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## Catalogue of Medical Devices Exempted from Clinical trials in China

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No.	Code	Category Name	Product name	Product description	Class
1	6801	Basic Surgical Operation Instruments	Medical suture needle	Made of stainless steel, etc.; without suture, can be divided by the shape(circle, equilateral triangle, Inverse trigonometric, short blade triangle, semi-bending triangle), curvature(straight, 1/2 arc, 3/8 arc), pinhole(common hole,) of the needle into several different types; Each type can devided into various specification according to the needle diameter, chord length, etc. Sterile or non-sterile; Used to suture visceral, soft and hard tissue, skin. Reference standard; YY 0043-2005 Medical suture needle	II
2	6801	Basic Surgical Operation Instruments	single-use scalpel blade	Can be made of carbon tool steel or alloy tool steel; can contain a blade holder; The blade can be devided into various kinds according todifferent types, while each kind can be devided into various specification according to the shape of blade holder or blade; Sterile; Used for cutting soft tissues. Reference standard: YY 0174-2005 Scalpel blade, GB 8662 – 2006 Fitting dimension between scalpel blades and handles	II
3	6801	Basic Surgical Operation Instruments	single-use umbilical Scissors	The main materials are polymer materials (such as polyethylene, etc.) and metal materials; consist of umbilical cord scissors, indwelling umbilical cord clamp and accessories; sterile. Used for cutting off and closing umbilical stump of the newborns.	II
4	6801	Basic Surgical Operation Instruments	single-use surgical electrodes clean tablet	Mainly consist of (sponge) basal layer, (SiO2, etc.) fine abrasive layer, pressure-sensitive adhesive layer (barium line) developing lines, (silicone oil) release paper; Can be devided into various specifications according to shape and size; Sterile; Used for clean the burnt tissues and other attachment on the high	II
5	6801	Basic Surgical Operation Instruments	single-use surgical instruments for finger operating	Consist of polycarbonate sleeve and stainless steel end effector; Can be devided into various specifications according todesign, technical parameters, intended use, etc. Sterile state; Used in colorectal, urological, gynecological, etc.laparoscopic surgery (HALS) and open surgery, used for grasping, moving, separating, cutting and suturing tissue.	II
6	6802	Microsurgical Operation instrument	single-use surgical flushing needle	Made of polymer material and metal material, consist of needle seat, flat needle tube; Can be devided into various specifications according to texture, capacity and needle diameter, etc Sterile; Used with syringes, used for rinsing wound in microscopic surgery, ophthalmology, dentistry, orthopedic surgery and other	II

7	6803	Neurological Surgical Devices	IntraIntracerebral Scissors	Made of metal, consist of handle and head part; Generally reusable instrument; Single joint; The head part can be straight, bent; The angle of the handle and the head part can be two-dimension, three-dimensional to be suitable for different anatomical position, the head part can sharp and blunt, the surface shall be smooth to avoid damaging tissues around; Can be devided into various specifications according to texture, design, technical parameters, intended use etcGenerally be reusable; Used for cutting off the diseased bone or necrotic nerve / brain tissue in brain surgery.	II
8	6803	Neurological Surgical Devices	Intracerebral Pliers	Made of metal, consist of handle and head part; generally reusable instrument; Single joint; The head part can be straight, bent; The angle of the handle and the head part can be two-dimension, three-dimensional to be suitable for different anatomical position, the head part can round and oval, the surface shall be smooth to avoid damaging tissues around; Can be devided into various specifications according to texture, design, technical parameters, intended use etcGenerally be reusable; Used for gripping intracranial tumors and	II
9	6803	Neurological Surgical Devices	Intracerebral Forceps	Made of metal, consisting of handle part and head part; The head tip can be taper or round, generally reusable instrument; The angle of the handle and the head part can be two-dimension; The handle is designed into concave-convex to inprove skid resistance, the surface shall be smooth to avoid damaging tissues around; Can be devided into various specifications according to texture, design, technical parameters, intended use etc Generally be reusable; Used for gripping dressings, soft tissue in brain	II
10	6803	Neurological Surgical Devices	Intracerebral Hook	Made of metal, consist of handle and head part; The head tip can be harf round or smooth hook; The angle of the handle and the head part can be two-dimension, three-dimensional; The handle part can be skid resistant; The surface shall be smooth to avoid damaging tissues around; Can be devided into various specifications according to texture, design, technical parameters, intended use etcGenerally be reusable; Used for pulling nerves or brain tissue in brain surgery.	II
11	6803	Neurological Surgical Devices	Intracerebral curette	Made of metal, consist of handle and head part; The head tip can be spoon shape; Handle part and head part can be coaxial; The handle part can be skid resistant; The surface shall be smooth to avoid damaging tissues around; Can be devided into various specifications according to texture, design, technical parameters, intended use etcGenerally be reusable; Used for necrotic tissue and diseased bone curettage in	II
12	6803	Neurological Surgical Devices	ventricular fluid sucker	Made of metal, consist of tube body and luer composition; The tube body is slender tubular; There are holes on the head part; Can be devided into various specifications according to texture, design, technical parameters, intended use etcGenerally be reusable; Used for sucking ventricular fluid for inspection or ventricular fluid drainage in brain surgery.	II
13	6803	Neurological Surgical Devices	Intracerebral dissector	Made of metal, consist of handle part and head part; The head tip can be designed into various shapes with different width; Handle part and head part can be coaxial; generally reusable instrument; The handle part can be skid resistant; The head surface shall be smooth to avoid damaging tissues around; Can be devided into various specifications according to texture, design, technical parameters, intended use etcGenerally be reusable; Used for stripping meninx in brain surgery.	II
14	6804	Ophthalmic operation	single-use ophthalmic scalpel	Consist of shank (polycarbonate) and blade (stainless steel); sterile; Can be devided into various specifications according to texture, design, technical parameters, intended use etcSterile state; Used for	II

15	6804	Ophthalmic operation instruments	single-use ophthalmic puncture system	Including the stab knives, puncture cannula, handle, protective cap, self-closing valve and infusion tube head, can be respectively made of stainless steel, polycarbonate, polypropylene, silicone resin or the like; Can be devided into various specifications according to texture, design, technical parameters, intended use etcSterile state; Used for eye surgery, such as vitrectomy, establish instrument channel at sclera flat	II
16	6804	Ophthalmic operation instruments	single-use foldable IOL implantation system	Mainly made of polypropylene and other applicable materials, consist of injector, implant device; sterile; Can be devided into various specifications according to texture, design, technical parameters, intended use etcSterile state; Used for injecting foldable IOL in IOL implantation.	II
17	6807	Thoracic and Cardiovascular Surgical Instruments	scatheless artery/vein vascular clamps	Made of metal, single joint, consist of handle and head part; The head part can be straight, bent; The angle of the handle and the head part can be two-dimension, three-dimensional to be suitable for different anatomical position; The inner head tip can be harf-hard insertion to increase its stability to induce injury; The forceps can be lockable; Can be devided into various specifications according to texture, design, technical parameters, intended use etcGenerally be reusable; Used for arteriovenous blocking when it	II
18	6807	Thoracic and Cardiovascular Surgical Instruments	Vascular puncher	Divided into two types of single-use and re-use. single-use punch is made of stainless steel and ABS and other applicable materials, shall be sterile; Reusable punch is made of stainless steel which is accord with ASTM F899, non-sterile; Can be devided into various specifications according to texture, design, technical parameters, applicable blood vessel etc Used for punching circular opening on the arterial/venous blood vessel walls, to facilitate the subsequent vascular graft \( \Lambda \) anastomosis;	II
19	6807	Thoracic and Cardiovascular Surgical Instruments	Mitral dilator	Made of metal material, consist of handle with distraction rod, the body part and the head of the stent component, the expansion width can be adjusted; Can be devided into various specifications according to texture, design, technical parameters, etc Generally be reusable; Used for expansion of the mitral in heart	II
20	6807	Thoracic and Cardiovascular Surgical Instruments	Intracardiac Aspirators	Made of metal, consist of head part, pipe body and connector; Head part can be various angles and shapes to be suitable for different anatomical position; Can be devided into various specifications according to texture, design, technical parameters, etc Can be reusable; Equiped with aspirator, attracting pericardium for heart surgery when / heart liquids.	II
21	6807	Thoracic and Cardiovascular Surgical Instruments	Vascular flushing / suction tube	Made of stainless steel, consist of the head part, the pipe body and fittings; can be used repeatedly; Can be devided into various specifications according to texture, design, technical parameters, etc Can be reusable; Flushing device matching for surgery perfusion / attractive, used for rinsing in vivo or in vitro blood vessel.	II
22	6807	Thoracic and Cardiovascular Surgical Instruments	Suture knot pusher	Made of metal and other materials, consist of head part and handle part, the head end has suture penetration hole; Can be devided into various specifications according to texture, design, technical parameters, etc  Thoracic surgery, suture knot used to push the inner body surface or chest.	II
23	6807	Thoracic and Cardiovascular Surgical Instruments	Intercostal soft tissue retractor	Consist of open-loop retractor, the retractor wall and adhesive tape. The open-loop retractor is made of elastic material such as polyester, the retractor wall can be made of polyether polyurethane and other suitable wall material, the tape backing is made of nonwoven, the adhesive layer is acrylic adhesive; Can be devided into various specifications according to texture, design, technical parameters, etc Sterile; Intercostal into cardiac surgery, surgical retractor operating mouth tissue formation, visible intrathoracic	II
24	6807	Thoracic and Cardiovascular Surgical Instruments	Heart Valve Sizer	Made of medical silicone rubber. For the detection of mechanical heart valve leaflets flexibility.	II

25	6807	Thoracic and Cardiovascular Surgical Instruments	Heart valve installation kit	Consist of knot pusher, valve probe, valve placement. Knot pusher is used for pushing the invitro suture to body surface or chest. Valve probe is used for testing mechanical valve leaflets; Placement is used to place mechanical valves.	II
26	6807	Thoracic and Cardiovascular Surgical Instruments	Atrial retractor	Made of stainless steel, consist of triangular frame, retractor blades and tweezers. Used for valve surgery, the anterior wall of the right atrium of the retractor to expose the mitral valve, to facilitate observation of internal and external structure of the heart.	II
27	6807	Thoracic and Cardiovascular Surgical Instruments	Plier for valve surgery	Made of stainless steel, used for grabing or removing hard substances on cardiac structure in valve surgery, such as calcified material and fibrous tissue.	II
28	6807	Thoracic and Cardiovascular Surgical Instruments	tweezers for minimally invasive heart surgery	Made of stainless steel, Used for pinching and operations on heart surgery in minimally invasive cardiac structure.	II
29	6807	Thoracic and Cardiovascular Surgical Instruments	single-use ECG stable board	Consist of stable plate(middle-type, left-type, right-type, plastic), arms(stainless steel), locking bracket, locking bracket rotary knob (ABS), pedestal and arms adjusting rotary knob; Can be devided into various specifications according to texture, design, technical parameters, etc Sterile; Used to stabilize partial heart in off-pump coronary artery bypass grafting, provide conditions for coronary anastomosis.	II
30	6807	Thoracic and Cardiovascular Surgical Instruments	single-use Heart Stabilizer	Used to establish a fixed surgery area in target blood vessel in coronary bypass operation. Can be Stable-V1 (extraxtion fixation) and Stable-M1 (Mechanical fixation). Mainly consist of presser foot leaves(suction cups, suction cups fixed seat), vacuum connecting tube, three-way valve, directional collet assembly, adjustment arm, mounts, adjustable handle, rotary handle, etc; Sterile; This product do not enter into blood circulation system. It can be also named cardiac stabilizer.	II
31	6808	Abdominal Surgical Operation	single-use tube-type anastomat	The nail part is made of titanium or tantalum, the other parts are made of metal, polymer materials, etc.; Mainly consist of nail anvil, the body and components(nail bin, nail pulling piece and nail anastomoses); Can be devided into various specifications according to texture, design, technical parameters, intended use etcSterile state, Strike the derangement nails placed in the components into tissues which need to be perpetual nail together, mainly for digestive tract reconstructive surgery in end to end, side and side-to-side anastomosis. Reference Standard: YY/T0245-2008 General specifications for stapler	II
32	6808	Abdominal Surgical Operation	Reusable tube-type anastomat	The nail part is made of titanium or tantalum, the other parts are made of metal, polymer materials, etc.; Mainly consist of nail anvil, the body and components(nail bin, nail pulling piece and nail anastomoses); Can be devided into various specifications according to texture, design, technical parameters, intended use etc Can be reused, the components are sterile state; Strike the derangement nails placed in the components into tissues which need to be perpetual nail together, mainly for digestive tract reconstructive surgery in end to end, side and side-to-side anastomosis. Reference Standard: YY/T0245-2008 General specifications for	II

				The nail part is made of titanium or tantalum, the other parts are made of metal, polymer materials, etc.;	
33	6808	Abdominal Surgical Operation	single-use Linear anastomat	Mainly consist of nail anvil, the body and components(nail bin, nail pulling piece and nail anastomoses); Can be devided into various specifications according to texture, design, technical parameters, intended use etc Sterile state; Place tissue between componets and nail anvil, and install the location needle.; Strike the derangement nails placed in the components into tissues with a "B" shape, so the two layers of tissues can be perpetual nail together, but a cutting function. Mainly for digestive organ reconstruction and stump removal surgery or incision closed. Reference Standard: YY 0875-2013 Linear stapler and cartridge	II
34	6808	Abdominal Surgical Operation	single-use curved anastomat	It is a combination of tube-type anastomat and linear anastomat. Anastomat nails are made of titanium or tantalum, the other parts are made of metal, polymer materials, etc.; Mainly consist of nail anvil, the body and components(nail bin, nail pulling piece and nail anastomoses); Can be devided into various specifications according to texture, design, technical parameters, intended use etc. The component can be changed; Sterile state; Used for digestive tract reconstruction with a difficult surgical field exposure and stump or incision closure, anastomotic stoma reconstruction in visceral organ	II
35	6808	Abdominal Surgical Operation	single-use linear cutter anastomat	The nail part is made of titanium or tantalum, the other parts are made of metal, polymer materials, etc.; Mainly consist of nail anvil, the body and components(nail bin, nail pulling piece and nail anastomoses); Can be devided into various specifications according to texture, design, technical parameters, intended use etc Sterile state; The component can be changed; Mainly used for digestive tract reconstruction with a difficult surgical field exposure and stump or incision closure, anastomotic stoma reconstruction in visceral organ. Used to provide clinical evaluation for lung resection operation. Reference standard: YY 0876-2013	II
36	6808	Abdominal Surgical Operation	single-use purse-string suture needle	Made of metal and suture, consist of a non-absorbable suture(polyamide 6, polyamide 6/6) and two needles; Can be devided into various specifications according to texture, design, technical parameters, etc Sterile state; Used with suturing forceps for gastrointestinal anastomosis purse string. Reference standard: YY 0877-2013 Purse string needle(with suture)	II
37	6808	Abdominal Surgical Operation	single-use automatic purse string suture device	Made of metal, polymer materials, non-absorbable surgical suture, mainly consist of clamp base, nail base, nail and purse suture; Can be devided into various specifications according to texture, design, technical parameters, etc Sterile state; Used for gastrointestinal surgery purse string.	II
38	6809	Urinary anorectal surgical instruments	single-use anorectal anastomat	It is one of the kinds of the single-use tube-type anastomat; The nail part is made of titanium or tantalum, the other parts are made of metal, polymer materials, etc.; Mainly consist of nail anvil, the body and components(nail bin, nail pulling piece and nail anastomoses); Can be devided into various specifications according to texture, design, technical parameters, intended use etc Sterile state; Strike the derangement nails placed in the components into tissues which need to be perpetual nail together; Mainly used for cutting mucosa tissues selectively of rectum to recover normal anatomical structure under rectum. Reference standard: YY/T 0245-2008 General specifications for stapler	II

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39	6809	Urinary anorectal surgical instruments	Reusable anorectal anastomat	It is one of the kinds of the single-use tube-type anastomat; The nail part is made of titanium or tantalum, the other parts are made of metal, polymer materials, etc.; Mainly consist of nail anvil, the body and components(nail bin, nail pulling piece and nail anastomoses); Can be devided into various specifications according to texture, design, technical parameters, intended use etc Can be reusable; The components are sterile; Mainly used for cutting mucosa tissues selectively of rectum to recover normal anatomical structure under rectum. Reference standard: YY/T 0245-2008 General specifications for stapler	II
40	6809	Urinary anorectal surgical instruments	single-use circumcision anastomat	Made of ABS or stainless steel and other materials, the suture nail is made of stainless steel or suitable metal, generally consist of annular cutter, positioning springs, metal gaskets, fixed pin and active connecting plates, suturing nail made of suturing nails and concave base, annular knife anvil, cartridge cover, nail bin, top body, main body shell, mover, main body fixed ring, locational adjusting screw nut, main body cover, active handle, safety pin. Product should be sterile. Suitable for clinical circumcision suture.	II
41	6809	Urinary anorectal surgical instruments	single-use foreskin ligation device	Mainly made of metals and plastics, consist of clamping ring, rings(inner ring, rubber mat; with or without handle), connecting device(connecting rod or guide sleeve, screw, nut); Can be devided into various specifications according to texture, design, technical parameters, intended use etc Sterile; Used for healing without suturing and assist with circumcision.	II
42	6809	Urinary anorectal surgical instruments	single-use Sterile fistula brush	Mainly consist of brush handle, bristles and silk thread; Sterile; Used for identification, cleaning rectal fistula.	II
43	6809	Urinary anorectal surgical instruments	single-use urethral dilator	Mainly consist of the head, the rod portion and the handle, can be made of applicable plastic material; Sterile; Can be devided into various specifications according to texture, design, technical parameters, etc Used for expansion when the urethra urethral stricture.	II
44	6809	Urinary anorectal surgical instruments	single-use anorectal ligation device	Made of suitable metal, plastic and silica gel, mainly consist of gun body(with spring inside), barrel, silicone ring, negative pressure suction joint, bobbin winder, switch of ligator and cap; Can be with one or more silicone ring, can be with a auxiliary lighting apparatus; Sterile; Applicable to each ligation of hemorrhoids and mixed hemorrhoids or rectal benign polyps.	II
45	6809	Urinary anorectal surgical instruments		Made of nylon, PTFE, stainless steel, polyethylene, polypropylene and the like, consist sheath and dilator, may also include guide wire, sheath may be a single or dual chamber; Can be devided into various specifications according to texture, design, technical parameters, etc Sterilile; Used in urological surgery, such as the establishment of an endoscopic instrument channel by entering the urinary tract.	II
46	6810	Orthopedic surgery (orthopedic) surgical instruments	Vertebral rongeur	Made of suitable metal material, mainly consist of clamp head, clamp handle, strontium shaft screw, hold spring screws, hold spring, spring pulleys and other components. Can be single joints, double joints, side angle, etc. Used for biting and refurbishment bone sequestrum. with time for orthopedic surgery. Reference standard: YY/T1127—2006 Rongeur	II
47	6810	Orthopedic surgery (orthopedic) surgical instruments	Nucleus clamp	Mainly consist of clamp head, cover plate, clamp body, left clamp handle, support springs; The types can be straight end and bent end; Can be devided into various specification according to different size. Used for biting soft tissues such as nucleus pulposus in orthopedic surgery	II

