance of Sleep Apnea Therapy Equipment (Implementation Date: May 1, 2024) |  |  |  |
| 08-02 Anesthesia equipment | 01 Anesthesia machine | anesthesia system, anesthesia machine | GB 9706.213-2021 Medical Electrical Equipment Part 2-13: Special Requirements for Basic Safety and Basic Performance of Anesthesia Workstations (Implementation Date: May 1, 2023) |  |  |  |
| 08-03 First aid equipment | 01 External defibrillation equipment | — | GB 9706.204-2022 Medical Electrical Equipment Part 2-4: Special Requirements for Basic Safety and Essential Performance of Cardiac Defibrillators (2024/8/1) |  |  |  |
| 02 baby incubator | — | GB 9706.219-2021 Medical Electrical Equipment Part 2-19: Special Requirements for Basic Safety and Basic Performance of Infant Incubator (Implementation Date: May 1, 2023) Infant  Transport Incubator: YY 9706.220-2021 Medical Electrical Equipment Part 2- Part 20: Particular requirements for basic safety and essential performance of infant transport incubators (implementation date: May 1, 2023) |  |  |  |
| 03 baby radiant warmer | — | YY 9706.221-2021 Medical Electrical Equipment Part 2-21: Special Requirements for Basic Safety and Essential Performance of Infant Radiant Warmers (Implementation Date: May 1, 2024) |  |  |  |
| 05 Manual resuscitator (simple respirator) | Portable oxygen respirator, simple respirator, artificial resuscitator, artificial respirator, disposable simple respirator, disposable artificial resuscitator | YY 0600.4-2013 Special Requirements for Basic Safety and Main Performance of Medical Ventilators Part 4: Manual Resuscitators |  |  |  |
| 06 Pneumatic first aid resuscitator | Pneumatic emergency resuscitator | YY 0600.5-2011 Special Requirements for Basic Safety and Main Performance of Medical Ventilators Part 5: Pneumatic First Aid Resuscitator |  |  |  |
| 08-04 Medical oxygen equipment | 02Medical molecular sieve oxygen generator | Medical molecular sieve oxygen concentrator, household molecular sieve oxygen concentrator, small medical oxygen concentrator, portable oxygen concentrator, medical oxygen concentrator | YY 9706.269-2021 Medical Electrical Equipment Part 2-69: Special Requirements for Basic Safety and Essential Performance of Oxygen Concentrators (Implementation Date: May 1, 2023) |  |  |  |
| 04Medical membrane separation oxygen generator | Medical membrane separation oxygen generator, household membrane separation oxygen generator, small medical oxygen generator, portable oxygen generator, membrane separation dispersion oxygen enrichment machine | YY 9706.269-2021 Medical Electrical Equipment Part 2-69: Special Requirements for Basic Safety and Essential Performance of Oxygen Concentrators (Implementation Date: May 1, 2023) |  |  |  |
| 08-05 Auxiliary devices for breathing, anesthesia and first aid equipment | 01 Anesthesia vaporizer | Anesthetic vaporizers, vaporizers, anesthetic gas delivery devices | GB 9706.213-2021 Medical Electrical Equipment Part 2-13: Special Requirements for Basic Safety and Basic Performance of Anesthesia Workstations (Implementation Date: May 1, 2023) |  |  |  |
| 02Medical respiratory humidifier | Medical respiratory humidifier | YY 0786-2010 Special requirements for respiratory humidification system of medical respiratory humidifier |  |  |  |
| 06Laryngoscope for endotracheal intubation | Anesthesia laryngoscope | YY 0499-2004 General technical requirements for anesthesia laryngoscope | yy 0498.1-2004 Laryngoscope connector part 1: conventional hook type handle-peeping piece connector | YY 0498.2-2004 Laryngoscope Connector Part 2: Miniature Lamp Thread and Lamp Holder with Conventional Peeping Blade |  |
| Anesthesia Laryngoscope | YY 91123-1999 Anesthesia laryngoscope (the connecting part is obsolete) | yy 0498.1-2004 Laryngoscope connector part 1: conventional hook type handle-peeping piece connector | YY 0498.2-2004 Laryngoscope Connector Part 2: Miniature Lamp Thread and Lamp Holder with Conventional Peeping Blade |  |
| 10 Anesthetic gas purification delivery and collection system | Anesthetic Gas Purification System | GB 9706.213-2021 Medical Electrical Equipment Part 2-13: Special Requirements for Basic Safety and Basic Performance of Anesthesia Workstations (Implementation Date: May 1, 2023) |  |  |  |
| 15 oxygen inhalers | buoy oxygen inhaler | YY 1107-2003 buoy type oxygen inhaler |  |  |  |
| 09-01 Electrotherapy equipment/apparatus | 01Potential therapy equipment | Potential Therapy Apparatus | YY 0649-2016 Potential Therapy Equipment |  |  |  |
| 03Low and intermediate frequency therapy equipment | Interference Electrotherapy Apparatus | YY 9706.210-2021 Medical Electrical Equipment Part 2-10: Special Requirements for Basic Safety and Essential Performance of Nerve and Muscle Stimulators (Implementation Date: 5/1/2023) |  |  |  |
| Nerve and Muscle Stimulators | YY 9706.210-2021 Medical Electrical Equipment Part 2-10: Special Requirements for Basic Safety and Essential Performance of Nerve and Muscle Stimulators (Implementation Date: 5/1/2023) |  |  |  |
| 05 Electrodes for nerve and muscle stimulators | Internal Electrodes for Nerve and Muscle Stimulators, Surface Electrodes for Nerve and Muscle Stimulators | YY 9706.210-2021 Medical Electrical Equipment Part 2-10: Special Requirements for Basic Safety and Essential Performance of Nerve and Muscle Stimulators (Implementation Date: 5/1/2023) |  |  |  |
| 09-02 Warm (cold) therapeutic equipment/apparatus | 01 Heat conduction therapy equipment | medical heating blanket | YY 9706.235-2021 Medical Electrical Equipment Part 2-35: Special Requirements for Basic Safety and Essential Performance of Medical Blanket, Pad or Mattress Heating Equipment (Implementation Date: 5/1/2023) |  |  |  |
| Hot compress | YY 0060-2018 Hot compress (bag) |  |  |  |
| Medical warming blanket | YY 9706.235-2021 Medical Electrical Equipment Part 2-35: Special Requirements for Basic Safety and Essential Performance of Medical Blanket, Pad or Mattress Heating Equipment (Implementation Date: 5/1/2023) |  |  |  |
| 02 Thermal Radiation Therapy Equipment | All products under 09-02-02 are applicable | YY0323-2018 Special requirements for safety of infrared therapy equipment | YY 0306-2018 "Special Requirements for Safety of Thermal Radiation Therapy Equipment" | YY 0323-2018 Special Requirements for Safety of Infrared Therapy Equipment |  |
| 09-03 Phototherapy equipment | 01Laser therapy equipment | Nd-doped yttrium aluminum garnet laser therapy machine | YY 0307-2011 Continuous wave neodymium-doped yttrium aluminum garnet laser treatment machine | YY 1300-2016 Laser Therapy Equipment Pulse Nd-Doped Yttrium Aluminum Garnet Laser Therapy Machine | YY 1475-2016 Laser therapy equipment Q switch Nd-doped YAG laser therapy machine | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024) |
| GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements |  |  |  |
| carbon dioxide laser therapy machine | GB 11748-2005 Carbon dioxide laser therapy machine | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024) | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements |
| Erbium-doped Fiber Laser Therapeutic Instrument | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024) | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements | YY 1301-2016 Laser Therapy Equipment Erbium Laser Therapy Machine |  |
| Ruby Laser Therapy Apparatus | YY 0983-2016 Laser Therapy Equipment Ruby Laser Therapy Machine |  |
| He-Ne Laser Therapy Machine | GB 12257-2000 General Technical Specifications for He-Ne Laser Therapy Machines |  |
| 02Photodynamic laser therapy equipment | Diode Laser Photodynamic Therapy Machine | YY 0845-2011 Laser Therapy Equipment Semiconductor Laser Photodynamic Therapy Machine | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024) | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements |  |
| 03 Photodynamic therapy equipment | All products under 09-03-03 are applicable | YY 9706.257-2021 Medical Electrical Equipment Part 2-57: Special Requirements for Basic Safety and Basic Performance of Non-laser Light Source Equipment Used in Treatment, Diagnosis, Monitoring and Plastic Surgery/Medical Aesthetics (Implementation Date: 5/1/2023) |  |  |  |
| 04Intense pulsed light therapy equipment | All products under 09-03-04 are applicable | YY 9706.257-2021 Medical Electrical Equipment Part 2-57: Special Requirements for Basic Safety and Basic Performance of Non-laser Light Source Equipment Used in Treatment, Diagnosis, Monitoring and Plastic Surgery/Medical Aesthetics (Implementation Date: 5/1/2023) |  |  |  |
| 05Red light therapy equipment | All products under 09-03-05 are applicable | YY 9706.257-2021 Medical Electrical Equipment Part 2-57: Special Requirements for Basic Safety and Basic Performance of Non-laser Light Source Equipment Used in Treatment, Diagnosis, Monitoring and Plastic Surgery/Medical Aesthetics (Implementation Date: 5/1/2023) |  |  |  |
| 06Blue light therapy equipment | Baby Light Therapy Apparatus, Neonatal Jaundice Therapy Apparatus, Baby Light Therapy Bed | YY 9706.250-2021 Medical Electrical Equipment Part 2-50: Special Requirements for Basic Safety and Basic Performance of Infant Light Therapy Equipment (Implementation Date: 5/1/2023) |  |  |  |
| 07Ultraviolet therapy equipment | All products under 09-03-07 are applicable | YY 9706.257-2021 Medical Electrical Equipment Part 2-57: Special Requirements for Basic Safety and Basic Performance of Non-laser Light Source Equipment Used in Treatment, Diagnosis, Monitoring and Plastic Surgery/Medical Aesthetics (Implementation Date: 5/1/2023) |  |  |  |
| 09-04 Strength therapy equipment/apparatus | 06 Balloon type external counterpulsation device | Balloon type external counterpulsation device | GB 10035-2017 Airbag External Counterpulsation Device |  |  |  |
| 09-06 Ultrasonic therapy equipment | 01 Ultrasound therapy equipment | Ultrasound Therapy System | YY 0830-2011 Superficial Tissue Ultrasound Therapy Equipment |  |  |  |
| Ultrasonic physiotherapy instrument | GB 9706.205-2020 Medical Electrical Equipment Part 2-5: Special Requirements for Basic Safety and Basic Performance of Ultrasonic Physiotherapy Equipment (Implementation Date: 2023/5/1) | YY 9706.262-2021 Medical Electrical Equipment Part 2-62: Special Requirements for Basic Safety and Essential Performance of High Intensity Ultrasound Therapy (HITU) Equipment (Implementation Date: 5/1/2023) |  |  |
| 09-07 High frequency therapy equipment | 01 Radio frequency hyperthermia equipment | RF hyperthermia system, RF hyperthermia machine | YY 0777-2010 Radio frequency hyperthermia equipment |  |  |  |
| 02 Radio frequency superficial treatment equipment | All products under 09-07-02 are applicable | GB9706.202-2021 Medical Electrical Equipment Part 2-2: Special Requirements for Basic Safety and Basic Performance of High-Frequency Surgical Equipment and High-Frequency Accessories (Implementation Date: May 1, 2023) |  |  |  |
| 03 Microwave therapy equipment | microwave hyperthermia machine | YY 0839-2011 Microwave hyperthermia equipment |  |  |  |
| Microwave hyperthermia machine, microwave assisted therapy system, microwave therapy instrument | GB 9706.206-2020 Medical Electrical Equipment Part 2-6: Special Requirements for Basic Safety and Basic Performance of Microwave Therapy Equipment (Implementation Date: 2023/5/1) | YY 0899-2020 General requirements for accessories of medical microwave equipment |  |  |
| 04 Shortwave Therapy Apparatus | Shortwave Therapy Apparatus | GB 9706.203-2020 Medical Electrical Equipment Part 2-3: Special Requirements for Basic Safety and Basic Performance of Shortwave Therapy Equipment (Implementation Date: 2023/5/1) |  |  |  |
| 10-01 Blood separation, processing and storage equipment | 01 Blood component separation equipment | Centrifugal blood component separation equipment | YY 1413-2016 Centrifugal blood component separation equipment |  |  |  |
| 05 Plasma virus inactivation equipment | Virus inactivation equipment | YY 0765.1-2009 Disposable blood and blood components virus inactivation equipment Part 1: Methylene blue virus inactivation equipment |  |  |  |
| 10-02 Blood separation, processing and storage equipment | 01 blood bag | Disposable UV diathermy blood container | YY 0327-2002 Disposable ultraviolet diathermy blood container |  |  |  |
| Disposable Blood Bags, Disposable Blood Component Collection Bags, Disposable Plasma Bags | GB 14232.1-2020 Bag-type plastic containers for human blood and blood components Part 1: Traditional blood bags (implementation time: 2/1/2022) | GB 14232.3-2011 Bag-type plastic containers for human blood and blood components - Part 3: Blood bag systems with special components | GB 14232.4—2021 Bag-type plastic containers for human blood and blood components—Part 4: Single blood collection bag system with special components (implementation time: 2023-06-01) |  |
| 02 Centrifugal blood component separator | Disposable centrifugal bag blood component separator | YY 0613-2007 Disposable centrifugal bag blood component separator |  |  |  |
| Disposable Centrifugal Cup Blood Component Separator | YY 0584-2005 Disposable Centrifugal Cup Blood Component Separator |  |  |  |
| 04 blood transfusion set | Disposable pump blood transfusion set | GB 8369.2-2020 Disposable blood transfusion set Part 2: For pressure blood transfusion equipment (implementation time: 2022/6/1) |  |  |  |
| Disposable blood transfusion set | GB8369.1-2019 Disposable blood transfusion set Part 1: Gravity transfusion |  |  |  |
| 10-03 Blood purification and peritoneal dialysis equipment | 01Hemodialysis equipment | Hemodialysis equipment, hemodiafiltration equipment | YY 0054-2010 Hemodialysis equipment | GB9706.216-2021 Medical Electrical Equipment Part 2-16: Special Requirements for Basic Safety and Essential Performance of Hemodialysis, Hemodiafiltration and Hemofiltration Equipment (Implementation Date: 2023-05-01) |  |  |