Made of stainless steel, the handle part can use other applicable materials, typically be hand-held manual single-piece surgical instruments with single cutting edge, the far-end can be sharp blade with various shapes; Can be devided into various specifications according to texture, design, technical parameters, etc Can transfer force from the near-end to far-end with a surgery hammer. Used for chiseling, trimming, stripping vertebra such as cervical vertebra to shape them up.  Mainly consist of bone cement glue gun, detachable nozzle sleeve, bone cement preparation container, cement spoon, stirring rod, sleeve seat and other components. Metal parts are generally reused, non-metallic members are generally single-use. The stuite can be sterile; Used to stir bone cement and inject it into marrow cavity. Including low viscosity bone cement filling suite.  Supply power with rechargeable battery, consist of host, phone (such as drills, milling, grinding, saws, etc.), a variety of knife tools (optional) and accessories (phone can be integrited with the host and can also be detachable); The equipment can be devided into various specifications according to power, supply, technical parameter, accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, sawing and other operations in surgery. Reference standard: YY O04-2013 battery power, consist of host, phone (such as drilling rigs, etc.), various knife tools and accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, saving and other operations in surgery. Reference standard: YY TO 752-2009 Electric surgical equipment instruments  Orthopedic surgery orthopedic) surgical instruments  Orthopedic surgery orthopedic) surgical instruments  orthopedic surgery orthopedic) surgical instruments  Supply power is compressed fair, consist to host, phone (such as drilling rigs, etc.), various knife tools and accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, saving and other operation
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Stripping vertebra such as cervical vertebra and lumbar vertebra to shape them up.
Orthopedic surgery (orthopedic) surgical instruments  Battery-powered bone tissue surgical equipment  orthopedic surgery (orthopedic) surgical instruments  Orthopedic surgery (orthopedic) surgical equipment with network power is network power (can be devided into various specifications according to power, supply, technical pararmeter, accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, saving and other operations in surgery. Reference standard: YY/T 0752-2009 Electric surgical equipment for osseous tissue surgical equipment
cement spoon, stirring rod, sleeve seat and other components. Metal parts are generally reused, non-metallic members are generally single-use. The suite can be sterile; Used to stir bone cement and inject it into marrow cavity. Including low viscosity bone cement filling suite.  Supply power with rechargeable battery, consist of host, phone (such as drills, milling machines, grinders, saws, etc.), a variety of knife tools (optional) and accessories (phone can be integrated with the host and can also be detachable); The equipment can be devided into various specifications according to power, supply, technical pararmeter, accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, sawing and other operations in surgery. Reference standard: YY 6904-2013 Battery power supply surgical supply power with network power (can be double-power of network power and battary power), consist of host, phone (such as drilling, milling, grinding, saving and other operations in surgery. Reference standard: YY/T 0752-2009 Electric surgical equipment to rosseous tissue.  Supply power is operations in surgery, Reference standard: YY/T 0752-2009 Electric surgical equipment to rosseous tissue.  Supply power is compressed (in: consist of host, phone (such as drilling rigs, etc.), various knife tools and accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, saving and other operations in surgery. Reference standard: YY/T 0752-2009 Electric surgical equipment to rosseous tissue.  Supply power is compressed (in: consist of host, phone (such as drilling rigs, etc.), various knife tools and accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, sawing and other operations in surgery.  Supply power is network power(can be double-power of network power and battary power), consist of host, phone (such as drilling rigs, etc.), various knife tools and accessories, Can be devided into various specifications according to power, supply, technical pararmete
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instruments equipment technical pararmeter, accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, sawing and other operations in surgery. Reference standard: YY 0904-2013 Battery power supply surgical  Supply power is network power(can be double-power of network power and battary power), consist of host, phone (such as drilling rigs, etc.), various knife tools and accessories; Can be devided into various specifications according to power, supply, technical pararmeter, accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, sawing and other operations in surgery. Reference standard: YY/T 0752-2009 Electric surgical equipment for osseous tissue  Supply power is compressed air, consist of host, phone (such as drilling rigs, etc.), various knife tools and accessories; Can be devided into various specifications according to power, supply, technical pararmeter, accessories; Can be devided into various specifications according to power, supply, technical pararmeter, accessories; Can be devided into various specifications according to power, supply, technical pararmeter, accessories; Can be devided into various specifications according to power supply, technical pararmeter, accessories; Can be devided into various specifications according to power and battary power), consist of host, phone (such as drilling, milling, grinding, sawing and other operations in surgery).  Supply power is network power (can be double-power of network power, supply, technical pararmeter, accessories; Can be devided into various specifications according to power supply, design, technical pararmeter, accessories; Can be devided into various specifications according to power supply, design, technical pararmeter, accessories; Can be devided into various specifications according to power supply, design, technical pararmeter, accessories; Can be devided into various specifications according to power supply, design, technical pararmeter, accessories; Can be devided into various speci
sawing and other operations in surgery. Reference standard: YY 0904-2013 Battery power supply surgical  Supply power is network power (can be double-power of network power and battary power), consist of host, phone (such as drilling rigs, etc.), various knife tools and accessories; Can be devided into various specifications according to power, supply, technical pararmeter, accessories, intended use, etc. Used for implementing bone drilling, grinding, sawing and other operations in surgery. Reference standard: YY/T 0752-2009 Electric surgical equipment for osseous tissue  Supply power is compressed air, consist or host, phone (such as drilling rigs, etc.), various knife tools and accessories; Can be devided into various specifications according to power, supply, technical pararmeter, accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, sawing and other operations in surgery.  Supply power is network power (can be double-power of network power and battary power), various knife tools and accessories; Can be devided into various specifications according to power, supply, technical pararmeter, accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, sawing and other operations in surgery.  Supply power is network power (can be double-power of network power, supply, technical pararmeter, accessories; Can be devided into various specifications according to power and battary power), consist of host, phone (such as drilling rigs, etc.), various knife tools and accessories; Can be devided into various specifications according to power supply, design, technical pararmeter, accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, sawing and other operations in microsurgery accessories; can be devided into various specifications according to power supply, design, technical pararmeter, accessories; Can be devided into various specifications according to power supply, design, technical parameter, accessories; can be devided into v
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laccessories, foot switch: Can be equiped with water-cooling system. The equipment can be devided into
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Orthopedic surgery Orthopaedic electric / Made of stainless steel or alloy, mainly consist of the rod and head part; Can be devided into different
55 6810 (orthopedic) surgical pneumatic tool specifications according to the head shapes or sizes. Can be respectively with pneumatic or electric tools to
instruments accessories - Polishers cut, sculpt in orthopedic surgery
Orthopedic surgery Orthopaedic electric / Made of stainless steel or alloy, mainly consist of the rod and head part; Can be devided into different
56 6810 (orthopedic) surgical pneumatic tool specifications according to the head shapes or sizes. Can be respectively with pneumatic or electric tools to
instruments accessories - diamond cut, sculpt in orthopedic surgery

57	6810	Orthopedic surgery (orthopedic) surgical instruments	Orthopaedic electric / pneumatic tool accessories - Blades	Made of applicable metals such as 301, 420, 420MODIFIED stainless steel; There are fixed collar on the blade; Can be devided into different specifications according to texture, shapes and sizes, etct Can be respectively with pneumatic or electric tools to cut, sculpt in orthopedic surgery	II
58	6810	Orthopedic surgery (orthopedic) surgical instruments	Pneumatic rongeur	Mainly consist of working rod, reducing valve, pneumatic handle, single-use snorkel etc.; single-use snorkel is made of plastic with sterile state. Can be devided into various specifications according to texture, design, technical parameters, applicable sites, intended use, etc Used for biting rotten bones, cartilage and tissue, etc. in microscopic surgery.	II
59	6810	Orthopedic surgery (orthopedic) surgical instruments	Orthopedic external fixator	Made of suitable material (stainless steel / aluminum alloy / carbon); Mainly consist of a plurality of brackets and fixed member, can be one-arm or annular arm, may have a universal structure; Can be devided into various specifications according to texture, design, technical parameters, applicable sites, intended use, etc Used with bone nail for long bone or pelvic fracture fixation endures.	II
60	6812	Obstetrical and Gynecological Surgical Operation Instruments	single-use embryo transfer catheter	Consist of guide catheter, transplant catheter and sheath etc.; guide catheter is made from PVC material, the transplant catheter is consist of stainless steel catheter, polycarbonate, silicone material; sterile; Can be devided into various specifications according to texture, design, technical parameters, etc Sterile state; Used with syringe to transfer in vitro fertilization (IVF) embryos or fertilized ovum to the uterus via	II
61	6812	Obstetrical and Gynecological Surgical Operation Instruments	single-use embryo transfer tube with sheath	Consist of protection tube, guide catheter and grafting conduit. The guide catheter consists of conduit (PTFE), pipe carrier(polyethylene), protection tube (PE); the grafting conduit is consist of the conduit (polyurethane), pipe carrier (polyurethane), pipe core, Echotip head end(304 stainless steel); Can be devided into various specifications according to texture, design, technical parameters, etc Sterile state; Used with syringe to transfer in vitro fertilization (IVF) embryos or fertilized ovum to the uterus via	II
62	6812	Obstetrical and Gynecological Surgical Operation Instruments	single-use fetal head vacuum aspirator	Made of applicable polymer materials such as polypropylene, consist of a handle and a sucker; Can be devided into various specifications according to texture, design, size, etc Can be sterile state; When puerpera can not be a normal delivery causing by various reasons, vacuum suction cups can produce a vacuum aspiration on the fetal head to assist vaginal or caesarean delivery. Excluding pneumatic vacuum	II
63	6815	Puncture Injection Equipment	All-glass syringes	Mainly made of aluminoborosilicate glass material, consist of conical head, sleeving and core; Can be metriocranic and unsymmetric; Each kind can be devided into various specifications according tonominal capacity; Install a needle on it, then you can operate subcutaneous, muscle, intravenous injection or draw liquid. Reference standard: YY 1001.1-2004 Glass syringes—Part 1:Syringes with all-glass	II
64	6815	Puncture Injection Equipment	Blue core all-glass syringes	Mainly made of aluminoborosilicate glass material, consist of conical head, sleeving and core(made of blue glass); Generally be metriocranic; Can be devided into various specifications according tonominal capacity; Install a needle on it, then you can operate biochemical test, subcutaneous test. Used to inject vaccination, dental anesthesia or other liquid. Reference standard: YY 1001.2-2004 Glass syringes—Part 2:Blue	II
65	6815	Puncture Injection Equipment	Metal injection needle	Mainly consist of needle seat(copper base chrome-plated) and needle tubing(high-grade stainless steel). The nominal outside diameter of needle tubing can be 0.4mm—1.6mm, and the length can be 10mm—100mm. The wall of the needle tubing can be normal wall and thin-wall. Use with syring for subcutaneous, intracutaneous, muscle, oral cavity liquid injection. Reference standard: YY/T 0282-2009 Syringe needle	II

66	6815	Puncture Injection Equipment	Metal Spinal needle	Mainly made of copper base chrome-plated (needle seat, core seat) and high-grade stainless steel(needle tubing, core); Mainly consist of core seat, locating pin,needle seat, core,needle tubing; The nominal outside diameter of needle tubing can be 0.4mm—1.6mm, and the length can be 25mm—200mm; The wall of the needle tubing can be normal wall and thin-wall. Use with syring for subarachnoid space puncturation or liquid injection or cerebrospinal fluid drawing. Can be reusable. Reference standard: YY/T 1148—2009	II
67	6815	Puncture Injection Equipment	single-use laparoscopic puncture outfit	Mainly made of suitable polymer and metal material, the typical structure may include puncture needle, puncture cannula, injection valve, choke valve, sealing cap; Can be devided into various specifications according to texture, design, technical parameters, etc Can be sterile; Used to puncture naples tissues to establish enterocoelia operation pass in laparoscopy examination and operation. Reference standard: YY 0672.1-2008 Endoscopic Instruments—Part1: Trocars for Laparoscope Use	II
68	6815	Puncture Injection Equipment	single-use syringe for dispensing	Shall be made of polypropylene which confirm to YY 0242 Polypropylene material for manufacture of infusion transfusion and injection equipments for medical use or other high polymer material which is non-poisonous side-effect. Mainly consist of protective cap, dispensing needle, outer thimble, core pin and piston. Can be devided into various specifications according tonominal capacity; Can have side opening or bevel dispensing needle. Sterile state; Used for liquid extraction or preparation. Reference standard: YY/T	II
69	6815	Puncture Injection Equipment	single-use dispensing needle	Made of polypropylene and high-grade stainless steel; Mainly consist of needle seat, needle tubing and protection cap. Can be side opening and beyel. Use with single-use syringe for dispensing for liquid extraction or preparation. Reference standard: YY/T0821 single-use syringe for dispensing	II
70	6815	Puncture Injection Equipment	Metal needle used in thoracentesis	Mainly made of copper base chrome-plated (needle seat) and high-grade stainless steel (needle tubing).  Mainly consist of needle seat, three direct links, positioning device and scale needle tubing. The nominal outside diameter of needle tubing can be 1.2mm or 1.6mm, and the length can be 65mm—65mm or more;  Use with syring for extracting pleural effusion to establish access in forthoracocentesis. Can be reusable	II
71	6815	Puncture Injection Equipment	single-use dental rinsing needle with flat head	Mainly made of high polymer material and high-grade stainless steel. Mainly consist of needle seat,flat-head needle tubing and protective cap. Can be straight and bent. Sterile state; Use with syring for oral cavity pressure washing in department of stomatology.	II
72	6815	Puncture Injection Equipment		Made of suitable stainless steel, consist of oblate handle and triangle needle tip; Used to puncture skin in immediate hypersensitivity skin test to transfer antigen into subcutaneous. Exemption does not include products with antigen in them	II
73	6815	Puncture Injection Equipment	Insulin pen-syringe	Consist of dosage adjusting button(ABS), pen body(Polycarbonate), releasing button  (copolyoxymethylene), guiding screw(nylon), cartridge frame(PBT), pen cap(ABS); Excluding medicine and needle; All part do not contact liquid; Shall use with insulin syring needle or standard syring needle for	III
74	6815	Puncture Injection Equipment	Thyrocricocentesis needle	Made of metal material such as stainless steel, consist of lockable sleeve and the cone punture needle. Can be devided into various specifications according to texture, design, technical parameters, etc Used to establish artificial airway in thyrocricocentesis to release respiratory tract blocking.	III
75	6815	Puncture Injection Equipment		Mainly consist of needle seat and needle tubing. Establish a percutaneous access for devices in blood vessel with Seldinger. Seldinger mainly refers to blood vessel in angiography.	III
76	6815	Puncture Injection Equipment		Mainly consist of catheter and catheter seat. Establish a percutaneous access for devices in blood vessel with Seldinger. Seldinger mainly refers to blood vessel in angiography.	III

77	6815	Puncture Injection Equipment		Mainly consist of protection cover for blood taking needle, blood taking needle, needle handle, clamps, blood taking tube, female cone joint; protection cover for joint. Used for blood vessel puncturation in clinical hematodialysis. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function	III
78	6815	Puncture Injection Equipment	Enterocoelia puncture needle	The structure is limited to abdominocentesis puncture needle with needle tubing, needle seat, connecting pipe. Used for abdominocentesis. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	III
79	6815	Puncture Injection Equipment	single-use biopsy needle	The structure is limited to biopsy needle with puncture needle and needle core, the material shall conform to GB 18457, the biopsy needle will contact human tissues and organs to puncture to achieve pathological tissue. Exemption does not include biopsy needle use with endoscope system, vacuum aspiration device or need to be guided by ultrasound or X-ray image documentation equipment. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action	III
80	6815	Puncture Injection Equipment	single-use Venous Blood Lancet	Mainly consist of puncture needles, sheath, catheters, lancets; Use with single-use human venous blood taking containers for venous blood taking. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function	III
81	6815	Puncture Injection Equipment	single-use intravenous indwelling needle	Properties, structure, composition, usage, etc are covered by industry standard "single-use intravenous indwelling needle" which is about to be published. Mainly consist of catheter module and needle tubing module, catheter module mainly consist of catheter, catheter seat, extension tubes (if any) and assemblies composed of any one of the connectors; needle tubing module mainly consist of needle tubing and needle hub and/or assemblies composed of any one of the connectors; Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or	III
82	6815	Puncture Injection Equipment	One-time use of intravenous infusion needle	Properties, structure, composition, usage, etc.shall belong to products covered in GB 18671" Intravenous needles for single use", usually consist of needle tubing(nominal diameter 0.36-1.2mm), needle handle, hose, connecting seat and protective cap; Used with infusion sets, transfusion sets for the establishment of peripheral venous access. If the product has special properties or structures (such as self-destruct, filtering, anti-acupuncture), new materials (besides the main material, there are additives such as lucifugal agent, plasticizers, etc.), the clinical trails can not be exempted. Exemption does not include products with new materials, active ingredients, new technologies, new design or with a new action mechanism or function	III
83	6815	Puncture Injection Equipment	single-use anesthesia needle	Properties, structure, composition, usage, etc.shall belong to products covered in YY 0321.2 "Single-use needle for anaesthesia". Products are generally composed of core print seat, needle seat, needle tubing and core print. Used to puncture or inject medicine anesthesia. Exemption does not include products with new materials, active ingredients, new technologies, new design or with a new action mechanism or function	III
84	6815	Puncture Injection Equipment	single-use breast and guided needle localization wire	Properties, structure, composition, usage, etc. shall belong to products covered in YY / T 0880 "Breast localization wire and introducer needle for single use". Introducer needle tubing shall be made of materials which conform to GB 18457; The localization wire should use stainless steel or other alloy material; Used in clinical for cutting small breast lesions in surgery. Use localization wire or introducer needle to locate the lesions thus guiding the clinical doctors to shrink the incision to decrease the surgical injury. Exemption does not include products with new materials, active ingredients, new technologies, new design or with a	III

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85	6815	Puncture Injection Equipment	single-use sterile syringes	Properties, structure, composition, usage, etc. shall belong to products covered in GB 15810"Sterile hypodermic syringes for single use"; Generally composed of syringe cover, piston, seal ring, core pin, handle, cone. It is a syringe used for pumping or injecting immediately after liquid injecting. If the product has special properties or structures (such as self-destructive, anti-acupuncture, etc.), the clincal trails can not be exempted. Exemption does not include products with new materials, active ingredients, new technologies, new design or with a new action mechanism or function.	III
86	6815	Puncture Injection Equipment	single-use sterile needles	Performance, structure, composition, use, etc. shall belong to products covered in GB 15811 " Sterile hypodermic needles for single use". Mainly consist of needle seat, connecting portion, needle tubing, sheath; Used for subcutaneous, intramuscular, intravenous injection or pumping liquid. If the product has special properties or structures (such as self-destructive, anti-acupuncture, etc.), the clinical trails can not be exempted. Exemption does not include products with new materials, active ingredients, new technologies, new design or with a new action mechanism or new function	II
87	6815	Puncture Injection Equipment	single-use needle thoracentesis	The composition is limited to needle tubing, needle seat, connecting tubes. Used in thoracentesis. Exemption does not include products with new materials, active ingredients, new technologies, new design or with a new action mechanism or function	II
88	6820	General examination equipment	Glass thermometer	Glass thermometer is made of glass, with measuring point structure. Temperature sensing liquid is mercury or other metals. Can be divided into triangular rod, neonatal rod, ingot type rod, internal standard rod according to types, while different specifications can be devided according to different sizes. Measuring range is usually: 35-42 °C, the temperature minimum scale value is 0.1 °C, used for temperature measurement for clinical or personal use. Reference standard: GB 1588-2001 thermometer.	II
89	6820	General examination equipment	Medical electronic thermometer	It is an electronic devices which intermittent contact patients for temperature monitoring; Mainly consist of plastic shell, circuit boards, temperature measurement unit, display screen, power supply, etc.; Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, intended use, etc. Used for measuring body temperature or monitoring female ovulation cycle. Do not include prediction model or medical infrared thermometer. Reference standard: GB / T 21416-2008	II
90	6820	General examination equipment	Ear cavity medical infrared thermometer	Mainly consist of plastic shell, circuit boards, temperature measurement unit, display screen, power supply, isolation film; Can be devided into carious specifications according to different design, technical parameters, additional auxiliary functions, intended use, etc.; Shows ear cavity temperature by thermal radiation. Shall provide clinical accuracy and repeatability reports. Reference standard: GB/T 21417.1-2008	II
91	6820	General examination equipment	Mercury sphygmomanometer	Mercury sphygmomanometer can have a table type, such as vertical type and hanging type, basic parameters: Measuring range: 0-40kPa (0-300mmHg), children sphygmomanometer 0-20kPa (0-150mmHg); dual-scale ruler, the minimum division value is 0.5 kPa (2 mmHg); indication tolerance of ± 0.5kPa (± 3.75 mmHg); the cuff can be divided into various specifications acording to balloon size; Children sphygmomanometer is with adjustable parameters; Used for measuring blood pressure.Reference	II