| 02 Continuous blood purification equipment | Continuous blood purification equipment | YY 0645-2018 Continuous blood purification equipment | GB9706.216-2021 Medical Electrical Equipment Part 2-16: Special Requirements for Basic Safety and Essential Performance of Hemodialysis, Hemodiafiltration and Hemofiltration Equipment (Implementation Date: 2023-05-01) |  |  |
| 03 Hemoperfusion equipment | Hemoperfusion machine | YY 0790-2010 Hemoperfusion equipment | GB9706.216-2021 Medical Electrical Equipment Part 2-16: Special Requirements for Basic Safety and Essential Performance of Hemodialysis, Hemodiafiltration and Hemofiltration Equipment (Implementation Date: 2023-05-01) |  |  |
| 04 Artificial liver equipment | — | GB9706.216-2021 Medical Electrical Equipment Part 2-16: Special Requirements for Basic Safety and Essential Performance of Hemodialysis, Hemodiafiltration and Hemofiltration Equipment (Implementation Date: 2023-05-01) |  |  |  |
| 05 Hemodialysis auxiliary equipment | Blood Purification Auxiliary Blood Pump | GB9706.216-2021 Medical Electrical Equipment Part 2-16: Special Requirements for Basic Safety and Essential Performance of Hemodialysis, Hemodiafiltration and Hemofiltration Equipment (Implementation Date: 2023-05-01) |  |  |  |
| Hemodialysis machine water treatment equipment | YY 0793.1-2010 Technical requirements for hemodialysis and related therapeutic water treatment equipment Part 1: For multi-bed dialysis |  |  |  |
| 06Peritoneal dialysis equipment | peritoneal dialysis machine | GB9706.239-2021 Medical Electrical Equipment Part 2-39: Special Requirements for Basic Safety and Basic Performance of Peritoneal Dialysis Equipment (Implementation Date: 2023-05-01) |  |  |  |
| 08 Blood lipid separation equipment | — | GB9706.216-2021 Medical Electrical Equipment Part 2-16: Special Requirements for Basic Safety and Essential Performance of Hemodialysis, Hemodiafiltration and Hemofiltration Equipment (Implementation Date: 2023-05-01) |  |  |  |
| 10-04 Blood purification and peritoneal dialysis equipment | 01 Hemodialysis equipment | Disposable blood purification circuit for extracorporeal circulation, disposable continuous blood purification circuit | YY 0267-2016 Extracorporeal circulation blood circuit of blood purification device for hemodialysis and related treatment |  |  |  |
| Disposable Hollow Fiber Hemodialyzer, Disposable Hollow Fiber Hemodialysis Filter, Disposable Hollow Fiber Hemofilter, Disposable High Flux Dialyzer | YY 0053-2016 Hemodialysis and Related Treatment Hemodialyzers, Hemodiafilters, Hemofilters and Hemoconcentrators |  |  |  |
| 02 Hemoperfusion equipment | Disposable plasma bilirubin absorber | YY 1290-2016 Disposable Bilirubin Plasma Adsorber |  |  |  |
| 03 Blood purification aids | Disposable hollow fiber plasma separator | YY 0465-2019 Disposable hollow fiber plasma separator and plasma component separator |  |  |  |
| 10-05 Cardiopulmonary bypass equipment | 01 Cardiopulmonary bypass pump | Centrifugal pumps for cardiopulmonary bypass | YY 1412-2016 Cardiopulmonary bypass system centrifugal pump |  |  |  |
| Roller type blood pump for cardiopulmonary bypass system | GB 12260-2017 Cardiopulmonary bypass system rolling blood pump |  |  |  |
| 03Heat exchange equipment | Heat exchange water tank for cardiopulmonary bypass system | GB 12263-2017 Heart-lung bypass system heat exchange water tank |  |  |  |
| 10-06 Cardiopulmonary bypass appliances | 01 Oxygenator | Disposable hollow fiber oxygenator, disposable bubble oxygenator, disposable integrated membrane oxygenator | YY 0604-2016 Cardiopulmonary bypass system blood gas exchanger (oxygenator) |  |  |  |
| 03 micro plug filter | Disposable cardiopulmonary bypass system arterial line blood filter, disposable arterial filter, disposable blood microemboli filter | YY 0580-2011 Cardiovascular implants and artificial organs cardiopulmonary bypass system arterial line blood filter |  |  |  |
| 04 blood concentrator | single-use blood concentrator | YY 0053-2016 Hemodialysis and Related Treatment Hemodialyzers, Hemodiafilters, Hemofilters and Hemoconcentrators |  |  |  |
| 05 Cardiac arrest fluid perfusion device | Disposable cardioplegia perfusion tube | YY 0485-2020 Disposable cardioplegia perfusion set |  |  |  |
| 06 Tubes and connectors for cardiopulmonary bypass | Disposable extracorporeal circulation tubing for artificial heart-lung machine, disposable carotid bypass tube, and supporting vascular circuit for disposable extracorporeal circulation | YY 1048-2016 cardiopulmonary bypass system extracorporeal circulation pipeline |  |  |  |
| Disposable venous cannula, disposable arterial cannula | YY 0948-2015 Cardiopulmonary bypass system single-use arteriovenous cannula |  |  |  |
| 11-01 Moist heat disinfection and sterilization equipment | 03Pressure steam sterilizer | Portable Pressure Steam Sterilizer | YY 0504-2016 Portable Steam Sterilizer |  |  |  |
| Large Pressure Steam Sterilizer | GB 8599-2008 Technical Requirements for Large Steam Sterilizer Automatic Control Type | YY 0731-2009 Large steam sterilizer manual control type |  |  |
| 11-02 Dry heat disinfection and sterilization equipment | 02Hot air sterilizer | Hot air type dry heat sterilizer | YY 1275-2016 hot air dry heat sterilizer |  |  |  |
| 11-03 Chemical disinfection and sterilization equipment | 03Ethylene oxide sterilizer | Ethylene oxide sterilizer | YY 0503-2016 Ethylene Oxide Sterilizer |  |  |  |
| 12-01 Cardiac rhythm management equipment | 01 Implantable cardiac pacemaker | implantable pacemaker | GB 16174.2-2015 Surgical Implants Active Implantable Medical Devices Part 2: Cardiac Pacemakers |  |  |  |
| 13-01 Osseointegrated implants | 01Single/multi-component metal bone fixation instruments and accessories | Metal locking plate, metal non-locking plate | YY 0017-2016 Metal Bone Plates for Bone Engagement Implants |  |  |  |
| Metal locking bone screws, metal non-locking bone screws | YY 0018-2016 Metal Bone Screws for Bone Engaging Implants |  |  |  |
| 13-04 Joint Replacement Implants | 01 Hip prosthesis | Hip prosthesis system, hip prosthesis, acetabular prosthesis, hip femoral prosthesis | YY 0118-2016 Joint Replacement Implant Hip Joint Prosthesis |  |  |  |
| 02 Knee prosthesis | Knee prosthesis system, knee prosthesis, knee femoral prosthesis, knee patellofemoral prosthesis, knee patellofemoral prosthesis, knee femoral prosthesis, knee patellar prosthesis, knee tibial prosthesis | YY 0502-2016 Joint Replacement Implants Knee Joint Prosthesis |  |  |  |
| 13-05 Orthopedic filling and repair materials | 01 Acrylic resin bone cement | acrylic bone cement | YY 0459-2003 Acrylic resin bone cement for surgical implants |  |  |  |
| 13-09 Orthopedic and general surgical implants | 01 plastic filling material | Silicone Rubber Orthopedic Implants | YY 0334-2002 General requirements for silicone rubber surgical implants |  |  |  |
| 03 breast implants | artificial breast implants, breast implants, silicone gel filled breast implants | YY 0334-2002 General requirements for silicone rubber surgical implants |  |  |  |
| 10 soft tissue expanders | soft tissue expander | YY 0333-2010 Soft tissue expander |  |  |  |
| 14-01 Injection and puncture instruments | 01 Syringe pump | Injection pump | GB 9706.224-2021 Medical Electrical Equipment Part 2-24: Special Requirements for Basic Safety and Essential Performance of Infusion Pumps and Infusion Controllers (Implementation Date: May 1, 2023) |  |  |  |
| 02 sterile syringe | Disposable sterile syringe | GB 15810-2019 Disposable sterile syringes |  |  |  |
| 05 glass syringe | All Glass Syringes | YY 1001.1-2004 Glass Syringes Part 1: All Glass Syringes | YY 1001.2-2004 Glass Syringes Part 2: Blue Core Full Glass Syringes |  |  |
| 06 injection needle | Disposable sterile injection needles | GB 15811-2016 Disposable sterile injection needles |  |  |  |
| 14-02 Intravascular infusion devices | 01 Infusion pump | Electronic analgesic pump, electronic infusion pump, micro injection pump, automatic injection pump, microcomputer electric injection pump, portable infusion pump, infusion pump, emergency infusion pump, volumetric infusion pump, medical infusion pump | GB 9706.224-2021 Medical Electrical Equipment Part 2-24: Special Requirements for Basic Safety and Essential Performance of Infusion Pumps and Infusion Controllers (Implementation Date: May 1, 2023) |  |  |  |
| 04Passive infusion pump | Disposable Infusion Pump | YY 0451-2010 Disposable portable infusion pump non-electric drive |  |  |  |
| 05 infusion set | Disposable microporous filter infusion set | YY 0286.1-2019 Special infusion set Part 1: Disposable microporous filter infusion set |  |  |  |
| Light-proof infusion set | YY 0286.3-2017 Special infusion sets Part 3: Disposable light-proof infusion sets |  |  |  |
| Burette infusion set | YY 0286.2-2006 Special infusion set Part 2: Disposable burette type infusion set Gravity infusion type |  |  |  |
| gravity infusion set, gravity infusion set | GB 8368-2018 Disposable infusion set gravity infusion type |  |  |  |
| 06 intravenous infusion needle | Disposable IV needle | GB 18671-2009 Disposable intravenous infusion needles |  |  |  |
| 08 Infusion connection line | Infusion connection line | YY 0585.2-2019 Disposable liquid circuit and accessories for pressure infusion equipment Part 2: Accessories |  |  |  |
| Pump infusion line  pressure infusion line micropump front tube | YY 0585.1-2019 Disposable liquid circuit and accessories for pressure infusion equipment Part 1: Liquid circuit |  |  |  |
| 09 Connections and accessories for infusion and blood transfusion | Two-way switch for infusion, backflow prevention valve for infusion,  high-pressure tee for infusion | YY 0585.2-2019 Disposable liquid circuit and accessories for pressure infusion equipment Part 2: Accessories |  |  |  |
| Infusion filter | YY 0585.3-2018 Disposable liquid circuit and accessories for pressure infusion equipment Part 3: Filter |  |  |  |
| Anti-reflux valve for infusion | YY 0585.4-2009 Disposable liquid circuit and its accessories for pressure infusion device Part 4: Backflow prevention valve |  |  |  |
| Disposable leukocyte removal filter | YY 0329-2009 Disposable leukocyte-removing filter |  |  |  |
| 14-05 Non-vascular catheter (insertion) | 03 catheter | Non-balloon catheter, double-lumen balloon catheter, triple-lumen balloon catheter, silicone rubber catheter, rubber catheter, urinary catheter, silicone rubber bladder catheter, urethral catheter, double balloon Three-lumen catheter, sterile plum blossom head catheter, balloon catheter, double-bag four-chamber catheter, medical rubber catheter, latex catheter, multi-lumen balloon catheter, temperature measuring catheter , Latex fungal catheter, single lumen catheter, double lumen balloon catheter, intermittent catheter | YY 0325-2016 Disposable sterile urinary catheter |  |  |  |
| 14-07 Cleaning, irrigation, suction, drug delivery equipment | 01 flushing equipment | gastric lavage machine | YY 1105-2008 Electric gastric lavage machine |  |  |  |
| 14-09 Non-absorbable Surgical Dressings | 01 Surgical woven cloth dressing | surgical gauze dressing | YY 0594-2006 General requirements for surgical gauze dressings |  |  |  |
| 14-13 Operating room infection control supplies | 02 Surgical film | Surgical film, surgical film, medical surgical film towel, surgical film, medical surgical protective film | YY 0852-2011 Disposable sterile surgical film |  |  |  |
| 14-14 Protective equipment for medical staff | 01 protective mask | surgical mask | YY 0469-2011 Medical Surgical Mask |  |  |  |
| Medical protective mask | GB 19083-2010 Technical requirements for medical protective masks |  |  |  |
| 02 protective clothing | Disposable medical protective clothing | GB 19082-2009 Technical requirements for medical disposable protective clothing |  |  |  |
| 15-03 Medical bed | 01 electric hospital bed | All products under 15-03 are applicable | YY 9706.252-2021 Medical Electrical Equipment Part 2-52: Special Requirements for Basic Safety and Basic Performance of Medical Beds (Implementation Date: May 1, 2024) |  |  |  |
| 02 Manual hospital bed |  |  |  |
| 03 Medical crib |  |  |  |
| 16-03 Optical Equipment and Appliances | 01 Optometry equipment and appliances | Optometry | YY 0673-2008 Ophthalmic Instruments Refractometer |  |  |  |
| optometrist | YY 0674-2008 Optometry head for ophthalmic instruments |  |  |  |
| 02 Visual function inspection equipment and appliances | Keratometer | GB 38455-2019 Ophthalmic Instrument Keratometer (implementation time 2022/1/1) |  |  |  |
| 16-04 Ophthalmic Measurement and Diagnosis Equipment and Appliances | 01Ophthalmic laser diagnostic equipment | All products under 16-04-01 are applicable | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024) | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements |  |  |
| 05 eye camera | Fundus camera, digital fundus camera, non-mydriatic fundus camera, non-mydriatic digital fundus camera, non-mydriatic digital fundus camera, hand-held non-mydriatic fundus camera | YY 0634-2008 Ophthalmic Instruments Fundus Camera |  |  |  |
| 16-05 Ophthalmic Therapeutic and Surgical Equipment, Assistive Devices | 02 Ophthalmic Laser Therapy Equipment | All products under 16-05-02 are applicable | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024) |  |  |
| Semiconductor laser eye treatment machine | YY 1289-2016 Laser Therapy Equipment Ophthalmic Semiconductor Laser Photocoagulation Apparatus | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024) |  |
| Excimer laser corneal refractive therapy machine | YY 0599-2015 Laser Treatment Equipment Excimer Laser Corneal Refractive Therapy Machine | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024) |  |