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92	6820	General examination equipment	Mechanical elastic element blood pressure meter	Mechanical elastic element blood pressure meter is with dual scale measurement, the measurement range for adults is 0-40kPa (0-300mmHg), minimum scale values were 0.5kPa and 2mmHg, tolerance is of $\pm$ 0.5kPa ( $\pm$ 3.75mmHg), Cuffs can be devided into various specifications according to balloon sizes; Children sphygmomanometer is with adjustable parameters; Can be devided into various specification according to type, technical parameters and application objects; Used for blood pressure measurement. Reference	II
93	6820	General examination equipment	Simple spirometer	They are mainly table type. Mainly consist of base, sink, floats, rods and threaded pipe, etc.; Can be divided into several different models according to design, technical parameters, application object, etc.; Used for measuring human lung capacity.	II
94	6820	General examination equipment	Schirmer detection filter paper	Mainly made of filter paper with sodium fluorescein labeled line, used for detecting in various tear paracrisis.	II
95	6821	Medical electronic equipment	ECG machine	Electrical cardiac excitement generated after heart mechanical contraction will form micro-current, the micro-current will pass through body tissues to body surface, and then different potential will be formed on different parts of body surface, the visible record of heart action potential is ECG. ECG can output and display potential difference between two points according to time sequence of cardiac excitement, sequential recording and processing via two cable electrodes on patient surface. Mainly be desktop or handheld. Consist of host, patient cable, electrodes. Electrodes may be reusable or single-use form. Recording means can be heat stylus or hot line array. Some products have a signal input or output port. Can be divided into various specifications according to technical parameters and functions, such as can be single channel, dual-channel, multi-channel, etc. according to simultaneous measurement lead number, the collected electrical signal can be input into computer for processing (e.g. high-frequency signal processing, etc.), but	II
96	6821	Medical electronic equipment	Dynamic ECG Recorder	Mainly consist of portable recorder and leadwires, can include data management software and accessories (ECG cable, charger, USB cable, etc.); Can be devided into specification according to the number of leads, technical parameters, intended use, additional auxiliary functions, etc. Used for 24h dynamic electrocardiogram/monitoring. Do not include autoanalysis function.Reference standard: YY 0885-2013 Medical electrical equipment—Part 2: Particular requirements for the safety,including essential	II
97	6821	Medical electronic equipment	Fetal ECG machine	Mainly consist of host, lead wair, electrode, can contain data management software,print facility; Can be devided into various specifications according to the number of lead wair, technical parameters, intended use, additional miscellaneous function. Used for fetus electrocardio examination, monitoring. Exemption does not include products with auxiliary analysis and diagnostic functions	II
98	6821	Medical electronic equipment	Single-use ECG Electrodes	It is a accessory of ECG acquisition device and mainly consist of sensing element and electrolyte, can be with or without connecting wires. Electrode is composed of based lining materials, conductive paste, electrode buckle, etc. The based lining materials can be breathable paper, spunlace fabric, non-woven fabric, foam paper, cotton cloth or PE coated with pressure-sensitive adhesive; Can be round, oval, square, etc., Can be devided into various specifications according to according to their size; Use with instrument for ECG detection or monitoring. Reference standard: YY / T 0196-2005 Disposable ECG electrodes	II

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99	6821	Medical electronic equipment	EEG (electroencephalograp	Mainly consist of amplifier input boxes, computers, monitors, proprietary software, electrode; Can include flashlight, or flashlight controllers; Can be devided into various specification according to design, type, technical parameters, additional auxiliary functions, etc. Used for to detect, process, display and store EEG	II
				human physiological signal. Reference standard: GB 9706.25-2005 Medical electrical equipment-Part 2:	
		Medical electronic	BEAM (Brain	Mainly consist of host, display screen, amplifiers, printer, keyboard, mouse; Can be devided into various	
100	6821	equipment	electrical activity	specifications according to different design, type, technical parameters, additional auxiliary functions, etc.	II
		- quipmont	mapping)	Used for EEG physiological signals data processing, analysis, but without a automatic diagnosis function.	
				Mainly consist of host, stimulating electrodes, may also include computer, dedicated data management	
		Medical electronic	EMG	software and printer; Can be devided into various specifications according to different design, type,	
101	6821	equipment	(electromyography)	technical parameters, additional auxiliary functions, etc.Used for human EMG and nerve conduction data	II
		equipment	(cicculoniy ograpity)	acquisition, processing, analysis, does not include automatic diagnosis section. Reference standard: YY	
				0896-2013 Medical electrical equipment. Part 2: Particular requiremetrs for the safety of electromyographs	
				Mainly consist of power supply, sound card, power amplifier, controller, electro-acoustic transducer devices	
		Medical electronic		(air conduction headphones, bone conduction headphones), operating software, patient responses	
102	6821	equipment	equipment Pure tone audiometer	composed; Can be devided into various specifications according to different design, type, technical	II
				parameters, additional auxiliary functions, etc; Used for listening threshold detection for those who have a	
				response ability. Reference standard: GB / T 7341.1-2010 Electroacoustics—Audiological equipment—Part	
		Medical electronic	alactronic	Mainly consist of host and accessories, The accessories can include ECG cable, blood pressure cuff, oxygen	
				probe, temperature probe, end-expiratory carbon dioxide gas measurement components, anesthesia depth	
				external accessories; Can be devided into various specifications according to different design, type,	
				technical parameters, additional auxiliary functions, etc Used for monitoring patient's ECG, noninvasive	
103	6821	equipment	Multi-parameter monitor	blood pressure, pulse, oxyhemoglobin saturation, body temperature, respiration, end-tidal carbon dioxide,	II
		equipment	quipment	anesthesia depth. Reference standard: YY 1079-2008 Electrocardiographic monitors, YY 0670-2008 Non-	
				invasive automated sphygmomanometer, YY 0784-2010 Medical electrical equipment—Particular	
				requirements for the basic safety and essential performance of pulse oximeter equipment for medical use,	
				YY 0785-2010 Clinical thermometers—Performance of electrical thermometers for continuous	
				Multi-parameter central monitoring system is divided into wired and wireless. Wired monitoring system is	
				composed of a central host and multi-parameter monitor, wireless monitoring system consists of a central	
				host computer, transmitter and multi-parameter monitor; Can be devided into various specifications	
		Medical electronic	Multi-parameter central	according to different design, technical parameters, auxiliary functions, etc Used in medical institutions for	
104	6821	equipment	monitoring system	varieties of physiological parameters monitoring and management. Human body assessment report of overall	II
		equipment	momoring system	effectiveness of NIBP system and accuracy of blood oxygen oxygen shall be provided. Reference standard:	
				YY 1079-2008 Electrocardiographic monitors, YY 0670-2008 Non-invasive automated	
				sphygmomanometer, YY 0784-2010 Medical electrical equipment—Particular requirements for the basic	
				safety and essential performance of pulse oximeter equipement for medical use, YY 0785-2010 Clinical	

105	6821	Medical electronic equipment	Mother/fetus multi- parameter monitor	Mainly composed of host and accessories, accessories can include detection cable, blood pressure cuff, blood oxygen probe, temperature probe, ultrasound probe, uterine contraction pressure probe, labeled handles, etc., Can be divided into different specifications according to the design, type, technical parameters, additional auxiliary functions, etc.; Used for monitoring mother's ECG, noninvasive blood pressure, pulse, blood oxygen saturation, body temperature, respiration, uterine contraction press and fetal heart rate, fetal movement, etc Human body assessment report of overall effectiveness of NIBP system and accuracy of blood oxygen oxygen shall be provided. Reference standard: YY 1079-2008 Electrocardiographic monitors, YY 0670-2008 Non-invasive automated sphygmomanometer, YY 0784-2010 Medical electrical equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipement for medical use, YY 0785-2010 Clinical thermometers—Performance of	II
106	6821	Medical electronic equipment		Mainly consist of host, software and accessories; Can be divided into different specifications according to the design, type, technical parameters, additional auxiliary functions, etc., Used to monitor and analyse oronasal airflow, blood oxygen and/or abdominal movement and other related physiological signal under sleeping state for sleep apnea syndrome diagnosis or screening. Does not include automatic analysis and	II
107	6821	Medical electronic equipment		Mainly consist of probe (halogen lamps probe, laser probe), camera, host (including monitors, printers, computers, software); Can be divided into different specifications according to the design, type, technical parameters, additional auxiliary functions, etc.; Used for infrared light examination of breast disease.  Reference standard: YY 0324-2008 Infrared examining equipment for mammary gland	II
108	6821	Medical electronic equipment		Mainly consist of host (including control, data processing/display module) and associated oxygen probe; Can be divided into different specifications according to the design, type, technical parameters, additional auxiliary functions, etc.; Used for clinical noninvasive estimation of arterial oxygen saturation and pulse rate through relationships established between optical radiation with human tissue oxygen saturation. Reference standard applicable parts, such as: YY 0784-2010 Medical electrical equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use	II
109	6821	Medical electronic equipment		Mainly consist of physiological signal acquisition module, processing module, data display, record/memory modules and other components and accessories, and can include special software. Can be divided into different specifications according to the design, technical parameters, additional auxiliary functions, etc.; Used for comprehensive assessment of sleep breathing condition to diagnose sleep apnea hypopnea and other related disease via monitoring and analysing EEG, eye movement, muscle, abdominal exercise, ECG, oronasal airflow, snoring, blood oxygen, posture and other sleep-related physiological signals under sleep state. Does not include automatic analysis and diagnosis software.	II
110	6821	Medical electronic equipment	Electric sucking foreign matter in nose	Mainly consist of suction tip, host, battery. The suction tip will contact nostril outer edge when used, and the host can produce suction, then the children nasal cavity secreta will be sucted out by making use of	II
111	6821	Medical electronic equipment	Electronic urine meter	Mainly consist of host (including terminal display), matching urine bag, brackets and other components (excluding catheter); Can be divided into different specifications according to technical parameters, additional auxiliary functions, etc.; Used for calculating parameters of urine volume by measuring urine liquid weight and volume in urine bag.	II

112	6821	Medical electronic equipment	Compressor nebulizer system	Mainly consist of reciprocating piston minitype compressor, connection hose, anual switch and nozzles, hoses, masks; Can be divided into different specifications according to technical parameters, additional auxiliary functions, etc.; Transmit gases flow aerosolized medication produced by compressed gas to respiratory tract for respiratory tract aerosolized medication respiratory therapy.	II
113	6821	Medical electronic equipment		Mainly consist of host, cardiopulmonary treadmill testing and ancillary components; Can be devided into various specifications according to different design, technical parameters, intended use etc; Used for cardiopulmonary function assessment under different exercise stress.	II
114	6821	Medical electronic equipment		Mainly consist of caterpillar band, electric motor and control block. The front and side handle of the treadmill can be integration to guarantee safety; Electrical equipment; Can be divided into various specification according to different design, technical parameters, etc.; Used for autochthonous walking, jogging or sprinting to express different exercise to assess physiological state under a certain sports load.	II
115	6821	Medical electronic equipment	Nerve and muscle stimulator electrodes	Mainly consist of electrode sheet (conductive plastic and metal coating), guide wires and equipment connectors; Can be devided into various specifications according to texture, technical parameters, sizes, etc Can be connected to nerve and muscle stimulator at one end and to body intact skin at the other end. Sterile state; Can be reused within a limited time by a single patient. Used to transmit electrical signal stimulated by nerve and muscle stimulator to human body noninvasively. Reference standard: YY 0868-	II
116	6821	Medical electronic equipment	Medical conductive paste	Generally bewater-based polymer gel, containing good biocompatible and stable electrolyte; Used for ECG examination and electrotherapy electrode coupling.	II
117	6821	Medical electronic equipment	Single-use non-invasive EEG electrodes	Mainly consist of electrode sheet (conductive plastic and metal coating), guide wires and equipment connectors; Can be connected to EEG (electroencephalograph) at one end and to body head skin at the other end. Used for EEG biological signal collection, transmission. Can be reused within a limited time by a	II
118	6821	Medical electronic equipment	Non-invasive medical sensors	Mainly consist of medical sensor such as temperature, pressure, gravity, and angle sensor. Reference standard: YY T 0781-2010 Blood pressure transducers. Special processing shall be done according	II
119	6822	Medical optical equipment, instruments and endoscopic	Endoscope tissue retractor	Mainly made of stainless steel and aluminum, etc. Mainly consist of working end (rod), instrument stem, grips, etc.; Can be divided into different specifications according to according to texture, design and technical parameters, etc. Sterile form; Used for tissue temporary traction in endoscopic surgical procedures.	II
120	6822	Medical optical equipment, instruments and endoscopic equipment	Slit lamp microscope	It is a binocular (also trinocular) microscope, a highlight narrow slit can be projected into eyes while observe reflected light from side-on by a movable microscope, then observe or measure the reflecting surface. A typical structure consists of a microscope and rotating lighting system which can produce cracks (narrow); Can be hand-held or desktop; The microscope can be continuous or non-continuous variable; Can manage images by software if equiped with cameras and computers; Can be divided into different specifications according to different design or technical parameters; Used for anterior segment or other eye desease examination; Reference standard: YY 0065-2007 Ophthalmic instruments—Slit-lamp	II

121	6822	Medical optical equipment, instruments and endoscopic equipment	Direct ophthalmoscope	Mainly consist of lighting system and observation system(including photoscope and raster group). Can generates forward direction or non-retroflex images, so the examiner can observe retina and other structures/media (cornea, aqueous humor, lens and vitreous). Mostly be handheld, battery-powered (also by net power supply); The typical structure consists of a light source mounted on the inside, retroreflector and a dial; The light direction can be changed by examiner; The examiner can observe through a circular hole in the middle of retroreflector while illuminating inside eyes; There are selectable compensating lens and auxiliary lens on the dial; Used for fundus lesions, abnormal refractive medium and retina positioning. Reference standard: YY 1080-2009 Ophthalmic instruments. Direct ophthalmoscopes	II
122	6822	Medical optical equipment, instruments and endoscopic	Indirect ophthalmoscope	Visual intermediate real image can be produced by a condenser lens (handheld or integral), mainly consist of a main light source, a lens, a filter system and a illumination beam for reducing reflection. Can be internal power supply or nets power supply. Used to exam intraocular media and fundus in eyes. Reference standard: YY0633-2008 Ophthalmic instruments—Indirect ophthalmoscopes	II
123	6822	Medical optical equipment, instruments and endoscopic equipment	Retinoscope	Mainly consist of refractive lens, projection systems with a center light through reflector, observation systems and power supply; Can be divided into strip light retinoscope and point-like light retinoscope; Can be divided into different specifications according to power supply, technical parameters, additional auxiliary functions, etc.; Used to observe in objective assessment of refractive error and displacement of retina reflect cross; Reference standard: YY 0718-2009 Opthalmic instruments—Retinoscopes	II
124	6822	Medical optical equipment, instruments and endoscopic equipment	Optometry lens	Mainly composed of positive and negative cylinder optometry lenses, prisms optometry lenses, auxiliary optometry lenses, etc. Can be divided into different specifications according to the number/kind of lens. Can be attached a optometry lens shelf. Used to exam human eye's refractive status (hyperopia, myopia, presbyopia, astigmatism), strabismus and other aspects of eye disease. Reference standard: GB 17342-2009 Ophthalmic instrument—Trial case lenses	II
125	6822	Medical optical equipment, instruments and endoscopic	Indentation ophthalmotonometer	Generally consist of fixed weights, pressure pin, hammer bow and pointers; Can be devided into different specifications according to different types; Exert external force on eyes manually by the instrument. Reference standard: YY 1036-2004 Impression tonometers	II
126	6822	Medical optical equipment, instruments and endoscopic equipment	Medical Optical rigid endoscopes (Otoscope, cystoscopy, hysteroscopy, rectoscope, amniotic	Mainly consist of hand-held part, rigid insert part, opticator and the head end, The anatomical image can be transmitted to the operator; Can be reusable; Can be devided into different specifications according to different structure types, technical parameters, additional features, intended use, etc.; Used for diagnosis and treatment by pass through human natural cavity. Reference standard: YY 0068 Medical Endoscopes—Rigid Endoscope—Part 1:Optical properties and test methods, YY 1075-2007 Rigid hysteroscope.	II
127	6822	Medical optical equipment, instruments and endoscopic equipment	Medical endoscope cold light resource	It is a auxiliary equipment, mainly consist of cold light, control circuit and the output of light resource, may contain light transmitting bundle. Can be divided into different specifications according to different kinds of light resource, technical parameters, etc. Can have a electrical connection with medical endoscope; Used for inward vision or deep lighting in clinical. Reference standard: YY 1081-2011 Medical endoscopes— Endoscope supply units—Cold light sources	II

128	6822	Medical optical equipment, instruments and endoscopic equipment	Biological Microscope	Mainly consist of observing systems, lighting systems, objective table and accessories. The observing systems is stereoptics microscopy system of a short optical distance with eyepiece lens and high power objective lens. Can connect image acquisition display systems; The accessories include contrast device, fluorescence device, polarizing device, photomicrography equipment, dark field illumination device, differential interference device, micro plotter, microphotometer, vertical lighting devices; Biological microscope can be divided into different specifications according to different structure, configuration and functions, technical parameters, etc. Used to observe tiny microscopic samples such as cells or tissues in clinical laboratory. Reference standard: GB/T 2985-2008 Biological microscope	II
129	6822	Medical optical equipment, instruments and endoscopic equipment	Microcirculation microscope tester	Mainly consist of microcirculation microscopic, light resource(LED light resource/cold light resource), CCD (black and white/multicolour), display (monitor) and other components; Can include image management software; Can be divided into different specifications according to structure and composition, technical parameters, intended use, additional auxiliary functions, etc. Used for microcirculation examination to assess human microcirculation. Reference standard: YY 0067-2007 Micro-circulation	II
130	6822	Medical optical equipment, instruments and endoscopic equipment	Digital Microscope	It is a combination of CCD and optical microscope.CCD camera is fixed on eyepiece of optical microscope, the acquisition image under optical microscope can be directly transmitted, displayed on various displays (such as televisions, computers, etc.) for direct observation; Can be divided into different specifications according to models, image acquisition related technical parameters, additional auxiliary image management functions, etc. Used for clinical examination to observe tangible matters such as blood	II
131	6822	Medical optical equipment, instruments and endoscopic equipment	Surgical microscope	Mainly consist of optical system, racks, lighting systems, electrical installations, etc Can also include camera/video systems and image management system; Can be divided into different specifications according to structure composition, technical parameters, intended use, additional auxiliary functions, etc Used for amplification, illuminating, image management, etc. in microsurgery zoom. Reference standard: GB 11239.1-2005 Operation microscopes Part1:Requirements and test methods	II
132	6822	Medical optical equipment, instruments and endoscopic	Digital electronic colposcope	Mainly consist of color camera, LED light source, host computer, software and monitors, etc Can be divided into different specifications according to structure, composition, technical parameters, additional auxiliary functions, etc. Used for vulva, vagina, cervix diseases non-contact observation and video recording.	II
133	6822	Medical optical equipment, instruments and endoscopic	Single-use endoscope pneumoperitoneum puncture needle sets	Made of polymer materials such as ABS; Mainly consist of outer tube and locking puncture inner core; Can be divided into different specifications according to texture, design, size, etc. It is a mating surgical instruments. Forming a pneumoperitoneum gas injection channel and a working channel for surgical instrument such as laparoscope by abdominal wall puncture and fixation.	II
134	6822	Medical optical equipment, instruments and endoscopic	Single-use endoscope sampling brush	Mainly consist of brush handle, tube sheath, pulling wire and brush, etc. Can be made of POM, PTFE, polyamide, stainless steel, etc. Can be divided into different specifications according to texture, design, technical parameters, applicable sites, etc. Sterile state. Used to extract tissue samples from human body in endoscopy.	II