| Q switch Nd-doped yttrium aluminum garnet laser eye treatment machine | YY 0789-2010Q Switch Nd: YAG laser eye treatment machine | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024) |  |
| 05Other ophthalmic treatment and surgery equipment | Ophthalmic Surgical Microscope | YY 1296-2016 Optical and Photonic Surgical Microscopes Light Hazards of Ophthalmic Surgical Microscopes |  |  |  |
| Ophthalmic Surgical Microscope | GB 11239.1-2005 Surgical Microscope Part 1: Requirements and Test Methods |  |  |  |
| 06 Ophthalmic Therapeutic and Surgical Aids | Intraocular Illuminator, Intraocular Illuminator Fiber Optic Probe | YY 0792.1-2016 Intraocular illuminator for ophthalmic instruments Part 1: Requirements and test methods |  |  |  |
| intraocular illuminator | YY 0792.2-2010 Intraocular illuminator for ophthalmic instruments Part 2: Basic requirements and test methods for optical radiation safety |  |  |  |
| 16-06 Ophthalmic Corrective and Protective Appliances | 01 contact lens | Rigid gas permeable contact lenses for orthokeratology | YY 0477-2016 Rigid breathable contact lenses for orthokeratology |  |  |  |
| Rigid contact lenses, rigid gas permeable contact lenses, rigid gas permeable contact lenses for orthokeratology | GB 11417.2-2012 Ophthalmic Optical Contact Lenses Part 2: Rigid Contact Lenses |  |  |  |
| Color soft hydrophilic contact lens, astigmatism soft hydrophilic contact lens, soft corneal contact lens, soft hydrophilic contact lens, soft contact lens | GB 11417.3-2012 Ophthalmic Optical Contact Lenses Part 3: Soft Contact Lenses |  |  |  |
| 02Contact lens care products | Contact lens sterile physiological saline care solution, contact lens care saline solution,   rigid breathable contact lens cleaning solution, rigid contact lens enzyme cleaner, contact lens protein removal care solution, protein removal care solution, contact lens protein removal sheet hydrogen oxygen care solution   , Hydrogen peroxide contact lens disinfectant   Rigid contact lens care solution, Contact lens care solution, Rigid breathable contact lens care solution, Soft contact lens care solution   Contact lens lubricant, Rigid breathable contact lens lubricant, Contact lens wetting solution | YY 0719.2-2009 Ophthalmic Optical Contact Lens Care Products Part 2: Basic Requirements |  |  |  |
| 04 Vision aids | Optical low vision aids, low vision magnifying glass, low vision telescope | GB 23719-2009 Ophthalmic Optics and Instruments Optical Vision Aids |  |  |  |
| 16-07 Ophthalmic Implants and Auxiliary Devices | 01 Intraocular lens | All products under 16-07-01 category are applicable | YY 0290.2-2009 Ophthalmic Optical Intraocular Lens Part 2: Optical Properties and Test Methods | YY 0290.2-2021 Ophthalmic Optical Intraocular Lens Part 2: Optical Properties and Test Methods (Implementation Date: 2023/4/1) | YY 0290.3-2018 Ophthalmic Optical Intraocular Lenses Part 3: Mechanical Properties and Test Methods | YY 0290.8-2008 Ophthalmic Optical Intraocular Lens Part 8: Basic Requirements |
| multifocal intraocular lens |  |  |  |  |
| Phakic refractive intraocular lens | YY 0290.10-2009 Ophthalmic Optical Intraocular Lens Part 10: Phakic Intraocular Lens |  |  |  |
| 04 Eye Viscoelastic | Ophthalmic Viscoelastic Agent, Ophthalmic Surgery Viscoelastic Agent, Ophthalmic Sodium Hyaluronate Gel, Ophthalmic Hydroxypropyl Methylcellulose, Corneal Protectant, Ophthalmic Sodium Hyaluronate | YY 0861-2011 Ophthalmic Optical Ophthalmic Viscoelastic Agent |  |  |  |
| 07 bladder tension ring | Capsular tension ring, capsular expansion ring | YY 0762-2017 Ophthalmic Optical Capsular Bag Tension Ring |  |  |  |
| 17-01 Dental examination equipment | 01 Periodontal pocket detection equipment | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 02 Pulp vitality test equipment | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 03 Dentin measurement equipment | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 04 Caries detection equipment | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 05Oral imaging equipment | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 06 Dental lighting equipment | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 17-03 Dental treatment equipment | 01 Dental unit | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 02Dental Chair | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 03Oral cleansing equipment and accessories | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 04Dental handpieces and accessories | Dental handpieces, dental straight handpieces, dental contra-angle handpieces, dental air motor handpieces, dental electric motor handpieces, high-speed air turbine handpieces, dental implant handpieces, root canal handpieces, polishing handpieces, disposable dental handpieces | YY 1045-2021 Dental handpieces and motors (implementation time: 5/1/2024) | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |
| Electric motors for dental handpieces, Air motors for dental handpieces | YY 1045-2021 Dental handpieces and motors (implementation time: 5/1/2024) | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |
| 05 Oral positive and negative pressure equipment | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 06 Curing equipment | LED light curing machine, halogen light curing machine | YY 0055-2018 Dental light curing machine | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |
| 07Dental implant equipment | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 08 Teeth Bleaching Equipment | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 09 Root canal treatment equipment | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 10 Oral anesthesia injection equipment | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 11 amalgam blender | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 12 Bone meal preparation equipment for oral cavity | — | GB9706.260-2020 "Medical Electrical Equipment Part 2-60: Special Requirements for Basic Safety and Essential Performance of Dental Equipment" |  |  |  |
| 17-05 Oral filling restoration materials | 01 cement | Glass ionomer cement, glass ionomer cement for crown core, silver powder glass ionomer cement, glass ionomer cement for bonding, zinc polycarboxylate cement, polycarboxylate cement for bonding, zinc phosphate cement, dental zinc oxide eugenol cement, not Containing Eugenol Cement, Calcium Hydroxide Cement | YY 0271.1-2016 Dentistry water-based cements Part 1: Powder/liquid acid-base cements |  |  |  |
| Adhesive resin cement, self-adhesive resin cement, dual-cure resin cement, self-etching resin cement, resin cement, light-curing resin cement | YY 0271.2-2016 Dental Science Water-based Cement Part 2: Resin Modified Cement |  |  |  |
| Dental Zinc Oxide Eugenol Cement, Eugenol Free Cement | YY 0272-2009 Dentistry zinc oxide/eugenol cement and zinc oxide cement without eugenol |  |  |  |
| 03 Tube filling sealing material | Root canal sealing material, root canal sealant, dental root canal filling material, root canal filling material, liquid root filling material, solid root canal filling material | YY 0717-2009 Dental root canal sealing material |  |  |  |
| 04 Composite resin | Light-curing composite resin, light-curing composite fluid resin, fluidity composite resin | YY 1042-2011 Dental polymer-based restorative materials |  |  |  |
| 17-06 Oral denture materials | 01 Metal materials and products for dentures | Cobalt chromium alloy, dental nickel porcelain alloy, cobalt chromium molybdenum porcelain alloy, dental cobalt chromium porcelain alloy, nickel chromium alloy, dental nickel base casting alloy | GB 17168-2013 Metal materials for fixed and movable restorations in dentistry |  |  |  |
| 02 Ceramic materials and products for dentures | porcelain teeth | YY 0300-2009 Artificial teeth for dental restoration |  |  |  |
| Dental porcelain powder, low-temperature porcelain powder, high-temperature porcelain powder, dental metal porcelain powder, dental porcelain powder, dental all-ceramic powder, dental zirconia porcelain block | GB 30367-2013 Dental ceramic materials |  |  |  |
| 03 Polymer materials and products for dentures | denture soft lining material | YY 0714.2-2016 Dental Removable Denture Soft Lining Materials Part 2: Long-term use materials |  |  |  |
| Synthetic resin tooth | YY 0300-2009 Artificial teeth for dental restoration |  |  |  |
| 17-08 Oral Implants and Tissue Reconstruction Materials | 01 dental implant | Pure titanium dental implant, titanium alloy dental implant | YY 0315-2016 Titanium and Titanium Alloy Dental Implants |  |  |  |
| Hydroxyapatite Coated Dental Implants, Dental Implants, Pure Titanium Dental Implants | YY 0304-2009 Plasma Sprayed Hydroxyapatite Coated Titanium-based Dental Implants |  |  |  |
| 06 Bone filling and repair materials | Dental bone powder, bone repair materials, oral artificial bone |  |  |  |  |
| 17-10 Other oral materials | 04Anti-caries material | Light-curing pit and fissure sealant, pit and fissure sealant, dental resin-based pit and fissure sealant | YY 0622-2008 Dental resin-based pit and fissure sealant |  |  |  |
| 18-01 Obstetrics and Gynecology Surgical Instruments | 02 Obstetrics and gynecology scissors | First Aid and Transport Ventilators | YY 0600.3-2007 Special Requirements for Basic Safety and Main Performance of Medical Ventilators Part 3: Ventilators for First Aid and Transfer |  |  |  |
| 05Dilators and retractors for obstetrics and gynecology | Disposable sterile vaginal dilators | YY 0336-2020 Disposable sterile vaginal dilator |  |  |  |
| Metal double wing vaginal dilator | YY 0006-2013 Metal Double Wings Vaginal Dilator |  |  |  |
| 18-02 Obstetrics and Gynecology Measurement and Monitoring Equipment | 01 Ultrasound Doppler fetal monitoring equipment | All products under 18-02-01 are applicable | GB 9706.237-2020 Medical Electrical Equipment Part 2-37: Special Requirements for Basic Safety and Basic Performance of Ultrasonic Diagnostic and Monitoring Equipment (Implementation Date: 5/1/2023) |  |  |  |
| 02 Ultrasound Doppler fetal heart rate equipment | All products under 18-02-02 are applicable | GB 9706.237-2020 Medical Electrical Equipment Part 2-37: Special Requirements for Basic Safety and Basic Performance of Ultrasonic Diagnostic and Monitoring Equipment (Implementation Date: 5/1/2023) |  |  |  |
| 18-03 Obstetrics and Gynecology Diagnostic Instruments | 01 Gynecological ultrasound diagnostic equipment | All products under 18-03-01 are applicable | GB 9706.237-2020 Medical Electrical Equipment Part 2-37: Special Requirements for Basic Safety and Basic Performance of Ultrasonic Diagnostic and Monitoring Equipment (Implementation Date: 5/1/2023) |  |  |  |
| 03 Gynecological endoscope | Hysteroscopy | YY 0068.1-2008 Medical Endoscope Rigid Endoscope Part 1: Optical Properties and Test Methods | YY 0068.4-2009 Medical Endoscope Rigid Endoscope Part 4: Basic Requirements |  |  |
| 18-04 Obstetrics and Gynecology Treatment Devices | 01 Gynecological physical therapy equipment | Radio Frequency Therapy Apparatus | YY 0650-2008 Gynecological Radio Frequency Therapy Apparatus |  |  |  |
| 18-06 Pregnancy Control Devices | 01 IUD and pick-and-place devices | Intrauterine Copper IUD | GB 11234-2006 Uterine Intrauterine Device |  |  |  |
| V-shaped copper IUD | GB 11235-2006VCu intrauterine device |  |  |  |
| T-shaped copper IUD | GB 11236-2006TCu intrauterine device |  |  |  |
| 18-07 Assisted reproductive devices | 05 Special instruments for assisted reproduction | Assisted Reproductive Laser System | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements |  |  |  |
| 20-01 TCM diagnostic equipment | 02 Inspection equipment | Electroacupuncture Therapy Apparatus | YY 0780-2018 Electroacupuncture Therapy Apparatus |  |  |  |
| 20-02 Chinese medicine treatment equipment | 07Acupoint laser stimulation equipment | All products containing laser light sources under 20-02-07 are applicable | GB 7247.1-2012 Safety of Laser Products Part 1: Equipment Classification and Requirements |  |  |  |
| 20-02-07 Applies to all products containing Class 3B and Class 4 laser light sources. | GB 9706.222-2022 Medical Electrical Equipment Part 2-22: Special Requirements for Basic Safety and Essential Performance of Laser Equipment for Surgery, Orthopedics, Therapy and Diagnosis (Implementation Date: May 1, 2024) |  |  |  |
| 20-03 Chinese medicine appliances | 01 acupuncture needles | Acupuncture needles, disposable sterile acupuncture needles | GB 2024-2016 acupuncture needles |  |  |  |
| 21-01 Treatment Planning Software | 01 Radiation therapy planning system software | Radiation therapy planning system software, Gamma ray stereotactic radiation therapy planning system software | YY 0775-2010 High-energy X(γ) beam dose calculation accuracy requirements and test methods for teletherapy planning system | YY 0637-2013 Safety requirements for radiotherapy planning system for medical electrical equipment |  |  |
| 02Radiation therapy assistant software | Radiation Therapy Recording and Verification System | YY 0721―2009 Radiation Therapy Record and Verification System |  |  |  |
| 22-01 Hematological Analysis Equipment | 22-01-00 | Products under 22-01 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | 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 |
| 01 Blood type analysis instrument | blood type analyzer | GB4793.7-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 7: Special requirements for laboratory centrifuges |  |  |  |
| 22-02 Biochemical analysis equipment | 22-02-00 | All products under 22-02 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | 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 |
| 22-03 Electrolyte and blood gas analysis equipment | 22-03-00 | All products under 22-03 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | 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 |