135	6822	Medical optical equipment, instruments and endoscopic	Single-use antifouling samples brush	Mainly consist of pipe assembly, brush assembly, polyethylene glycol and protective plug; Can be divided into different specifications according to texture, design, technical parameters, applicable site, intended use, etc. Sterile state; Used for brushing lesions tissues or secreta.	II
136	6822	Medical optical equipment, instruments and endoscopic	Single-use endoscopic specimen Pouch	Mainly consist of multiple casing, expansion devices, ligation string, storage bag. The casing and storage bag is made of applicable materials such as polymer; The expansion devices is made of stainless steel; Can be divided into different specifications according to texture, design, technical parameters, applicable sites, intended use, etc. Sterile state; Used for collectting tissue samples/ foreign matters to fetch them out of	II
137	6822	Medical optical equipment, instruments and endoscopic	single-use endoscopic stone extraction baskets	Mainly consist of handle with a luer connector, lead screw rod(or sleeve)with soft sheath and distal end 360 °, metal basket; Can be divided into different specifications according to texture, design, technical parameters, applicable sites, intended use, etc. Sterile state; Used for grabing, operating and fetching stones in digestion, urinary, etc. diagnosis under endoscope.	II
138	6822	Medical optical equipment, instruments and endoscopic	Endoscopic mechanical lithotripsy/stone fetching accessories	Mainly made of metal and polymer materials; Mainly consist of outside sheath, lithotripsy handle, extension tube, connecter; Can be divided into different specifications according to texture, design, technical parameters, applicable sites, intended use, etc. Can be asepsis or non-asepsis, can be reused; Used for mechanical biliary gravel stone fetching when failed in endoscope stone fetching	II
139	6822	Medical optical equipment, instruments and endoscopic	Single-use endoscopic forceps	Mainly made of metal and polymer materials; Mainly consist of clamp head, sheath and control handle, clamp head can have a variety of designs with biting, grabing function; Can be divided into different specifications according to texture, design, technical parameters, applicable sites, intended use, etc. Sterile state; Used for endoscopic grabing, biting tissue or foreign matters.	II
140	6822	Medical optical equipment, instruments and endoscopic	Single-use flexible pipe type endoscopic biopsy samples forceps	Mainly consist of clamp head, spring outer tube and handle; Can be with a locating pins; Can be divided into different specifications according to texture, design, technical parameters, applicable sites, intended use, etc Sterile state; Used for endoscopic biopsy sampling or clamping and removing foreign matters.  Reference standard: YY / T1076-2004 Hose biopsy sampling forceps used with endoscope-General	II
141	6822	Medical optical equipment, instruments and endoscopic	Laparoscopic knot pusher	Mainly made of stainless steel; Mainly consist of line knot fixed slot, push rods and handle; The tip is with penetrated hole; Can be divided into different specifications according to texture, design, technical parameters, etc Used for putting in vitro suture knot into laparoscopic area.	II
142	6822	Medical optical equipment, instruments and endoscopic	Endoscopic camera system	Mainly consist of control host, camera, adapter. Can be divided into different specifications according to texture, auxiliary functions, technical parameters, etc Used for enlarging surgical field video in endoscopic surgery.	II
143	6822	Medical optical equipment, instruments and endoscopic	Reusable endoscopic surgical instruments	Mainly made of stainless steel; Maily consist of handle, jaws, scissors tip; Can be divided into different specifications according to texture, design, technical parameters, applicable sites, intended use, etc Non-sterile state, can be reusable; Used with hysteroscopy, abdominal cavity endoscopy, nephroscope and cystoscope, etc. for grabing, biting, separating tissues or foreign matter via natural or surgical channel.	II

144	6822	Medical optical equipment, instruments and endoscopic equipment	Abdominal cavity endoscopic surgical instruments	Mainly made of polysulfone resins, stainless steel, etc. Mainly consist of pipeline, puncture needle, puncture needle cannula, pliers, knot pusher, fibroids screw rod, probe rod, tissue retractor, cotton swab applicators, dilator, surgical hook, flushing device, sealing caps, connectors, adapters, etc.; Can be divided into different specifications according to texture, design, technical parameters, applicable sites, intended use, etc Can be sterile/non-sterile state; Use with abdominal cavity endoscopes for abdominal cavity diseases diagnosis and	П
145	6822	Medical optical equipment, instruments and endoscopic	Laparoscopic pneumoperitoneum Insufflator	Mainly consist of gases gas filtration, temperature control, pressure control, processing\display and accessories (eg foot switch).; Can be divided into different specifications according to design, technical parameters, auxiliary function, etc Used for forming pneumoperitoneum to provide surgical space and field by inflating into intra-abdominal cavity in minimally invasive laparoscopic surgery	II
146	6822	Medical optical equipment, instruments and endoscopic	Laparoscopic pressurized punch\suction device	Mainly consist of host (including control unit), gas pathway, liquid pathway and gas-liquid conversion needles, etc Can be divided into different specifications according to design, technical parameters, auxiliary function, etc Used for inflating, flushing and liquid suction the surgery part in laparoscopy surgery.	II
147	6822	Medical optical equipment, instruments and endoscopic equipment	Foreign body forceps for endoscope	Mainly made of stainless steel and plastic, etc Mainly consist of clamp head, jacket pipe, rod, clamp handle; The type of clamp head can be alligator head, serrated head, wheat head, bead taking, cup-shaped head, etc Can be divided into different specifications according to texture, design, technical parameters, etc Can be sterile or non-sterile; Can match with bronchoscopy, esophagoscopy and laryngoscopy, etc. to fetching foreign matters in trachea or upper gastrointestinal.	II
148	6822	Medical optical equipment, instruments and endoscopic	Camera system for optical rigid tube lens	Mainly consist of camera controller, lenses, cables, etc. Can include image processing software; Can be divided into different specifications according to designs, technical parameters, optical microscopy; Use with optical endoscope and camera systems for providing target area video images.	II
149	6822	Medical optical equipment, instruments and endoscopic	single-use endoscope drug administration tube	Mainly made of stainless steel and polyethylene pipe, ABS; Mainly consist of sprinkler head, conduit, connectors, etc Can include guide wire; Can be divided into different specifications according to texture, design, technical parameters, applicable site, intended use, etc Sterile state; Use with endoscope for irrigation, spraying liquid or moving gallstone/bile sand.	II
150	6822	Medical optical equipment, instruments and endoscopic	Tip cap for single-use endoscope	Mainly made of silicone rubber, etc Can be divided into different specifications according to texture, technical parameters, applicable endoscopes; Sterile state; Mounted on the tip portion to maintain proper endoscopic vision.	II
151	6822	Medical optical equipment, instruments and endoscopic	Ligature wire cutting scissors for single-use endoscope	Mainly made of polyvinyl chloride, polystyrene sulfone, stainless steel, etc.; Mainly consist of handle, tube body, head/scissors storage part. Can be divided into different specifications according to texture, design, technical parameters, applicable sites; Can be sterilized and non-sterilized form; Used with endoscope for cutting ligature thread.	II
152	6822	Medical optical equipment, instruments and endoscopic	Endoscopic Curved Needle Drivers	Mainly made of stainless steel, silicone and resin, etc. Mainly consist of needle holding slot, pushing rods, control handle; Can be divided into different specifications according to texture, design, technical parameters, applicable sites; Can be sterile; Used for suturing in celiac endoscopic surgery.	II

153	6822	Medical optical equipment, instruments and endoscopic	Single-use endoscope loop ligature	Mainly consist of sleeve (PC, silicone rubber), trigger wire (PE fiber, PS), control handle (ABS, Y1Cr18Ni9, silicone rubber), flushing fittings (ABS, PU), loading catheter (POM, Y1Cr18Ni9), rings (natural rubber); Can be divided into different specifications according to texture, design, technical parameters, etc.; Sterile state; Use with endoscopy for esophageal varices artery ligation.	II
154	6822	Medical optical equipment, instruments and endoscopic	Single-use guide beam	Mainly consist of optical fiber and stainless steel tip. Can be divided into different specifications according to texture, design, technical parameters, etc.; Sterile form; Used for illuminating in invasive spine surgery.	II
155	6822	Medical optical equipment, instruments and endoscopic	Illuminated Medical Magnifier	Mainly consist of LED lights, objective, eyepiece, control buttons, rechargeable lithium battery and tie; Can be divided into different specifications according to light source, optical technology parameter, etc. Used for skin lesions diagnosis via optical enlargement.	II
156	6822	Medical optical equipment, instruments and endoscopic equipment	Non-vascular cavity guidewire for urinary tract	Mainly consist of guidewire and push tubes; The shapes and texture of guidewire are various(eg.metal guide wire, metal elbow guide wire, PE guidewire, PTFE guide wire, PTFE guide elbow wire, PTFE-coated guidewire, PTFE-coated guidewire elbow, etc.). Can be divided into different specifications according to texture, design, technical parameters, intended use, etc Sterile state; Use with "J" shape catheter and minimally invasive drainage expansion kits for surporting or guiding under endoscope.	II
157	6822	Medical optical equipment, instruments and endoscopic	Esophageal cardia stricture dilator	Mainly consist of dilator strips (with X-ray developer sign), guide wire, security soft springs, etc.; Dilator strips is made of soft PVC; Guide wire is made of nitinol alloy; Can be divided into different specifications according to texture, design, diameter/length, etc. Can be sterile/non-sterile form; Used for esophagus, cardia stricture expansion treatment in endoscope surgery.	II
158	6822	Medical optical equipment, instruments and endoscopic equipment	perimeter	Mainly consist of background screen, stimulate point display device, jaw mold, forehead mold, pupil monitoring devices, reactor, non-independent elevator, control circuit/mainframe, etcCan be divided into different specifications according to texture, technical parameters, auxiliary function, etc. Used for disease judgement and diagnosis, eg. glaucoma, ocular fundus. Can also be used for diseases development and treatment guidance. Reference standard: YY 0676-2008 Opthalmic instruments—Perimeters	II
159	6822	Medical optical equipment, instruments and endoscopic	Manual keratometry	Mainly consist of assembly unit, motion base, equipment station, electrical boxes, frame; Can be divided into different specifications according to design, technical parameters, auxiliary function, etc Used for corneal curvature and astigmia axial measurement.	II
160	6822	Medical optical equipment, instruments and endoscopic	Keratometry	Mainly consist of host (optical systems, observe and control systems), removable table and head rest; Can be divided into different specifications according to design, technical parameters, auxiliary function, etc  Used for measuring center curvature and meridian direction of corneal contact lens and corneal.Reference standards: YY 0579-2005 Ophthalmometers	II

161	6822	Medical optical equipment, instruments and endoscopic equipment	Corneal topography instrument	Mainly consist of data acquisition unit, data correction/processing unit and accessory, may include computer and special software. Can be divided into different specifications according to operating principle, design, technical parameters, auxiliary function, etc Used to measure corneal surface shape via non-contact way to achieve parameters such as corneal curvature and refractive power. Reference standard: YY 0787-2010 Opthalmic instruments—Corneal topographers	II
162	6822	Medical optical equipment, instruments and endoscopic equipment	Fundus Camera	Mainly consist of large objective lens systems, lighting systems, imaging systems, display systems, controllers, may also include a dedicated computer and data management software. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions. Used for fundus observation, photography to achieve retinal images under circumstances mydriasis. Reference standard: YY 0634-2008 Ophthalmic instruments—Fundus cameras	II
163	6822	Medical optical equipment, instruments and endoscopic	Flatten ophthalmotonometer	Mainly consist of ballasting control box, double image prism, measuring arms, measuring knobs, mounting assembly and calibration components. Can be divided into different specifications according to connection type with slit lamp microscope; Used for internal eye pressure measurement.	II
164	6822	Medical optical equipment, instruments and endoscopic	Springback ophthalmotonometer	Mainly consist of probe, the measuring system, display system. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions; Used for internal eye pressure measurement.	II
165	6822	Medical optical equipment, instruments and endoscopic	Non-contact ophthalmotonometer	Mainly consist of display system, jet, measuring optical system and three-dimensional motion system. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions; Used for internal eye pressure measurement.	II
166	6822	Medical optical equipment, instruments and endoscopic equipment	Non-vascular cavity guidewire- digestive tract, airway	Mainly consist of guide wire rod, spring soft head and guide wire core; Spring soft head is made of polyurethane; Guide wire rod and guide wire core is made of nickel titanium alloy.X-ray will not penetrate the head part; The guide wire may have a hydrophilic coating. Can be divided into different specifications according to texture, design, technical parameters, intended use, etc Sterile state. Use with endoscopy for digestive or airway guiding or instruments guiding.	III
167	6822	Medical optical equipment, instruments and endoscopic	Sinus lighting system	Mainly consist of fiber connectors, flexible tube containing a guide wire and the distal and proximal optical lenses. Can be divided into different specifications according to design, technical parameters, etc The flexible tube is sterile; Use with applicable light source for clinical nasal and sinus structure illumination/transillumination.	III
168	6822	Medical optical equipment, instruments and endoscopic	Electronic upper gastrointestinal endoscopes	Mainly consist of head, end portion, bending portion, insertion portion and light source and electrical connections. CCD head end portion will convert optical signals into electrical signals for observation on display via imaging system. Used to provide image via video monitor to observation, diagnosis, photography.	III

169	6822	Medical optical equipment, instruments and endoscopic	High frequency endoscopic surgical instruments	High-frequency electrode used in endoscopic surgical procedure. Belongs to application part of the high-frequency surgical devices; Pass through human body via endoscopic instrument pores pathway or other instrument channel into the body; Used for regular human tissue cutting and coagulation.	II
170	6822	Medical optical equipment, instruments and endoscopic	Rigid Optical abdominal endoscopes	Mainly consist of optical imaging systems and lighting systems. Optical imaging system consists of objective system, imaging transfer system, eyepiece system. The lighting systems are mainly optical fiber. Imaging transfer system can inverse the inverted image to erect image and transmit it to eyepiece for enlargement. Used for minimally invasive surgery for abdominal imaging.	II
171	6823	Medical ultrasound equipment and related equipment	ultrasonic mechanical scanning probe	Mainly consist of ultrasonic transducer and/or ultrasound transducer array tuple, acoustic lens, housing, shell, cables, transducer array elements flat or convex array. Can be divided into different specifications according to structure, type, technology parameters and functions, etc. Use with ultrasound equipment for biological information acquisition, tissue imaging through intact skin, mucosal cavity (eg. vagina, rectum, not including transesophageal ultrasound probe, ultrasound part of the upper and lower gastrointestinal endoscopic ultrasound). Reference standard: GB 10152-2009 B mode ultrasonic diagnostic equipment	II
172	6823	Medical ultrasound equipment and related equipment	Electronic linear array probe	Mainly consist of ultrasonic transducer and/or ultrasound transducer array tuple, acoustic lens, housing, shell, cables, transducer array elements flat array. Can be divided into different specifications according to structure, type, technology parameters and functions, etc. Use with ultrasound equipment for biological information acquisition, tissue imaging through intact skin, mucosal cavity (eg. vagina, rectum, not including transesophageal ultrasound probe, ultrasound part of the upper and lower gastrointestinal endoscopic ultrasound). Reference standard: GB 10152-2009 B mode ultrasonic diagnostic equipment	II
173	6823	Medical ultrasound equipment and related equipment	Electronic convex array probe	Mainly consist of ultrasonic transducer and/or ultrasound transducer array tuple, acoustic lens, housing, shell, cables, transducer array elements convex array. Can be divided into different specifications according to structure, type, technology parameters and functions, etc. Use with ultrasound equipment for biological information acquisition, tissue imaging through intact skin, mucosal cavity (eg. vagina, rectum, not including transesophageal ultrasound probe, ultrasound part of the upper and lower gastrointestinal endoscopic ultrasound). Reference standard: GB 10152-2009 B mode ultrasonic diagnostic equipment	II
174	6823	Medical ultrasound equipment and related equipment	Ultrasonic pulse echo imaging equipment	The principle is ultrasonic pulse echo to complete human organ and tissue ultrasonic imaging. Mainly consist of probe(linear, convex array, phased array, machinery sector scan, etc.), ultrasonic transmitter/receiver, signal processing and image display, etc. Can be divided into different specifications according to model, probe configuration, technical parameters, additional auxiliary functions, software processing, intended use, etc. Used for abdominal organs and parts of the superficial tissues ultrasound imaging. Reference standard: GB 10152-2009 B mode ultrasonic diagnostic equipment	II

175	6823	Medical ultrasound equipment and related equipment	Ultrasound Pulsed Doppler imaging equipment	The principle is ultrasonic pulse echo and ultrasonic doppler techniques for blood flow movement and human organ/tissue imaging. Mainly consist of probe (phased array, linear, convex array, machinery sector scan, three-dimensional probe, endoscopic probes), ultrasonic transmitter/receiver circuits, signal processing and image display, etc.; Can be divided into different specifications according to model, imaging properties, probe configuration, technical parameters, additional auxiliary functions, software processing, intended use, etc Mainly used for cardiac, abdominal ultrasound imaging and blood flow movement. Reference standard: GB 10152-2009 B mode ultrasonic diagnostic equipment	II
176	6823	Medical ultrasound equipment and related equipment	Medical ultrasonic nebulizer	Mainly consist of host (including fogging and control section) and atomization transportation annexes. Can be divided into different specifications according to structure, composition, technical parameters, additional auxiliary functions. Used for aerosolized medication for treatment. Reference standard: YY 0109-2003 Medical ultrasonic nebulizer	II
177	6823	Medical ultrasound equipment and related equipment	Ultrasonic doppler blood flow analyzer	Mainly used for detecting and measuring non-fetal blood flow information with ultrasonic Doppler shift principle. Mainly consist of probe, ultrasonic transmitter/receiver circuits, signal processing and display components; Can be divided into different specifications according to model, imaging properties (analog and digital), probe configuration, technical parameters, additional auxiliary functions, software processing, intended use, etc. Used for skull, neck, and peripheral vascular blood flow measurement, do not include analysis and diagnosis function. YY 0593-2005 Ultrasound transcranial doppler system	II
178	6823	Medical ultrasound equipment and related equipment	Ultrasonic Doppler fetal monitor	Used for continuous monitoring perinatal fetus and providing timely warning information when be abnormal with the principle of ultrasonic Doppler, Mainly consist of ultrasound probe, uterine pressure sensor and connected host; Can be divided into different specifications according to models, the probe configuration, technical parameters, additional auxiliary functions, software processing, intended use, etc. Mainly used for heart rate of perinatal fetal and uterine contractions of pregnant women continuous monitoring.	П
179	6823	Medical ultrasound equipment and related equipment	Ultrasonic Doppler fetal heart rate meter	Used for achieving fetal heart movement information from pregnant women abdomen. Mainly consist of probe, ultrasonic transmitter/receiver circuit, signal output part. Can be divided into different specifications according to model, probe configuration, technical parameters, additional auxiliary functions, software processing, intended use, etc. Used for fetal heart rate measurement. Reference standard: YY 0448-2009 Ultrasonic Doppler foetal heartbeat detector	II
180	6823	Medical ultrasound equipment and related equipment	Ultrasonic Doppler umbilical cord blood flow analyzer	Mainly consist of host and ultrasound Doppler probe. Can be divided into different specifications according to design, technical parameters and auxiliary functions, etc. Used for perinatal umbilical cord blood flow testing/monitoring.	II
181	6823	Medical ultrasound equipment and related equipment	Ultrasonic Endoscopic dedicated bladders	Mainly made of natural latex/silica and PTFE, etc. Mainly consist of aqueous capsule and aqueous capsule protection casing. Aqueous capsule protection casing consists of insertion portion and connecting portion; Mounted on the front of endoscope and injected with sterile saline to act as ultrasound intermediates; Can be divided into different specifications according to texture, capacity, shape, application site; Sterile state. Used for endoscopic ultrasound probe being coupled with skin/mucous of the checking parts.	II

182	6823	Medical ultrasound equipment and related equipment	Ultrasonic scaler	The ultrasonic energy can be acted on teeth through a handle tip to remove teeth stones, etc Mainly consist of ultrasonic generator, handle, and varieties of operation head(tip) mathing with handles. Can be with a flushing part. Can be divided into different specifications according to design, technical parameters, whether with a working head or not, additional auxiliary functions, etc Used for clinical use to remove tartar. Reference standard: YY 0460-2009 Ultrasonics dental descaler equipment	II
183	6823	Medical ultrasound equipment and related equipment	Ultrasound-guided uterine surgery Monitor	Mainly consist of host, special convex array probe and monitor, the ultrasound imaging section can be analog or digital imaging, the host may include vacuum aspiration system for abortion and related special accessories. Can be divided into different specifications according to design, technical parameters, auxiliary functions, accessories, etc. Used for real-time monitoring abortion, contraceptive ring fetching and taking surgery or in abdominal ultrasound examination.	II
184	6823	Medical ultrasound equipment and related equipment	Sterile ultrasound probe puncture bracket	Mainly made of titanium alloy, stainless steel or suitable polymer materials; Mainly consist of probe fixed portion and puncture needle fixed portion; The fixed portion can have a certain adjustment range; Can be divided into different specifications according to stand texture, design, adjustment range, fixed probe, puncture needle classifications, etc Sterile state. Used with various types of ultrasound probe for fixing	II
185	6823	Medical ultrasound equipment and related equipment	Disinfection medical ultrasound coupling agent	Mainly made of disinfectant (such as Triclosan), propylene glycol, glycerin (glycerol), triethanolamine, carbomer (cross-linked poly acrylic resin); Can be divided into different specifications according to recipe, technical parameters, applicable site, load quantity, etc.; Used for filling and coating skin-mucosa and probe radiating surface. Used for sound waves transmission to improve probe and skin-mucosa coupling effectiveness, and having a function of skin, mucous membrane disinfection.	III
186	6823	Medical ultrasound equipment and related equipment	Medical ultrasound coupling agent for cavity	Mainly made of Bock -DP (Triclosan), propylene glycol, glycerin, triethanolamine, carbomer (cross-linked poly acrylic resin); Sterile state. Use to improve coupling between mucosa and probe by coating the probe head in cavity.	II
187	6823	Medical ultrasound equipment and related equipment	Ultrasonic pulse echo equipment special for ophthalmology	Including ophthalmology type-A ultrasonic, type-B ultrasonic and typeA/B ultrasonic, its probe frequency is over 10MHz. Complete obtaining, displaying, measuring the information of ophthalmology diagnosis based on the principle of ultrasonic echo. Can realize ultrasound imaging, corneal thickness measuring, axial	II
188	6824	Medical laser equipment	Medical laser fiber	Consist of the connectors, optical fibre, patient end and plastic coiler; Can be divided into different specifications according to connector, tube length, etcSterile state; Use with laser therapeutic instrument to transmit energy for laser surgery.	II
189	6824	Medical laser equipment	Single-use nasal irradiation fiber head	Mainly consist of connector, fiber tubes, plastic coil; Patient end can be U-shaped; Can be divided into different specifications according to connector, tube length, etc Use with laser; Used for nasal cavity capillary illuminating by guiding laser into nasal cavity.	II
190	6825	High-frequency medical equipment	High-frequency electrocautery	Mainly consist of host, therapentic equipment, accessories. Usually the rated frequency and output power is far below the high-frequency surgical equipment; Can be divided into different specifications according to different designs, patterns, technical parameters, intended use, etcUsed for coagulation, vaporization the localized lesions of underarm sweat glands, rectal hemorrhoids, gynecological vulva, cervix, ENT and other surface, superficial natural cavity.	II

191	6825	High-frequency medical equipment	Single-use cathode plate for high frequency surgical equipment	Mainly consist of isolating paper, conductive glue, aluminum foil, base substrate and electrode wires, etc Can be divided into different specifications according to conductive medium use crowd, electrode quantity and shapes, etc. Connect to human body and high-frequency surgical equipment to low current density to prevent body burns; Another pole of the two poles is used as equipment alarm circuits. Reference standard: GB 9706.4 Medical electrical equipment - Part 2-2: Particular requirements for the safety 0f high frequency	II
192	6825	High-frequency medical equipment	HF surgical electrodes (electric knife pen, coagulation forceps, coagulation scissors, coagulation forceps)	It is a assessory of high frequency surgical equipment. Mainly consist of high-frequency device plug end, high-frequency wire, handle working end, etc.; Can be divided into different specifications according to working principle, cooling function, technical parameters, intended use, etc.; Can be sterile or non-sterile form; Used with high-frequency surgical equipment for tissues cuting, isolating, vascular occlusion hemostasis, tissue coagulation. Reference standard:GB 9706.4 Medical electrical equipment - Part 2-2: Particular requirements for the safety 0f high frequency surgical equipment	III
193	6825	High-frequency medical equipment	Aseptic pipeline high- frequency connection device	Is a sterile aseptic connections between two polymer sterile tubing by high-frequency radiation heating; Mainly consist of high-frequency generator, output and controller. Used for heat sealing sterile tube such as infusion tube, etc	III
194	6825	High-frequency medical equipment	High frequency surgical equipment	Mainly consist of high-frequency generator host and related accessories; Produce thermal effects on human tissue for cutting or coagulation by directly pass through human body. Used for human tissue cutting and coagulation in traditional electric surgery. The frequency range of high frequency generator should be limited to 200k-5MHz prescribed in GB 9706.4; Clinical exemption shall not include products which has special clinical application or use pattern such as tissue plasma cutting and coagulation under saline	III
195	6825	High-frequency medical equipment	Radiofrequency ablation needle shape electrode	Mainly use with puncture needle, drivepipe, etc. Ablation needle containing a temperature sensors; Transmit the high-frequency current produced by RF generator to specified human tissue, thus can realize purposes eg, ablation/coagulation/necrosi, etc.; Use with RF generator for human tissue ablation.	II
196	6825	High-frequency medical equipment	Argon controller	Mainly consist of controllers and airbrush argon; The high purity argon can be transmited into requires adjustable low flow argon gas through the gas valve and control module; Use with high-frequency to be Argon knife; Use with high-frequency electric knife to realize coagulation under an argon atmosphere in	II
197	6826	Physiotherapy and rehabilitation equipment	Foot Orthosis	The Foot care should be passive devices; Mainly consist of L-shaped plywood, lined insoles, water cushion, anti-rotation bar, magic stick, PVC matte buckle and safety sticky feet protection pad, etc; Used to keep foot, ankle physiological position for foot drop and secondary disease prevention and treatment.	II
198	6826	Physiotherapy and rehabilitation equipment	Joint continuous passive motion device (CPM instrument)	Active device. Mainly consist of host, control section and joints fixed parts. Can be divided into different specifications according to fixed joints, technical parameters, additional function; Used for prevention and treatment articulation amplitude decreases, joint stiffness and venous thrombosis caused by trauma or due to	II
199	6826	Physiotherapy and rehabilitation equipment	Electric traction bed	Mainly consists of bed body, traction power systems, control systems and ancillary components; Can be divided into different specifications according to design types, technical parameters application site, intended use, etcUsed for cervical, spinal traction treatment. Does not include quick pulling traction bed. Reference standard: YY 0697-2008 Dynamoelectric traction-table	II
200	6826	Physiotherapy and rehabilitation equipment	Electric cervical traction device	Mainly consists of bed body, traction power systems, control systems and ancillary components; Can be divided into different specifications according to design types, technical parameters application site, intended use, etcUsed for cervical indications traction treatment. Does not include quick pulling traction	II

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201	6826	Physiotherapy and rehabilitation equipment	Tapping vibration expectoration machine	Mainly consist of host, drive shafts and varieties of percussion head, percussion head speed, kowtow frequency, adjustable intensity, tapping mode, adjustable operating time, can have multiplexed output; Can be divided into different specifications according to design, technical parameters, application object, etc. Improve blood circulation in the lungs of patients by tapping vibration to assist discharging respiratory	II
202	6826	Physiotherapy and rehabilitation equipment	Fumigation instrument	Maily consist of liquid medicine box, entry/exit fluid piping, heating equipment, temperature/liquid level control unit, display unit, treatment head, etc.(excluding drugs); Can be divided into different specifications according to design, technical parameters, applicable sites, intended use, auxiliary function; Can be used with liquid medicine for human partial fumigation treatment.	III
203	6826	Physiotherapy and rehabilitation equipment	Fumigation bed	Maily consist of bed, control unit, medicine tank, temperature controllers, level controllers, heating devices, LCD, etc Can be divided into different specifications according to design, technical parameters, applicable sites, intended use, auxiliary function; Can be used with liquid medicine for human torso and	III
204	6826	Physiotherapy and rehabilitation equipment	Pressurized oxygen chamber	Maily consist of cabin, oxygen supply and exhaust systems, air conditioning systems and control system. Pressurized medium is medical oxygen while the maximum operating pressure is less than 0.2MPa, one person each. Mainly used for adult patients who need high concentration supplemental oxygen for adjuvant therapy ischemic, hypoxic diseases. The patient can breath hyperbaric oxygen by exposing to hyperbaric oxygen environment to achieve the purpose of treating disease.	II
205	6826	Physiotherapy and rehabilitation equipment	Air pressurized cabin	Maily consist of cabin (housing, door, window, safety valves, etc.), exhaust system, oxygen supply and exhaust systems, air conditioning systems, electrical systems, sprinkler systems, control console. Pressurized medium is air while the maximum operating pressure is less than 0.3MPa. Can be divided into single and multiplayer oxygen chamber according to the number of cabin oxygen chamber therapy persons. The patient can breath hyperbaric oxygen by exposing to hyperbaric oxygen environment to achieve the purpose of treating disease. Mainly used for adult patients who need high concentration supplemental oxygen for	II
206	6827	Traditional Chinese medical equipment	Acupuncture needles	Mainly consist of needles body and needle handle. The needles body is made of austenitic stainless steel,etc; The needle handle is made of stainless steel wire or copper (tube) or aluminum wire (pipe) or polypropylene, etc. Can be divided into different specifications according to with a needle tube or nor, needle handle type, needle handle diameter and length, etc. Can be sterile or non-sterile. Used for invasive stimulation body surface acupoint by professional persons. Reference standard: GB 2024-1994 Acupuncture	II
207	6827	Traditional Chinese medical equipment	press-needle	Mainly consist of needle body and needle plate. Can attach suitable attachment to facilitate lien. The needle body and needle seat are maily made of austenitic stainless steel wire, etc. Can be divided into different specifications according to intended use, structure type, needle diameter, length, etc. Mainly are non-sterile state; Used for invasive stimulation body surface acupoint by professional persons. Reference standard: YY 0105-1993 press-needle	II
208	6827	Traditional Chinese medical equipment	three edged needle	Mainly made of austenitic stainless steel. Mainly consist of handle and prismatic tip. Can be divided into different specifications according to needle handle type, size, etc. Used for human peripheral blood or point prick.Reference standard: YY 0104-1994 Three-edged needle	II

209	6827	Traditional Chinese medical equipment	Intradermal needle	Mainly consist of needle body and needle plate. Can attach suitable attachment to facilitate lien. The needle body and needle seat are maily made of austenitic stainless steel wire, etc. Can be divided into different specifications according to intended use, structure type, needle diameter, length, etc. Can be sterile or non-sterile state; Used for invasive stimulation body surface acupoint by professional persons. Reference standard: YY 0105-1993 press-needle	II
210	6827	Traditional Chinese medical equipment	Plum Needle	Plum needle, it is a skin cutaneous needle; Mainly consist of needle tip, needle seat and handle, etc The needle body is made of austenitic stainless steel wire; Needle seat and handle is made of horns or plastic pearl. Can be divided into different specifications according to type and poly needle, needle diameter, etc Used for multi-pin invasive stimulation body surface acupoint by professional persons.	II
211	6827	Traditional Chinese medical equipment	Small needle-knife	Mainly consist of hand holder, needle body, needle knife. Can be divided into different specifications according to shape and length. The width of needle and blade is similar. Can be sterile/non-sterile form; Used for indirect vision lysis for soft tissue injuries and bone joint disease by puncturing into lesion part to	II
212	6827	Traditional Chinese medical equipment	Negative pressure physiotherapy device	Mainly consist of manual/power vacuum device and plurality of vacuum tank. Can be divided into different specifications according to negative pressure principle, design, technical parameters, application site, intended use, etc. Used for body surface points cupping therapy.	II
213	6830	Medical X-ray equipment	Breast X-ray imaging equipment	X-ray tube target surface is made of rhodium, molybdenum etc, form low energy X-ray beam in conjunction with lower tube voltage, in conjunction with compression of the breast, image analysis and display system. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc. Mainy be dedicated to human breast tissue photography, obtain tissue imaging for clinical diagnosis.Reference standard: YY/T 0706-2008 Particular specifications for mammographic X-ray equipment, YY/T 0741 General specifications for digital medical X-ray radiography system.	II
214	6830	Medical X-ray equipment	Dental X-ray machine	Mainly consist of combination nose, intraoral image receiver, may also have retractable crank and other parts, it is a special X-ray machine; Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc Mainly used for teeth X-ray photography to achieve images for clinical diagnosis. Reference standard: YY/T 0106-2008 General specifications for medical diagnostic X-ray equipment, YY/T 0741 General specifications for digital medical X-ray radiography system, YY/T 0010-2008 Plasticized polyvinyl chloride(PVC) tubing for medical uses. Include	II
215	6830	Medical X-ray equipment	X-ray perspective equipment	Based on principles of different ray attenuation for different X-rays emitted from X-ray tube through the patient's body in different tissues and organs. Consist of X-ray source, imaging medium including a film, video board, digital flat panel, etc., may also be equipped with a patient support apparatus. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc., Include remote control device and digital equipment. Only used for patient perspective to achieve clinical continuous imaging. Reference standard: YY/T 0106-2008 General specifications for medical diagnostic X-ray equipment, YY/T 0741 General specifications for digital medical X-ray radiography system, YY/T	II

216	6830	Medical X-ray equipment	X-ray radiographic equipment	Based on principles of different ray attenuation for different X-rays emitted from X-ray tube through the patient's body in different tissues and organs. Consist of X-ray source, imaging medium including a film, video board, digital flat panel, etc., may also be equipped with a patient support apparatus. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc Only used to achieve continuous imaging for clinical diagnosis through perspective.Reference standard: YY/T 0106-2008 General specifications for medical diagnostic X-ray equipment, YY/T 0741 General	II
217	6830	Medical X-ray equipment	X-ray perspective, radiographic equipment	Have the function of both X-ray photography and perspective. Such equipment consist of the X-ray source, imaging medium including film, image plate, screen, television system, digital tablet, etc. May be have patient support equipment. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc Used to achieve single or continuous imaging for clinical diagnosis through photography and perspective. Reference standard: YY/T 0106-2008 General specifications for medical diagnostic X-ray equipment, YY/T 0741 General specifications for digital	II
218	6830	Medical X-ray equipment		With rollers and other devices. can be easily removable universal X-ray equipment during using it. Such equipment has the X-ray source, an imaging medium including a film, a digital tablet etc Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc Used for moving the patients who is not easy to move to the wards and operating room to do the photography or perspective.Reference standard: YY/T 0106-2008 General specifications for medical diagnostic X-ray equipment, YY/T 0741 General specifications for digital medical X-ray radiography system. YY/T 0707-2009 Mobile X-ray machine dedicated technical conditions, YY/T 0744-2009	II
219	6830	Medical X-ray equipment		Can be moved from one place to another. The main components including a X-ray tube top; Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc Used for clinical X-ray examination of limbs, or other smaller, thinner parts under orthopedic or field conditions Reference standard: YY/T 0106-2008 General specifications for medical diagnostic X-ray equipment, YY/T 0741 General specifications for digital medical X-ray radiography system.	II
220	6830	Medical X-ray equipment	Gastrointestinal X-ray equipment	X-ray radiographic and radioscopic apparatus, lock the intrest region by the perspective moving image, and then achieve a clear image in the region by a larger dose photography. Such equipment has the X-ray source, high voltage generating means, image display system, special gastrointestinal bed, can also be with a compressor, spot film equipment. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc. Reference standard: YY/T 0106-2008 General specifications for medical diagnostic X-ray equipment, YY/T 0741 General specifications for digital medical X-ray radiography system. YY/T 0742-2009 Particular specifications for gastrointestinal diagnostic X-ray	II
221	6830	Medical X-ray equipment		Depending on varying degree of X-rays absorption of varying density of the bone and tissue, deliver the digital signals with the body of information into the computer to analyze the outcome of bone mineral density. Such equipment has the X-ray source, detector, information analysis and display system. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc Used to measure X-ray attenuation when through human body, so to assess the bone mineral density and bone mineral content of the patient skeleton and adjacent tissue for clinical diagnosis. Reference standard: YY/T 0724 Particular specifications for dual energy X-ray bone densitometer	II

				Mounted on moving vehicle for perspective or photographic functions. Can be divided into different		
	6830	Medical X-ray		specifications according to design, technical parameters, additional auxiliary functions, etc Car X-ray		
222		equipment	Car X-ray machine	machine, used in maneuver conditions, carry out X-ray photography diagnostic tests away from the hospital.	II	
		equipment		Reference standard: YY/T 0106-2008 General specifications for medical diagnostic X-ray equipment, YY/T		
				0741 General specifications for digital medical X-ray radiography system. YY/T 0746-2009 Particular		
		Module and		It is the main component of X-ray machine, control and generate electrical energy in the X-ray tube, usually		
223	6831	subsidiary	High voltage generator	contains high-voltage transformer assembly and high-voltage controller. Can be divided into different	II	
223	0031	equipment for	Trigit voltage generator	specifications according to design, technical parameters, additional auxiliary functions, etc Used to provide	11	
		medical X-ray		power to the X-ray tube assembly to produce X-rays.		
		Module and		The free electron on the surface of cathode impact the anode by the high voltage applied the cathode and the		
224	6831	subsidiary	X-ray tube	anode of X-ray tube, generate X-rays by controlling the load time, voltage and current, to the purpose of	II	
224	0031	equipment for	A-1ay tube	different medical diagnostic. Can be divided into different specifications according to design, technical	11	
		medical X-ray		parameters, additional auxiliary functions, etc Mounted on X-ray tube element.		
		Module and		It is a medical X-rays generating devices with a fixed anode. The free electron on the surface of cathode		
	6831	subsidiary	cubcidiary		impact the anode by the high voltage applied the cathode and the anode of X-ray tube, generate X-rays by	
225			uipment for Fixed anode X-ray tube	controlling the load time, voltage and current, to the purpose of different medical diagnostic. Can be	II	
		medical X-ray		divided into different specifications according to technical parameters. Reference standard: YY/T 0197-		
		medical 71 Tay		2007 X-ray tube for medical diagnosis—XD1-3/100 stationary anode X-ray tube		
		Module and subsidiary equipment for medical X-ray		Decrease temperature by rotating anode. The free electron on the surface of cathode impact the anode by the		
			Rotating anode X-ray	high voltage applied the cathode and the anode of X-ray tube, generate X-rays by controlling the load time,		
226	6831		voltage and curren	voltage and current, to the purpose of different medical diagnostic. Can be divided into different	II	
			- I ISDECTOCATIONS ACCOMMING TECHNICAL DATAMETERS. RETERENCE STANDARD: Y Y / I UT9 / 3-700 / X-ray			
				medical diagnosis XD51-20、40/100 and XD51-20、40/125 rotating anode X-ray tube.		
		Module and		Add grid into the internal X-ray tube between the cathode and the anode, produce pulse X-rays by		
227	6831	subsidiary		controlling grid voltage. Can be divided into different specifications according to design, technical	II	
1227	0031	equipment for	ray tube	parameters, additional auxiliary functions, etc Generally assembled in X-ray tube assembly of	11	
		medical X-ray		angiographic equipment. Reference standard: YY/T 0607-2007 General specifications of medical diagnostic		
		Module and		General material of target is molybdenum or rhodium, tube voltage is low, resulting in a soft rays. Can be		
228	6831	subsidiary	Breast X-ray tube	divided into different specifications according to design, technical parameters, additional auxiliary	II	
1220	0031	equipment for	Dicust 71 Tay tube	functions, etc. It is a dedicated X-ray tube used in mammography equipment.Reference standard:	11	
		medical X-ray	•	YY/T0607-2007 General specifications of medical diagnostic X-ray tube assemblies		
Ĭ		Module and		Maximum tube voltage is usually above 200kV, generally equipped with a cooling device, can continuous		
229	6831	subsidiary	X-ray tube for	work for a long time. Can be divided into different specifications according to design, technical parameters,	II	
229	3031	equipment for	therapeutic machine ad	additional auxiliary functions, etc. Fitted into X-ray therapy equipment tube assembly. Reference standard:	11	
		medical X-ray		YY/T 0747-2009 XZ1-4/250 Therapy X-ray tube		