| 22-04 Immunoassay equipment | 22-04-00 | All products under 22-04 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | 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 |
| 22-05 Molecular biology analysis equipment | 22-05-00 | All products under 22-05 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | 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 |
| 22-06 Microbiological analysis equipment | 22-06-00 | All products under 22-06 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | 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 |
| 22-07 Scanning image analysis system | 22-07-00 | All products under 22-07 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | 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 | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment (applicable if the equipment has an additional heating function) |
| 22-08 Radionuclide Specimen Determination Device | 22-08-00 | All products under 22-08 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | 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 |
| 22-09 Urine and other body fluid analysis equipment | 22-09-00 | All products under 22-09 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | 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 | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment (applicable if the equipment has an additional heating function) |
| 22-10 Other medical analysis equipment | 22-10-00 | Products under 22-10 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | 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 |
| 22-12 Sample processing equipment before morphological analysis | 22-12-00 | Products under 22-12 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | 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 |
| 22-13 Sample separation equipment | 22-13-00 | Products under 22-13 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | 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 |
| 01 Medical centrifuge | — | GB4793.7-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 7: Special requirements for laboratory centrifuges |  |  |  |
| 02 Nucleic acid extraction and purification instrument | — | GB4793.7-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 7: Special requirements for laboratory centrifuges |  |  |  |
| 22-14 Cultivation and Incubation Equipment | 22-14-00 | Products under 22-14 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | 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 |
| 22-15 Inspection and other auxiliary equipment | 22-15-00 | Products under 22-15 are applicable | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements | GB 4793.6-2008 Safety requirements for electrical equipment for measurement, control and laboratory use Part 6: Special requirements for laboratory material heating equipment | GB 4793.9-2013 Safety requirements for electrical equipment for measurement, control and laboratory use Part 9: Particular requirements for automatic and semi-automatic equipment for analysis and other purposes in laboratories | 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 |
| 22-16 Medical biological protection equipment | 01 biological safety cabinet | Class II Biological Safety Cabinet | YY 0569-2011 Class II Biological Safety Cabinet | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements |  |  |
| 02 Clean bench | — | GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements |  |  |  |

Appendix 1

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| |  |  |  |  | | --- | --- | --- | --- | | List of common mandatory standards for medical devices | | | | | **serial number** | **standard encdoing** | **standard name** | **scope of application** | | 1 | GB 4793.4-2019 | Safety requirements for electrical equipment for measurement, control and laboratory use - Part 4: Particular requirements for sterilizers and washer-disinfectors for handling medical materials | This section applies to the safety requirements for electrical equipment intended to sterilize, clean and disinfect medical materials in the fields of medical institutions, veterinary medicine, pharmaceuticals and laboratories under the environmental conditions of 1.4.  For example:  a) Sterilizers and sterilizers using steam;  b) Sterilizers and sterilizers using toxic gas, toxic mist or toxic steam;  c) Sterilizers and sterilizers using hot air or hot inert gas ;  d) washer-disinfectors. | | 2 | GB 9706.1-2020 | Medical electrical equipment Part 1: General requirements for basic safety and essential performance | This part of GB 9706 specifies the general requirements for the basic safety and essential performance of me equipment and me systems.  This standard applies to medical electrical equipment and medical electrical systems (hereinafter referred to as ME EQUIPMENT and ME SYSTEMS).  If a chapter or clause specifically states that it applies only to me equipment or me systems, the title and text of the chapter or clause will say so. If this is not the case, the relevant clause or subclause applies to both me equipment and me systems.  With the exception of 7.2.13 and 8.4.1, hazards (sources) posed by intended physiological effects of me equipment or me systems within the scope of this standard are not specified in this standard. | | 3 | YY 9706.102-2021 | Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility requirements and tests | This standard applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems. This standard applies to the electromagnetic compatibility of medical electrical equipment and medical electrical systems. This standard specifies the general requirements and tests for electromagnetic compatibility of medical electrical equipment and medical electrical systems. These general requirements and tests are not only the requirements of the general standard, but also serve as the basis for the specific standard. | | 4 | YY 9706.108-2021 | Medical electrical equipment Part 1-8: General requirements for basic safety and essential performance Collateral standard: General requirements, tests and guidelines for alarm systems in medical electrical equipment and medical electrical systems | This standard specifies the requirements for alarm systems and alarm signals in medical electrical equipment and medical electrical systems. This standard applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems. It also provides guidance for the application of alarm systems. | | 5 | YY 9706.111-2021 | Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance Collateral standard: Requirements for medical electrical equipment and medical electrical systems for use in the home care environment | This standard specifies the basic safety and essential performance requirements for medical electrical equipment and medical electrical systems used in the home care