230	6831	Module and subsidiary equipment for medical X-ray	X-ray tube assembly	Mainly consist of X-ray tubes and tube sets, high-voltage insulating oil are fully filled pipe kit and the pipe is sealed, to achieve the purpose of insulation and heat exchange. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc Assembled into X-ray equipment, the high voltage from the high voltage generator is applied to the X-ray tube assembly, to produce X-rays.Reference standard: YY/T 0607-2007 Medical electrical equipment—Part 2: Particular	II
231	6831	Module and subsidiary equipment for medical X-ray	Medical X-ray beam limiting device	Mainly consist of beam limiting plates/beam limiting door and manual/automatic control components; Beam limiting door or plates are generally made of materials which do not penetrate X-rays such as lead material. Limit radiation field by limiting the X-ray primary light beam; Can be divided into different specifications according to limit beam methods and technical parameters, etc. Reference standard: YY/T 0129-2007 General Specification for medical diagnostic X-ray adjustable beam limiting	II
232	6831	Module and subsidiary equipment for	X-ray source assembly	Mounted on X-ray equipment; Mainly consist of X-ray tube assembly and collimator; Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc	II
233	6831	Module and subsidiary equipment for medical X-ray	X-ray tube for X-ray computed tomography equipment	It is of high calorific capacity and can be long continuous exposure, usually equipped with a cooling device; mainly consist of tube core, sleeves and high-voltage circuits, cooling systems, etc Mounted into X-ray tube subassembly. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc	II
234	6831	Module and subsidiary equipment for medical X-ray	X-ray image intensifier	It is a opto-electrical vacuum tube which can transmit the X-ray signal into visible image, widely used in various X-ray equipment. Can be divided into different specifications according to conversion principle and technical parameters, etc Reference standard: YY/T 0457-2003 Medical electrical equipment—  Characteristics of electro-optical X-ray image intensifiers—Part 1:Determination of the entrance field size, YY/T 0093-2013 Medical diagnostic X-ray image intensifier	II
235	6831	Module and subsidiary equipment for medical X-ray	X-ray image intensifier television system	Mainly consist of X-ray image intensifier, optical system, camera signal processing system and image display device, etc Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc Assembled in X-ray diagnostic system to transform X-ray image into visible image. Reference standard: YY/T 0608-2013 General specifications for X-ray image intensifier TV	II
236	6831	Module and subsidiary equipment for medical X-ray	Flat panel detector and imaging system	Transform X-ray signal comes from human body into digital signal by using special photoelectric conversion medium. Generally equipped with flat-panel detectors, used for image transmission, processing and displaying; Can be divided into different specifications according to working principle, design, technical parameters, additional auxiliary functions, etc Assembled into X-ray diagnostic system and can	II
237	6831	Module and subsidiary equipment for medical X-ray	CCD, CCD imaging systems and other digital imaging systems	Transmit X-rays signal into a visible light signal, and transmit the light signal into digital signal through image forming apparatus. Such as CCD detector, CMDS detector. Can be divided into different specifications according to working principle, design, technical parameters, additional auxiliary functions, etc. Generally assembled into X-ray diagnostic systems, convert X-ray signal into a digital signal.	II

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238	6831	Module and subsidiary equipment for medical X-ray	Image plate imaging	Collect X-ray information from the body and form a latent image by the image plate. Read the information stored in the image plate by laser scanning and convey it into computer to store, treat and display. Generally include iamge plate, laser scanning devices and displays. Can be divided into different specifications according to working principle, design, technical parameters, additional auxiliary functions, etc. Can be used with X-ray which is using the original film imaging of medical institutions, to achieve acquisition, storage,	II
239	6831	Module and subsidiary equipment for	X-ray image processing workstation	Used for processing X-ray image computer and its assessories, including software. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc Can be used with X-ray machine for processing, transmission digital diagnostics images.	II
240	6831	Module and subsidiary equipment for medical X-ray	X-ray Gastrointestinal photography bed	It is a X-ray diagnostic affiliated equipment. Mainly consist of bed body, X-ray penetrating flat-bed, remote control devices and / or near stations operating devices. Can realize functions eg. translation, rotation, etc. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc Used for supporting patients in X-ray gastrointestinal photography to provide soft tissue photography position. Reference standard: YY/T 0743-2009 Particular specifications for X-ray	II
241	6831	Module and subsidiary equipment for medical X-ray	X-ray catheter bed	Patient support device, no skeleton structure, while X-ray equipment is in conjunction with the C-arm, U arm interventional procedures and do the multi-direction planigraphic, thus the vision is not impeded. Mainly used for ordinary intervention treatment and digital subtraction angiography (DSA). Can be divided into different specifications according to design, technical parameters, functions, etc Used for supporting patients in interventional radiodiagnosis to provide diagnostic position.Reference standard: YY/T 0738-2009 Particular specifications for cardiovascular table	II
242	6831	Module and subsidiary equipment for medical X-ray	Bed for computed tomography systems (CT)	Mainly consist of bed base, X-ray penetrating flat-bed and electric flat bed drive and control section. Can include a patient communication facilities. Can realize photography flat bed translation. Can also be non-skeletal structure; Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc. Patient supportting device. Used with computed tomography system (CT). Reference standard: GB 9706.18-2006 Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray equipment for computed tomography, YY 0310-2005 General specifications for X-	II
243	6831	Module and subsidiary equipment for	X-ray tomography device	Clearly intake a layer or layers which parallel to the longitudinal axis of the body, but also make the image of the other layer blurry. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc. Used with photographic flat bed for human body	II
244	6831	Module and subsidiary equipment for medical X-ray	X-ray electric photography flat bed	Mainly consist of base, X-ray flat bed and electric flat bed drive and control components; Can realize photographic flat bed translation, rotation. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc. Used for supporting patient in X-ray examination and photography to provide general position.	II
245	6831	Module and subsidiary equipment for medical X-ray	X-ray diagnostic equipment subsidiary electric suspension, support device (hanger/post/rail)	Mainly consist of base, columns, supporting arm, etc. Can be photographic flat bed translation, rotation.  Used for supporting X-ray tube, monitor or human.	II

246	6831	Module and subsidiary equipment for	sternum stand	Mainly consist of base, columns, supporting arm, etc. Can be photographic flat bed translation, rotation. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc. Used for X-ray monitors and chest radiography spot film to provide appropriate body	II
247	6831	Module and subsidiary equipment for medical X-ray	X-ray contrast agent injection device	Mainly consist of host(with control/display unit), injection head, etc., can be with a remote control device; Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc Achieve a clear image of the blood vessels through injection of contrast agents into blood vessels, such equipment has injected nose, control section, etc.Reference standard:YY/T 0891-2013 Particular specifications for angiographic injector	II
248	6831	Module and subsidiary equipment for medical X-ray	Subsidiary anti-scatter grids of X-ray diagnostic equipment	Placed in front of image receiving surface to reduce scattered radiation to image receiving surface to improve X-ray image contrast. Mainly consist of lead strip and media, etc. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc. Used with X-ray machines to increase X-ray image contrast.Reference standard: YY/0480-2004 Diagnostic X-ray imaging equipment—Characteristic of general purpose and mammographic anti-scatter grids	II
249	6831	Module and subsidiary equipment for medical X-ray	Medical Radiation Protection Spray	Mainly contains superoxide dismutase and stabilizers; Be stored in brown plastic bottles with a spray pump cover by a lyophilized powder state. Other auxiliary ingredients are stored in white-capped plastic bottle in a form of an aqueous solution. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, installed capacity etc Used for prevention and mitigation of free radical produced by physical and chemical factors such as medical radiation from damaging human skin,	II
250	6833	Medical radionuclide equipment	Liquid scintillation counter	Mainly consist of detection unit, measurement unit, data processing/display unit. Can be divided into different specifications according to design, technical parameters, intended use, additional auxiliary functions, etc Scintillation fluid can accept rays and convert it into fluorescence photons. Used for human samples radionuclide H-3. C-14 content measurement.	II
251	6834	Medical radiation protection products and instruments	Medical radiation protective masks	The inner structure is thickness uniformity and soft Lead-rubber and plastics, lead rubber, lead glass and other protective materials tablets containing heavy metal elements. Used for protection of human body during radiation diagnosis and therapy. Reference standard: YY 0292-1997 Protective devices against diagnostic medical X-radiation-Part1: Determination of attenuation properties of materials	II
252	6834	Medical radiation protection products and instruments	Medical-ray protective gloves	The inner structure is thickness uniformity and soft Lead-rubber and plastics, lead rubber, lead glass and other protective materials tablets containing heavy metal elements. Used for protection of human hand during radiation therapy. Reference standard: YY 0292-1997 Protective devices against diagnostic medical X-radiation-Part1: Determination of attenuation properties of materials	II
253	6834	Medical radiation protection products and instruments	Medical-ray protective glasses	Mainly made of lead glass and heavy metal glass. Used for protection of human eye during radiation diagnosis and therapy. Reference standard: YY 0292-1997 Protective devices against diagnostic medical X-radiation-Part1: Determination of attenuation properties of materials	II
254	6834	Medical radiation protection products and instruments	Medical-ray protective vest	The inner structure is thickness uniformity and soft Lead-rubber and plastics, lead rubber, lead glass and other protective materials tablets containing heavy metal elements. Used for protection of human body during radiation diagnosis and therapy. Reference standard: YY 0292-1997 Protective devices against diagnostic medical X-radiation-Part1: Determination of attenuation properties of materials	II

255	6834	Medical radiation protection products and instruments	Medical radiation protective clothing	The inner structure is thickness uniformity and soft Lead-rubber and plastics, lead rubber, lead glass and other protective materials tablets containing heavy metal elements. Used for protection of human body during radiation diagnosis and therapy. Reference standard: YY 0292-1997 Protective devices against diagnostic medical X-radiation-Part1: Determination of attenuation properties of materials	II
256	6834	Medical radiation protection products and instruments	Medical-ray protective cap	The inner structure is thickness uniformity and soft Lead-rubber and plastics, lead rubber, lead glass and other protective materials tablets containing heavy metal elements. Used for protection of non-treated head areas during radiation diagnosis and therapy. Reference standard: YY 0292-1997 Protective devices against diagnostic medical X-radiation-Part1: Determination of attenuation properties of materials	II
257	6834	Medical radiation protection products and instruments	Medical-ray protective skirt	The inner structure is thickness uniformity and soft Lead-rubber and plastics, lead rubber, lead glass and other protective materials tablets containing heavy metal elements. Used for protection of human body during radiation diagnosis and therapy. Reference standard: YY 0292-1997 Protective devices against diagnostic medical X-radiation-Part1: Determination of attenuation properties of materials	II
258	6834	Medical radiation protection products and instruments	Medical-ray Protective Collar	The inner structure is thickness uniformity and soft Lead-rubber and plastics, lead rubber, lead glass and other protective materials tablets containing heavy metal elements. Used for protection of human neck during radiation diagnosis and therapy. Reference standard: YY 0292-1997 Protective devices against diagnostic medical X-radiation-Part1: Determination of attenuation properties of materials	II
259	6834	Medical radiation protection products and instruments	Medical-ray multipurpose Shields	The inner structure is thickness uniformity and soft Lead-rubber and plastics, lead rubber, lead glass and other protective materials tablets containing heavy metal elements. Used for protection of human body during radiation diagnosis and therapy. Reference standard: YY 0292-1997 Protective devices against diagnostic medical X-radiation-Part1: Determination of attenuation properties of materials	II
260	6840	Clinical examination and analysis instrument	Haemglobin instrument	It is a clinical inspection equipment for testing blood hemoglobin content. Manual loading, shared cuvette; Test results can be printed out. Can be devided into various specifications according to spectral theory, technical parameters and additional functions. Reference standard: YY / T 0032-2004 Haemglobin	II
261	6840	Clinical examination and analysis instrument	Hemoglobin detector	Mainly consist of detection unit (containing trace detection container), control units, data processing, display and printing unit, etc Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions. Determinate of venous blood hemoglobin by using photoelectric colorimetry. Reference standard: YY/T 0032-2004 Haemglobin instrument	II
262	6840	Clinical examination and analysis instrument	Hemoglobin dry chemistry analyzer	Use with hemoglobin test strip. Mainly consist of detection unit, control unit, data processing, display and printing unit, etc Can be devided into various specificaitons according to design, technical parameters, intended use, additional auxiliary functions, etc Used for human end and venous whole blood determination.Reference standard: YY/T 1150-2009 General technical requirements for hemoglobin dry	II
263	6840	Clinical examination and analysis instrument	Hemocytometer	Mainly consist of counting chamber, counting squares, slope. The material shall be flat glass which conform to GB 4871 and the thickness is 5mm.	II

264	6840	Clinical examination and analysis instrument	Automatic blood analyzer	Mainly consist of host and accessories. The accessories are mainly composed of sensors, probes, autosampler systems, data computing and processing system; Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc Used for erythrocytes, leukocytes, platelet counting with impedance method and can calculate related parameters of	П
265	6840	Clinical examination and analysis instrument	Semi-automatic hematology analyzer	blood cell. Exemption is without WBC Differential Count.Reference standard: YY/T 0653-2008  Mainly consist of host and accessories, dilution outside. Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc Used for erythrocytes, leukocytes, platelet counting with impedance method and can calculate related parameters of blood cell. Exemption is without WBC Differential Count.Reference standard: YY/T 0653-2008	II
266	6840	Clinical examination and analysis instrument	Semi-automatic coagulation analyzer	Mainly consist of detection unit, control unit, data processing, displaying and printing unit, etc Can be devided into various specifications according to working principle, design, technical parameters, intended use, additional auxiliary functions, etc Used for clinical determination of prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT), fibrinogen (FIB), coagulation factors by coagulation methods, chromogenic substrate method or immunoturbidimetric method. Reference standard:	II
267	6840	Clinical examination and analysis instrument	Automatic platelet aggregation instrument	Mainly consist of autosampler unit, sample processing unit, detection unit, control and data processing unit, etc.; Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc Used for determination of platelet number and aggregation rate in clinical blood samples by using turbidimetry and resistivity method.	II
268	6840	Clinical examination and analysis instrument		Mainly consist of autosampler unit, sample processing unit, detection unit, control and data processing unit, etc.; Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc Used for determination of platelet number and aggregation rate in clinical blood samples by using turbidimetry and resistivity method.	II
269	6840	Clinical examination and analysis instrument	Self-test blood glucose	Used for detection of human capillary whole blood and/or venous whole blood glucose concentration on the electrochemical, photochemical theory. Mainly consist of host and accessories. Can be devided into various specifications according to working principle, design, technical parameters, additional auxiliary functions, etc., Use with corresponding test paper for blood glucose monitoring. Do not used for diabetes diagnosis. Reference standard: GB/T 19634-2005 In vitro diagnostic test systems-General technical requirements for blood-glucose monitoring systems for self-testing	II
270	6840	Clinical examination and analysis instrument	Automatic biochemical analyzer	Mainly consist of autosampler unit, sample processing unit, detection unit, control and data processing unit; Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc Used for analysis of clinical chemical components in serum, plasma, urine, cerebrospinal fluid, etc Does not include an integrated analysis section electrolytes. Reference standard: YY/T 0654-2008 Automatic chemistry analyzer	II
271	6840	Clinical examination and analysis instrument	Semi-automatic biochemical analyzer	Mainly consist of detection unit, control unit,data processing, displaying and printing unit, etc.; Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc Used for analysis of clinical chemical components in serum, plasma, urine, cerebrospinal fluid, etc Reference standard: YY/T 0654-2008 Semiautomatic biochemistry analyzer	II

272	6840	Clinical examination and analysis instrument	Dry chemistry analyzer	Use with test strip; Mainly consist of detection unit, control unit, data processing, displaying and printing unit, etc Can be devided into various specificaitons according to design, technical parameters, intended use, additional auxiliary functions, etc Used for analysis of clinical dry chemical components in serum, plasma, urine, cerebrospinal fluid, etc. by chemical photoelectric colorimetry. Reference standard: YY/T 0655-2008	II
273	6840	Clinical examination and analysis instrument	Electrolyte Analyzer	Mainly consist of detection unit, control unit, data processing, displaying and printing unit; Can be devided into various specificaitons according to design, technical parameters, intended use, additional auxiliary functions, etc. Used for human serum potassium electrode (K+), sodium (Na+), chlorine (Cl-), calcium (iCa 2+), total calcium (TCa), lithium (Li+), pH value (pH), AG (anion gap: Total number of remaining anion), KT (total cations) and calculate the concentration of total calcium (TCa), AG (anion gap: the remaining total anions), KT (total cation), etc.concentration determation. Reference standard: YY/T 0589-	II
274	6840	Clinical examination and analysis instrument	Semi-automatic ELISA analyzer	Mainly consist of detection unit, control unit and display/print units; Can be devided into various specifications according to detect location, detection channel, test speed, additional functions, etc Used for determination of human samples enzyme immunoassay by photoelectric colorimetric.	II
275	6840	Clinical examination and analysis instrument	Automated ELISA analyzer	Mainly consist of detection unit, control unit and display/print units; Can be devided into various specifications according to detect location, detection channel, test speed, additional functions, etc Used for determination of human samples enzyme immunoassay by photoelectric colorimetric.	II
276	6840	Clinical examination and analysis instrument	Fluorescence immunoassay analyzer	Mainly consist of microplate platforms, light source, detector, oscillator devices and other componentsCan be devided into various specificaitons according to design, technical parameters, intended use, additional auxiliary functions, etc Used for qualitative or quantitative detection of trace amounts of the test substance in human samples based on to spectroscopic spectrophotometry with microwell plate and related reagents.	II
277	6840	Clinical examination and analysis instrument	Dry fluorescence immunoassay analyzer	Mainly consist of optical unit, mechanical unit, control unit, output/display unit and system test card. Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc. Used for human sample immunofluorescence detection with special reagents.	II
278	6840	Clinical examination and analysis instrument	Semi-automatic time- resolved fluorescence immunoassay analyzer	Mainly consist of excitation light source, excitation light lens group, sample cell and motion platform, filter system, signal light receiving lens group, photoelectric detection systems, computer and data processing systems, printers, etc Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc. Used for clinical time resolution fluorescence	II
279	6840	Clinical examination and analysis instrument	Semi-automatic chemiluminescence immunoassay analyzer	Mainly consist of detection unit, control unit and display/print units; Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc. Used for human samples related substances quantitative or qualitative determination by counting analysis and processing photon which is produced by direct chemiluminiscence .Reference standard: YY/T 1174-2010 semi-automatic chemiluminescence immunoassay analyzer.	II
280	6840	Clinical examination and analysis instrument	Specific protein immunoassay analyzer	Mainly consist of detection unit, control unit, data processing/ displaying and printing units. Can be devided into various specificaitons according to design, technical parameters, intended use, additional auxiliary functions, etc. Used for qualitative or quantitative detection of one or several specific proteins in human body fluid by optical turbidity, chemical luminescence, fluorescence, time-resolved fluorescence, etc	II

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		Clinical examination		Mainly consist of incubation unit, fluorescence detection unit, control/alarm unit, display unit, etc., may	
281	6840	and analysis	Automatic bacterial	also include air filters, barcode scanning, etc. Can be devided into various specificaitons according to	II
		instrument	culture system	design, technical parameters, intended use, additional auxiliary functions,etc. Used for fast clinical	11
		mstrument		cultivation and determination of aerobic and anaerobic bacteria, yeasts, fungi, and mycobacteria in blood	
				Mainly consist of paper transfer unit, test unit, display unit, printing equipment and other components.Can	
		Clinical examination	Dry chemical urine	be devided into various specificaitons according to design, technical parameters, intended use, additional	
282	6840	and analysis		auxiliary functions, etc Use with urine test strip for urine test, including urine pH, urine leukocytes, nitrite	II
		instrument	analyzer	urine, urine protein, urine sugar, urine ketone body, urobilinogen, bilirubin in urine, urine specific gravity,	
				urine red blood cells. Reference standard: YY/T 0475-2011 Dry chemistry urine analyzer	
				Mainly consist of detection system, liquid path system, test tube stand. Can be devided into various	
		Clinical examination		specifications according to design, technical parameters, intended use, additional auxiliary functions, etc	
283	6840	and analysis	Automatic dry chemical	Use with urine test strip for urine test, including urine pH, urine leukocytes, nitrite urine, urine protein, urine	II
		instrument	urine analyzer	sugar, urine ketone body, urobilinogen, bilirubin in urine, urine specific gravity, urine red blood cells.	11
		mstrament		Reference standard: YY/T 0475-2011 Dry chemistry urine analyzer	
				Mainly consist of inlet/processing unit, test unit, data processing/display unit and accessories (including	
				various kinds of PO2electrode, pH electrode, PCO2 electrode, reference electrode, capillary assembly, etc.).	II
284	6840			Can be devided into various specifications according to design, technical parameters, intended use,	
204				additional auxiliary functions, etc Used for direct determination of pH, PCO 2, PO 2, Na + , K + , Ca 2+ ,	11
		mstrument			
				Cl - , Glu, tHb and SO 2 or serum and plasma pH, Na + , K + , Ca 2+, Cl - , Glu in arterial whole blood	
		Clinical examination and analysis instrument		Mainly consist of variable temperature metal modular components, switching power module,	
285	6840		PCR amplification	microcomputer control system, keyboard, display, thermal cover, etc. Can be devided into various	II
			_	specificaitons according to design, technical parameters, intended use, additional auxiliary functions, etc.	
				Used for clinical diagnostic polymerase chain reaction by controling precise temperature.	
		Clinical examination		Mainly consist of microscope, controller, supporting software. Can be devided into various specifications	
286	6840	and analysis	Biochip reading	according to design, technical parameters, intended use, additional auxiliary functions, etc Scan gene chip	II
200	0040	instrument	instrument	which was treated by chemical chromogenic method into images and identify and analyze them by a special	11
		mstrument		software. Shall be used with gene chip.	
		Clinical examination		Mainly consist of camera microscope, image analysis and processing unit, storage/printing units. Can be	
207	C0.40		CAMP On liter Variation	devided into various specificaitons according to design, technical parameters, intended use, additional	11
287	6840	and analysis	Sperm Quality Analyzer	auxiliary functions, etc Used for clinical sperm density, viability, track events, etc. If it is a automatic	II
		instrument	<b>*</b>	diagnosis device, reliability report shall be provided.	
		au i i i	*	Mainly consist of microscopic optical unit, photography transmission unit and special software. Can be	
		Clinical examination		devided into various specifications according to design, technical parameters, intended use, additional	II
288	6840	and analysis instrument	Urine sediment analyzer	auxiliary functions, etc Used for analysis of urine sediment and other tangible component. Does not	
			instrument		include automatic detection, automatic interpretation equipment.
Щ_	<u> </u>		l	merade automate detection, automate interpretation equipment.	

289	6840	Clinical examination and analysis instrument	Bacterial endotoxin analyzer	Mainly consist of control unit, incubation unit, photoelectric colorimeter/photoelectric turbidity test unit, data processing/ display/printing unit and accessories, etc.; Can be devided into various specificaitons according to working principle, design, technical parameters, auxiliary functions, etc. Used for quantitative detection of bacterial endotoxin in human samples with reagents.	II
290	6840	Clinical examination and analysis instrument	Photochemical lipid analyzer	Mainly consist of LCD screen, buttons, temperature probes, test strips transposons, battery cover, USB ports. Can be devided into various specificaitons according to design, technical parameters, and other auxiliary functions, etc. Used for detection of total cholesterol concentrations in human fresh application capillary or venous blood by using photochemistry principle. Shall be provide system accurate reports.	II
291	6840	Clinical examination and analysis instrument	Electrochemical lipid analyzer	Mainly consist of LCD screen, buttons, temperature probes, test strips transposons, battery cover, USB ports. Can be devided into various specificaitons according to design, technical parameters, and other auxiliary functions, etc. Used for detection of total cholesterol concentrations in human fresh application capillary or venous blood by using electrochemistry principle. Shall be provide system accurate reports.	II
292	6840	Clinical examination and analysis instrument	Colloidal gold strip analyzer	Mainly consist of test strip mechanical positioning unit, image generation/transmission unit, data processing software, data display/print unit, correction annexes; Can be devided into various specifications according to design, technical parameters, and other auxiliary functions, etc. Used with special colloidal gold strip for colloidal gold strip semi-quantitative or quantitative analysis.	II
293	6840	Clinical examination and analysis instrument	Mechanical Counter	Form arabic numerals by manual press mechanical count. Used for clinical manual counting cells or tangible ingredients.	II
294	6840	Clinical examination and analysis instrument	Cell counting board	Made of glass or plexiglass with precise scale. Used for clinical microscopy counting cells or tangible ingredients in human blood, body fluid samples tangible ingredients.	II
295	6840	Clinical examination and analysis instrument	Cytometer	Mainly consist of input, calculation, display composition, etc. Can be devided into various specificaitons according to design, technical parameters, and other auxiliary functions, etc Use with microscope for counting and calculating clinical bone marrow cells and peripheral blood cells.	II
296	6840	Clinical examination and analysis instrument	Automatic microplate washer	Mainly consist of control circuit, positive, negative pump system, solenoid valve control part, reagent bottles, liquid crystal display components. Can be devided into various specificaitons according to technical parameters, etc Used for automatic cleaning microtiter plates with flat bottom, U-bottom, V-bottom.	II
297	6840	Clinical examination and analysis instrument	Freezing point osmotic pressure tester	Mainly consist of refrigeration unit, test unit, control unit, data processing, display and printing units. Can be devided into various specifications according to working principle, design, technical parameters, intended use, additional auxiliary functions, etc. Used for determination of body fluids osmotic pressure.	II

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298	6840	Clinical examination and analysis instrument	and susceptibility	Mainly consist of automatic inoculation, training and monitoring systems, data management system. Use the principles of digital identification of microorganisms to identify bacteria, convert test result achieved from colorimetric or fluorescence biochemical tests into digital code. The bacteria identification result will be achieved by comparing the digital code with coding database. Drug sensitivity test is according to the miniaturization of broth dilution with ratio turbidimetry or fluorescence test, the instrument automatically measure turbidity of bacterial growth, or fluorescent indicator medium intensity measurement, or fluorescent substance immunogenic hydrolysis at constant time intervals to achieve the slope of the growth of bacteria under various drug concentration, then the minimum inhibitory concentration MIC values will be gotten by regression analysis. Used for bacteria identification and drug sensitivity analysis of human body liquid.	III
299	6840	Clinical examination and analysis instrument	Automated coagulation analyzer	Mainly consist of autosampler unit, detection unit, control unit, data processing, display and printing unit, etc. Can be devided into various specifications according to working principle, design, technical parameters, intended use, additional auxiliary functions, etc Used for clincal determination of prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT), fibrinogen (FIB), coagulation factors and other purposes by coagulation method, chromogenic substrate method or immunoturbidimetric method. Reference standard: YY/T 0659-2008 Automated coagulation analyzer	Ш
300	6840	Clinical examination and analysis instrument	mycobacterial culture	Mainly consists of bar code scanning system, LCD display with picture dialogue function, test box, built-in system calibration tube, software and computer Reflect microbial growth conditions by monitoring CO2 or O2 generated by microbial metabolic activity; Used for analysis of mycobacterium tuberculosis growth by reflected light change caused by monitoring gas change or fluorescence in excited sensor which captured by the detector. The product is used for M. tuberculosis detection and drug susceptibility test.	III
301	6840	Clinical examination and analysis instrument	Automated immunoassay analyzer	Mainly consist of sampling center, processing centers, waste liquid and supply center, system control center, etc Analyse the target antigen or an antibody in human samples by a series of cascade amplification which can link optical or electrical signal and analyte concentration according to antigen-antibody binding reaction with enzyme-labeled or chemiluminescent agent labeled antigen or antibody. Used for quantitative, semi-quantitative or qualitative detection of various matters in human body liquid such as tumor markers,	II
302	6840	Clinical examination and analysis instrument	Automatic Medical PCR analysis system	Mainly consist of PCR system, fluorescence detection system and software, etc. PCR system mainly consist of temperature control unit; Fluorescence detection system mainly consist of excitation light source and detector. Based on polymerase chain reaction for specific gene synthesis amplification. Analyse target gene of human sample by measuring fluorescent signal via fluorescent detection system according to linear relationship between Ct value when fluorescent signal reaches to the threshold and starting copy number of the template. Used for qualitative or quantitative detection of human body liquid analytes such as nucleic acids of pathogens, tumor genes, human genes, etc.	II

303	6841	Medical assay device and basic equipment	Carbon dioxide incubator	It is an in vitro cell/tissue culture equipment which can forming a similar simulation cells / tissues in vivo growth environment, such as constant pH, stable temperature, high relative humidity, stable CO2 level.  Mainly consist of heating and temperature control system, CO2 concentration control system, humidity control system box, studio (interior). Can be divided into different specifications according to heating mode, CO2 concentration control or thermal conductivity sensor (TC), supporting function(auxiliary heating, ultraviolet disinfection, CO2 concentration, automatic calibration, air flow management, etc.), interior volume, important parameters control ability and precision, etc. Used for biological cells, tissues, bacteria	II
304	6841	Medical assay device and basic equipment	Ultra-clean standing- temperature cultivator	It is an in vitro cell/tissue, microorganism culture equipment which can forming a similar simulation cell/tissue in vivo growth environment, such as constant pH, stable temperature, relative humidity, clean environment. Mainly consist of heating and temperature control system, working room. Can be divided into different specifications according to heating mode, supporting function, interior volume capacity, important parameters control ability and precision, etc Used for biological cells, tissues, bacteria culturing in clinical	II
305	6841	Medical assay device and basic equipment	Anaerobic incubator	It is an in vitro cell/tissue, microorganism culture equipment which can forming a similar simulation cell/tissue in vivo growth environment, such as micro-oxygen concentration, stable temperature, relative humidity for anaerobe. Mainly consist of constant temperature incubation, anaerobic operating room, sampling room, pneumatic and circuits control systems, box frame, bottle rack, melting wax sterilizers, etc	II
306	6841	Medical assay device and basic equipment	Desktop incubator	Mainly consist of constant temperature system, electronic display systems, left/right incubator, single-use humidification bottles, connecting hoses and other components; Can be divided into different specifications according to capacity, design parameters, additional functions, etc The temperature is usually controlled at $35 \sim 40$ °C, can be with humidification, ventilation function; Used for clinical cell culture.	II
307	6841	Medical assay device and basic equipment	Single-use tip lancet	Mainly consist of needle body and handle. The needle body is made of stainless steel or suitable metallic material. The needle handle can be made of polypropylene; Can be devided into various specifications according to design, needle diameter, length, additional function, etc Can be sterility state. Used for pricking to take blood samples from human fingertip, earlobe circulation end. Including self-destruction	II
308	6841	Medical assay device and basic equipment	Heel Lancing Devices	Mainly consist of spring blade, eject mechanism and shell, the blade is usually made of stainless steel. Can be devided into various specifications according to texture, design, technical parameters, auxiliary functions, etc Can be sterile state. Used for newborns heel blood sampling.	II
309	6841	Medical assay device and basic equipment	Single-use cervical sampling brush	Mainly consist of brush and handle; Brush is made of multi-strand nylon wire twining round multi-strand stainless steel. Handle is made of polymer sleeve fixed on stainless steel wire; Can be devided into various specifications according to texture, handle length, size, etc Non- sterile equipment; Used for endocervical cells collection, can also be used for vaginal secretions sampling.	II
310	6841	Medical assay device and basic equipment	Single-use Sterile swabs	Mainly consist of handle and sampling head. The handle part can be made of natural bamboo, wood or polymer materials; The sampling head is made of cotton; Can be devided into various specifications according to texture, design, size, etc Can be sterile form; Used for taking biological samples in body's natural cavity, such as nose, mouth, vagina, urethra and other parts.	II
311	6841	Medical assay device and basic equipment	Single-use Gynecological scraper	Mainly consist of bamboo, wood, polymer materials, composed by handle and head end, head end is a crescent smooth plate; Can be devided into various specifications according to different sizes; Be sterile form. Used for cervical sampling in gynecological examination.	II

312	6841	Medical assay device and basic equipment	Single-use vacuum blood collection container	Mainly consist of container, stopper and additives and addenda in collection tube. The container can be made of glass and PET plastic, may be coated; Can be devided into various specifications according to texture, additive (which may contain the culture medium), capacity, negative pressure value, sterilization and microbial status, intended use, etc The additives may include K2EDTA, K3EDTA, Na2EDTA, sodium citrate, sodium fluoride, potassium oxalate, heparin, heparin lithium, procoagulant agents, separating gel; Used with lancets. Used for clinical human venous blood samples/separation/cultivation and preservation. Shall provide blood additive confirmation report. Reference standard: YY 0314-2007 Single-	II
313	6841	Medical assay device and basic equipment	Single-use heparinization capillary micro blood collection	Mainly made of glass. Mainly consist of heparinized capillary, iron core, capillary duct cover; Mainly be sterile state; Used for human traces blood specimen collection.	II
314	6841	Medical assay device and basic equipment	Neonatal blood collection card	Mainly consist of information card and blood collection filter. Can be devided into various specifications according to texture, design, and blood collection requirements, etc Non-sterile packaging; Used for neonatal blootamples from the heel parts to dry for transporting, storing for further clinical testing.	II
315	6841	Medical assay device and basic equipment	Fecal analysis workstation	Mainly consist of workstation console, dyeing conveyor, full-automatic dual suction needles, optical flow count cell(OSA), portable tubes seat, etc. Used with feeal parasite centrifuge tube for sample centrifugation, concentration, counting. Does not include automatic diagnosis and automatic counting	II
316	6841	Medical assay device and basic	Single-use occult blood sampling capsule	Mainly consist of medical hollow capsules, medical degreasing cotton, cotton thread. Used to extract gastric juice for occult blood examination.	II
317	6845	Extracorporeal circulation and blood processing equipment	Hemodialysis reverse osmosis pure water water generator	It is a direct water supply mode of reverse osmosis water treatment device, mainly consist of pre-treatment process, membrane and post-treatment process. Reverse osmosis membrane series mainly consist of endotoxin filter, pipeline, reverse osmosis membrane tank, frame, micro-processing monitoring, alarm system and display panels: Can be devided into various specifications according to technical parameters, water capacity, etc Used to prepare reverse osmosis water and related therapy water. Reference standard: GB/T 19249 Reverse osmosis water treatment equipment, YY 0793 Technical requirements of water treatment equipments for haemodialysis applications and related therapies—Part 1:For multi-beds	II
318	6845	Extracorporeal circulation and blood processing equipment	Dialyzer reprocessing machine	Mainly consist of control system, monitoring system and water system. Can be devided into various specifications according to design, technical parameters, auxiliary functions, etc Use with hemodialyzer containing hydrogen peroxide and peroxyacetic acid for hollow fiber hemodialyzer flushing, cleaning, inspection, disinfection to reach the standard of reuse again.	II
319	6845	Extracorporeal circulation and blood processing	Frozen plasma thawing instrument	Mainly consist of heating tanks, thawing tank, circulation pipes, inlet pipe, drain pipe, control boxes, etc Can be water bath type, Water-jacket type. Can be devided into various specifications according to working principle, design, technical parameters, auxiliary functions, etc	II
320	6845	Extracorporeal circulation and blood processing	Transfusion dialysis tubing heating device	Mainly consist of host, heating pipes, alarm devices and fixtures. Used for instant heating pipeline in transfusion, infusion, hemodialysis and blood filtration. The equipment does not direct contact with the heated liquid.	II
321	6845	Extracorporeal circulation and blood processing	single-use peritoneal dialysis tube probe	Mainly consist of stainless steel. Can be devided into various specifications according to texture, design and technical parameters, etc Be sterile form. Used to assist peritoneal dialysis tube imbedding and dialysis tubes dredging.	II

322	6846	Implant materials and artificial organs	Cassette Hearing Aid	Mainly consist of input transducer, signal conditioning unit, output transducer and power supply. Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions; Used for hearing compensation for hearing loss patients. Reference standard: GB/T 14199-2010 Electroacoustics—General specification for hearing aids	II
323	6846	Implant materials and artificial organs	Bone cement smould forming for knee	Mainly made of medical grade silicone, does not include a reinforced handle. Be sterile; Used for knee joint bone cement setting.	II
324	6846	Implant materials and artificial organs	BTE hearing aids	Mainly consist of input transducers, signal conditioning unit, output transducer and ear hook shell, etc Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc.; Used for hearing compensation for gas conductive hearing loss patients. Reference standard: GB/T 14199-2010 Electroacoustics—General specification for hearing aids	III
325	6846	Implant materials and artificial organs	In-ear hearing aids	Mainly consist of input transducers, signal conditioning unit, output transducer and ear hook shell, etc Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc.; Used for hearing compensation for gas conductive hearing loss patients. Reference standard: GB/T 14199-2010 Electroacoustics—General specification for hearing aids	III
326	6846	Implant materials and artificial organs	U-nails	Its structure can refer to ISO 882, Mainly made of stainless steel, titanium alloy which conform to GB 4234, GB/T 13810, ISO 5832-1, ISO 5832-3 standard by conventional machining, heating treatment and surface treatment processes(not including innovation technology such as 3D printing technology). Used for limb fractures inner fixation.	III
327	6846	Implant materials and artificial organs	Bone plug	Mainly consist of screw and nut. Mainly made of stainless steel, titanium alloy which conform to GB 4234, GB/T 13810, ISO 5832-1, ISO 5832-3 standard by conventional machining, heating treatment and surface treatment processes (not including innovation technology such as 3D printing technology). Used for limb fractures inner fixation.	III
328	6846	Implant materials and artificial organs	Silicone tissue expander	Mainly consist of shell, catheter, injection seat(or components serving the same purpose) and connector (if any). The main material of the shell is silicone rubber. Action principle is filling with saline to increase volume of tissue for expansion. Used for orthopedic patient's skin tissue expansion.	III
329	6846	Implant materials and artificial organs	Angle metal bone fracture plate (non-locking)	Its structure can refer to YY 0017, Mainly made of stainless steel, titanium alloy which conform to GB 4234, GB/T 13810, ISO 5832-1, ISO 5832-2, ISO 5832-3 standard by conventional machining, heating treatment and surface treatment processes(not including innovation technology such as 3D printing technology). Used for limb fractures inner fixation. Mainly used for various bones fracture inner fixation, eg. proximal femur, distal femur, tibia proximal merge/not merge backbone.	III
330	6846	Implant materials and artificial organs	Anatomical metal bone fracture plate (non-locking)	Its structure can refer to YY 0017, Mainly made of stainless steel, titanium alloy which conform to GB 4234, GB/T 13810, ISO 5832-1, ISO 5832-2, ISO 5832-3 standard by conventional machining, heating treatment and surface treatment processes(not including innovation technology such as 3D printing technology). Used for limb fractures inner fixation.	III
331	6846	Implant materials and artificial organs	Metal femoral neck fixation nail	Its structure can refer to YY 0346, Mainly made of stainless steel, titanium alloy which conform to GB 4234, GB/T 13810, ISO 5832-1, ISO 5832-2, ISO 5832-3 standard by conventional machining, heating treatment and surface treatment processes(not including innovation technology such as 3D printing technology). Used for fracture of neck of femur inner fixation.	III