environment. This standard applies to medical electrical equipment and medical electrical systems intended for use in a home care environment as indicated in the manufacturer's instructions for use. The application of this standard does not take into account whether medical electrical equipment or medical electrical systems are used by inexperienced operators or by trained medical personnel. The home care environment includes: the residence where the patient lives; other indoor and outdoor environments where the patient is located, excluding professional medical institutions where trained operators receive whenever a patient visits. This standard does not apply to medical electrical equipment and medical electrical systems that are expected to be used only in the emergency medical service environment described in YY 9706.112 or in professional medical institutions described in GB 9706.1 (excluding YY 9706.112 or the additions to this standard). However, medical electrical equipment or medical electrical systems are expected to be used in a variety of use environments, as long as they can also be used in home care environments, they are within the scope of this standard. | | 6 | YY 9706.112-2021 | Medical electrical equipment Part 1-12: General requirements for basic safety and essential performance Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in an emergency medical services environment | This standard specifies the requirements for the basic safety and essential performance of medical electrical equipment and medical electrical systems intended to be used in an emergency medical service environment. This standard applies to medical electrical equipment and medical electrical systems intended for use in an emergency medical service environment as indicated in the manufacturer's instructions for use. This standard does not apply to medical electrical equipment and medical electrical systems used only in the home care environment in accordance with YY 9706.111, or in professional medical institutions in accordance with GB 9706.1 (and not in compliance with YY 9706.111 or this standard). | | 7 | GB 9706.103-2020 | Medical electrical equipment Part 1-3: General requirements for basic safety and essential performance Collateral standard: Radiation protection for diagnostic X-ray equipment | This part of GB9706 applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems. This section applies to X-ray equipment and its components for diagnosing, planning or guiding medical operations through radiological images of patients. | | 8 | GB 4234.1-2017 | Metallic materials for surgical implants - Part 1: Wrought stainless steel | This Part specifies the characteristics and corresponding test methods of wrought stainless steels for surgical implants. This section applies to wrought stainless steel for surgical implants. | | 9 | GB 4234.4-2019 | Metallic materials for surgical implants - Part 4: Cast cobalt-chromium-molybdenum alloys | This part specifies the characteristics and corresponding test methods of cast cobalt-chromium-molybdenum alloys for surgical implants. This section applies to cast cobalt-chromium-molybdenum alloys for surgical implants. | | 10 | GB 23102-2008 | Surgical implant metal material Ti-6Al-7Nb alloy processing material | This standard specifies the characteristics and corresponding test methods of Ti-6Al-7Nb alloy processing materials for surgical implants. | | 11 | YY 0605.9-2015 | Metallic materials for surgical implants Part 9: Wrought high nitrogen stainless steel | This standard is applicable to surgical implants, and the stainless steel rods, steel wires, steel plates and steel strips that meet the standard composition requirements, the mechanical properties of the finished samples may not follow this standard. This standard specifies the chemical composition, microstructure, corrosion resistance, mechanical properties and corresponding test methods of stainless steel with a nitrogen content of 0.25% to 0.50% for surgical implants. This standard replaces YY 0605.9-2007 "Surgical Implant Metal Materials Part 9: Forged High Nitrogen Stainless Steel". | | 12 | YY 0605.12-2016 | Metallic materials for surgical implants - Part 12: Wrought cobalt-chromium-molybdenum alloys | This standard specifies the chemical composition, microstructure, mechanical properties and related test methods of wrought cobalt-28 chromium-6 molybdenum alloys. This standard applies to forged cobalt-28 chromium-6 molybdenum alloy rods and wires for surgical implants, and the mechanical properties of finished samples may not follow this standard. This standard replaces YY 0605.12-2007 "Surgical Implant Metal Materials Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy". | | 13 | GB 23101.1-2008 | Hydroxyapatite for Surgical Implants Part 1: Hydroxyapatite Ceramics | This part of GB/T 23101 specifies the requirements for hydroxyapatite ceramics used as surgical implants. This standard does not apply to hydroxyapatite coatings, non-ceramic hydroxyapatite, hydroxyapatite powders, glass ceramics, α- and β-tricalcium phosphate or other forms of calcium phosphate. | | 14 | GB 23101.2-2008 | Hydroxyapatite for Surgical Implants Part 2: Hydroxyapatite Coatings | This Part of GB/T 23101 specifies the requirements for hydroxyapatite ceramic coatings for metallic and non-metallic surgical implants. This standard does not apply to coatings made of glass, glass ceramics, alpha- and beta-tricalcium phosphate or other forms of calcium phosphate, nor does it apply to coatings in which hydroxyapatite exists in powder form. | | 15 | YY 0341.1-2020 | Passive surgical implants Osseosynthetic and spinal implants Part 1: Particular requirements for osseosynthetic implants | This standard specifies the special requirements for passive surgical implants for osseosynthesis (hereinafter referred to as osseosynthesis implants), including terms and definitions, requirements, test methods, manufacture, sterilization, packaging and manufacture of osseosynthesis implants information provided by the supplier, etc. This standard applies to osteosynthetic implants and does not apply to coated parts of osteosynthetic implants with a surface coating. | | 16 | YY 0341.2-2020 | Passive surgical implants for osteosynthesis and spinal implants Part 2: Particular requirements for spinal implants | This standard specifies the special requirements for passive surgical spinal implants (hereinafter referred to as spinal implants). In addition to the requirements specified in YY/T 0640, it also specifies the definition, requirements, test methods, manufacturing, Sterilization, packaging and information provided by the manufacturer, etc. This standard applies to passive surgical spinal implants other than artificial disc implants. | |

Remarks : The strong standards applicable to a wider range will form the list of general mandatory standards for medical devices in Appendix 1 .