332	6846	Implant materials and artificial organs	Metal spicules	Mainly consist of kirschner wire and Steinmann Pin. Its structure can refer to YY 0345, Mainly made of stainless steel, titanium alloy which conform to GB 4234, GB/T 13810, ISO 5832-1, ISO 5832-2, ISO 5832-3 standard by conventional machining, heating treatment and surface treatment processes(not including innovation technology such as 3D printing technology). Used for limb fracture inner fixation or	III
333	6846	Implant materials and artificial organs	Metal bone screws (non-locking)	Its structure can refer to YY 0018. Mainly made of stainless steel, titanium alloy which conform to GB 4234, GB/T 13810, ISO 5832-1, ISO 5832-2, ISO 5832-3 standard by conventional machining, heating treatment and surface treatment processes(not including innovation technology such as 3D printing technology). Used for limb fracture inner fixation.	III
334	6846	Implant materials and artificial organs	Metal cables and ropes	Its structure can refer to YY/T 0812. Mainly made of stainless steel, titanium alloy which conform to GB/T 13810, ISO 5832-1, ISO 5832-2, ISO 5832-3 standard by conventional machining, heating treatment and surface treatment processes(not including innovation technology such as 3D printing technology). Used for limb fracture inner fixation.	III
335	6846	Implant materials and artificial organs	Metal intramedullary needle	Its structure can refer to YY 0019. Do not include lockable intramedullary nail. Mainly made of stainless steel, titanium alloy which conform to GB 4234, GB/T 13810, ISO 5832-1, ISO 5832-3 standard by conventional machining, heating treatment and surface treatment processes(not including innovation technology such as 3D printing technology). Used for limb fracture inner fixation.	III
336	6846	Implant materials and artificial organs	Hollow bone screws (non-locking)	Mainly made of stainless steel, titanium alloy which conform to GB 4234, GB/T 13810, ISO 5832-1, ISO 5832-3 standard by conventional machining, heating treatment and surface treatment processes(not including innovation technology such as 3D printing technology). Used for limb fracture inner fixation. Can	III
337	6846	Implant materials and artificial organs	Urinary incontinence suspensory	Implanted strips, mainly made of polypropylene, can be with partially resorbable material. Action principle is supporting urethra by implanting into urethra. Used for female urethra excessive movement and/or stress urinary incontinence caused by sphincter dysfunction.	III
338	6846	Implant materials and artificial organs	Flexible wire	Its structure can refer to YY/T 0816. Mainly made of stainless steel, pure titanium, high nitrogen stainless steel which conform to YY 0605.9、ISO 5832-1、ISO 5832-2 standard by conventional machining, heating treatment and surface treatment processes(not including innovation technology such as 3D printing technology). Used for limb fracture inner fixation.	III
339	6846	Implant materials and artificial organs	External fixator fixation nails	Mainly made of stainless steel, titanium alloy which conform to GB 4234、GB/T 13810、ISO 5832-1、ISO 5832-3 standard by conventional machining, heating treatment and surface treatment processes(not including innovation technology such as 3D printing technology). Used to partially implant into human body for limb fracture reduction inner fixation.	III
340	6846	Implant materials and artificial organs	Surgical hernia repair patch	Does not include ultimately absorption product. Implanted flat sheet or mesh plug formed by folding flat sheet. Mainly made of polypropylene, polyethylene terephthalate polyester. Can be with partial resorbable material. Action principle is filling up defect tissues or playing a bridging role. Used for abdominal hernia	II
341	6846	Implant materials and artificial organs	Straight metal bone fracture plate (non-locking)	Its structure can refer to YY/T 0017. Mainly made of stainless steel, pure titanium, titanium alloy which conform to GB 4234、GB/T 13810、 ISO 5832-1、ISO 5832-2、ISO 5832-3 standard by conventional machining, heating treatment and surface treatment processes(not including innovation technology such as 3D printing technology). Used for limb long bone shaft fracture inner fixation.	II

342	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Uterine pressurized Hysteroscopy pump	Mainly consist of pressurizer host, pipe and pneumatic needle, etc. Shall be with the function of over- pressure alarm and automatically discouraged function; Can be devided into various specifications according to design, technical parameters, auxiliary functions, intended use, etc Used for uterus pressurizing expansion to form a visible space.	II
343	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Percutaneous jaundice tester	Handheld percutaneous jaundice tester, mainly consist of testing unit, display unit, power supply/battery and charging accessories, etc Can be devided into various specifications according to working principle, design, technical parameters, application sites, suitable object, auxiliary function, etc Used for neonatal jaundice transcutaneous measurement via special wave length light reflex.	II
344	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Medical immersion bath therapeutic machine	Mainly consist of host, patient sunbeds, supply/drainage systems, temperature control unit, etc., may also include patient hanging bracket for transportion and other auxiliary bath functions. Can be devided into various specifications according to design, technical parameters, auxiliary functions, etc.; Used for burns patients bathing and wound treatment.	II
345	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Infusion Pump	Mainly consist of capacity type infusion pumps unit, detection unit, control units and alarming unit. Can be devided into various specifications according to working principle, design, technical parameters, additional auxiliary functions, etc Used with infusion facilities, do not contact with infusion liquid. Used for adjustable intravenous infusion. Reference standard: GB 9706.27-2005 Medical electrical equipment - Part 2:Particular requirements for the safety of infusion pumps and	II
346	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Syringe Pump	It is an equipment for controlling fluid flow of patient injection via one or more syrings with a single action or somelike containers. The infusion rate is set by the operator and will be displayed on the equipment. Mainly consist of pump casing, motor drive system, input systems, storage systems, control systems, display systems, sensor monitoring systems and alarm system. Product structure does not include syringe and infusion tubing. Can be devided into various specifications according to design, technical parameters, intended use, additional auxiliary functions; Used with specific transfusion equipment for artery and vein transfusion with constant infusion dose speed and accuracy infusion dose. Reference standard: GB 9706.27-2005 Medical electrical equipment - Part 2 :Particular requirements for the safety of infusion pumps and	II
347	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Pedal absorber	Mainly consist of piston-cylinder, liquid storage bottle, vacuum gauge, support frame, etc Used for clinical negative pressure suction in early pregnant women abortion by mechanical movement. Reference standard: YY 0636.2 Medical suction equipment—Part 2: Manually powered suction equipment	II
348	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Medical vacuum extractor	Mainly consist of negative pressure system, pressure display, main control circuit, liquid storage container. Usually does not include a suction tube. Can be devided into various specifications according to negative principle, design, technical parameters, intended use, additional auxiliary functions, etc. Do not be used for suction in abortion and do not include suction equipment powered by negative pressure source or pressure source. Reference standard: YY 0636.1-2008 Medical suction equipment-Part 1: Electrically powered	II

349	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Simple respirator	Mainly consist of breathing valve, right-angle connector, headband, mask connector, masks, air conduit, flexible breathing balls, etc Can be devided into various specifications according to structure, technical parameters, etc Used for artificial respiration and assisted breathing with mixed gas and oxygen.	II
350	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Small molecular sieve oxygenerator	It is an equipment for separating 90% oxygen by using molecular sieve to absorb nitrogen and other gases with the principle of changable presure. Mainly consist of host and accessories. It has a oxygen concentration alarming function. Can be devided into various specifications according to the amount of oxygen generation, additional components and functions, etc Used for oxygen therapy or relieve uncomfortableness caused by a variety of oxygen lack. Reference standard: YY 0732-2009 Oxygen concentrators for medical use—Safety requirements, GB 8982-2009 Oxygen supplies for medicine and	II
351	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Electric operating table	Mainly consist of operating table, pedestal, electrical control systems, parts and auxiliary equipment, etc Can be devided into various specifications according to driving mode, technical parameters, auxiliary functions, etc Mainly used for supporting patients to provide a suitable position in head, neck, chest, enterocoelia, perineum, limbs operations in departments such as surgery, gynecology, urology, ENT, orthopedics etc Reference standard: YY/T 1106-2008 Electrically powered operating table, YY 0570-2005 Medical electrical equipment-Part 2-46: Particular requirements for the safety of operating tables	II
352	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Hydraulic operating table	Mainly consist of table, pedestal, hydraulic control systems, parts and auxiliary equipment, etc Can be devided into various specifications according to driving mode, technical parameters, auxiliary functions, etc Mainly used for supporting patients to provide a suitable position in head, neck, chest, enterocoelia, perineum, limbs operations in departments such as surgery, gynecology, urology, ENT, orthopedics etc	II
353	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils		Mainly consist of table, pedestal, hydraulic control systems, parts and auxiliary equipment, etc Can be devided into various specifications according to driving mode, technical parameters, auxiliary functions, etc Mainly used for supporting patients to provide a suitable position in head, neck, chest, enterocoelia, perineum, limbs operations in departments such as surgery, gynecology, urology, ENT, orthopedics etc Reference standard: YY/T 1106-2008 Electrically powered operating table, YY 0570-2005 Medical electrical equipment-Part 2-46: Particular requirements for the safety of operating tables	II
354	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Static surgical patients carrier	Mainly consist of lifting mechanism, balance board mechanism, hanger, hanger lifting mechanism, operating system. Can be devided into various specifications according to working principle, design, technical parameters, and other auxiliary functions, etc Used to auxiliary transport patient from operating tables to beds.	II
355	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils		Mainly consist of pressure pump, control unit, flushing and sucking conversion device, filtration bottles, hoses, flushing fluid and waste containers, etc Can be devided into various specifications according to pressure pump, control mode, technical parameters, additional auxiliary functions, etc Used for gastric lavage before operation for the poisoning emergency treatment. Reference standard: YY 1105-2008 Electric apparatus for gastric lavage	II

356	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Hydrotubation diagnostic apparatus	Mainly consist of control systems, power systems, boosting systems, printers, etc Can be devided into various specifications according to design, technical parameters, additional auxiliary functions, etc Used for liquid injection diagnosis or dredging for salpingography	II
357	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	ENT examination and treatment units	Mainly consist of operation inspection treatment tables, host and accessories. Can be devided into various specifications according to structure composition, functions and technical parameters, etc Used for ENT examination, diagnosis, treatment, etc. with RNT endoscope.	II
358	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Surgical shadowless lamp	Mainly consist of permanent seat, beams, balance body, balance pipe, lamp elbow pipe, lamp, dimming handle, handle. Can be devided into various specifications according to light sources, structure type, technical parameters, configuration, additional functions, etc Used for surgical lighting. Reference standard: YY 0627-2008 Medical electrical equipment—Part 2-41:Particular requirements for the safety of surgical luminaries and luminaries for diagnosis	II
359	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Medical cold light fiber light guide surgical light	Mainly consist of supporting section, cold light source, light guide fibers and lamp. Can be devided into various specifications according to different structures, compositions and technical parameters, etc Used for clinical diagnosis, treatment.	II
360	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Medical vacuum machine	Used in medical gas pipeline system. Mainly consist of vacuum pumps, vacuum tanks, piping, connectors and and electrical control box; Used to assist pipeline system to produce medical vacuum via vacuum pump suction.	II
361	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Medical Air Compressor	Used in medical gas pipeline system. Mainly consist of gas tank, connected devices and electrical control box. Used to produce compressed gas.	II
362	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Medical air oxygen mixture machine	Mainly consist of oxygen concentration detector, air regulating valve, flow indicator, humidifier; Used with oxygen pipes for oxygen concentration detection, regulation and humidification during supply oxygen to patients.	II

		Equipment and		Medical gas alarm system monitoring point multi-point gas sensors by a variety of mechanical transmission	1
I		appliance used in		and display system consisting of centralized transmission via a wired connection to a central gas	
262	6854	operating rooms,		management system consisting of a central management system for medical gas monitoring point for	11
303	0654		System		II
		emergency rooms, clinics room utensils		centralized monitoring, automatic alarm value exceeded alarm; can be used for a variety of gas supply	
				system for the hospital, such as oxygen, anesthetic gas monitoring.	
		Equipment and		Mainly consist of handle, camera and spy slices. The handle can be connected by a display. The spy slices	
2.54	50 <b>7</b> 4	appliance used in	Anesthesia video	can be reusable if made of metal or single-use if made of polymer material; The handle and spy slices are	**
364	6854	operating rooms,	laryngoscope	generally detachable. Can be devided into various specifications according to suitable crowd, texture,	II
		emergency rooms,	<i>y &amp;</i> 1	design, technical parameters, spy slices size; Used for clinical provoking patients epiglottis exposed glottis.	
		clinics room utensils		Used for anesthesia or emergency use in airway intubation or can also be used in the oral examination and	
		Equipment and		Mainly consist of heating module, control module and water incubator. The water incubator temperature can	
		appliance used in		be controlled, adjustable; Can be devided into various specifications according to design type, technical	
365	6854	operating rooms,	Heater/humidifier for	parameters, additional functions, etc The equipment can be connected in series between the ventilator and	II
303	0054	emergency rooms,	ventilator	endotracheal intubation. Used for reducing mechanical stimulation and keeping pulmonary alveoli moist via	11
		clinics room utensils		heating and humidifying the inhaled gas flow to facilitate phlegm suction and prevent airway obstruction.	
		chines room densits		Do not include passive heating and humidifying heat and moisture exchanger(artificial nose).	
		Equipment and	Radial artery tourniquet a		
		appliance used in		Mainly consist of supporting plate and oppression mat with belt. Can be devided into various specifications	
366	6854	operating rooms,		according to texture, design and technical parameters, etc Used for hemostasis compression in radial artery	II
		emergency rooms,		catheterization.	
		clinics room utensils			
		Equipment and			
		appliance used in	Femoral artery	It is with a sterile pneumatic dome arch and equiped with inflatable gauge pipe, inflatable source, bandage,	
367	6854	operating rooms,	pneumatic compression	etc Can be devided into various specifications according to design, technical parameters, and other	II
		emergency rooms,	device	auxiliary functions, etc Used for femoral artery or vein compression hemostasis after vascular nasal	
		clinics room utensils		intubation or ultrasound-guided compression repair in femoral artery pseudoaneurysm.	
		Equipment and		<b>V</b>	
		appliance used in		Mainly consist of silicone rubber tube, elastic or non-elastic fabric belt and velcro fasteners. Can be tied up	
368	6854	operating rooms,	Passive sphygmo	type, snap joint type, elastic paste type, etc. Used for stopping blood or hemostasis via direct/indirect	II
300	0051	emergency rooms,	pressing tourniquet	oppression. Can be used for limb bleeding or vein puncture hemostasis. Reference standard: YY/T 0031-	11
		clinics room utensils		2008 Silicone tubes and elastomeric parts for infusion and transfusion	
		Equipment and	<b>4</b>	Mainly consist of base, connector, headgear or multifunctional headstock, head rest, sitting portal frame,	
		appliance used in		etc Can be made of stainless steel or titanium alloy, etc Partial assembly unit has exact length or angle	
360	6854	operating rooms,	Headstock and head rest	scale. Can be used in three-dimensional positioning; Can be devided into various specifications according to	II
309	0054		system	design, intended use, technical parameters, applicable crowd, etc Used for fixing, supporting and guiding	11
		emergency rooms, clinics room utensils			
		cimics room utensils		in neck/head image positioning and head and neck surgery.	

370	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Anesthesia and respiratory breathing system filters	Mainly consist of upper cover, filter media, lower cover, protective cap, etc The filter housing is made of ABS, etc The filter media is made of polypropylene composite materials. Can be devided into various specifications according to filter media, appearance, size, etc. Be sterile. Used with anesthesia and respiratory devices for inhaling or exhaling particulate matter. Reference standard: YY/T 0753 Breathing system filters for anaesthetic and respiratory use—Part 1:Salt test method to assess filtration performance	III
371	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Infusion Information Collection System	Mainly consist of infrared communication interface and traversing carriage for power supply, integrated software, etc. Used to provide power supply and data communication to to infusion pump/injection pump via infrared interface. Used for infusion pump/injection pump data collection and data transmiting to a central station via a wired/wireless network, it can also prompt alarm information.	III
372	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Anesthesia evaporator	Mainly consist of evaporation chamber, concentration control devices, injection system and pharmaceutical liquid level indicator, etc Input a certain amount of gas into anesthetics container, then partial gas can flow through a regulating valve to evaporator chamber, the saturated anesthetics can be taken away meanwhile. A certain concentration anesthesia steam flow can be formed at the outlet. This product is a component part of anesthesia system. Used to provide anesthetic vapor with regulating concentration.	III
373	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Biological safety cabinets	Mainly consist of cabinet, front window operation mouth, standing leg and casters, fans, sump, filters, control panels and UV lamps and lighting resource. Airflow at the lowest average inflow velocity shall flow into the front window while the downdraght can be transmitted into working area after flowing through the high efficiency filters, the polluted airflow can be exhausted to the next link after filtrated by high efficiency filters. All the contaminated sites are in the negative pressure state or surrounded by negative pressure state or negative pressure ventilation systems and channels. Biological safety cabinet is with a operation front window. The operator can operate via the front window. Used for protecting personnel, products and	II
374	6854	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	Blood Trail Connector	It is a cardiopulmonary bypass system. Used for transfusing blood, observing and connecting in cardiopulmonary bypass system. Products with new materials, active ingredients, new technologies, new design or with a new action mechanism or fucntion can not be exempt clinical trails.	II
375	6855	Equipment and appliance for department of stomatology	Pneumatic Dental Descaler	Mainly consist of pneumatic host/drill, connector, teeth cleaning head, attachments, etc Can be with functions of auxiliary lighting, water spray, etc Can be devided into various specifications according to design, technical parameters, auxiliary functions, intended use, etc Used for removing tartar, dental calculus or stain on the surface of teeth.	II
376	6855	Equipment and appliance for department of stomatology	Pneumatic Dental sand- blasting appaatus	Mainly consist of handle, connected devices, etc Can be devided into various specifications according to texture, design, technical parameters, etc Used for removing tartar, stain or polishing teeth by using high-pressure air flow and fine-grained alumina embedded in the air flow.	II

377	6855	Equipment and appliance for department of stomatology	Electric Dental Comprehensive Therapy Apparatus	Driven by electric power. Used to support patient sitting position for dental examination, treatment and/or monitoring surgical procedure. The height is usually adjustable to facilitate operations. Mainly consist of headrest and handrail. The deck chair back can be reclining from vertical position to a horizontal position with a rotation function; Some types of dental chair can also be programmed several standard posture. Dental examination and/or treatment devices can be fixed as components of fixed dental chairs or mounted separately. The typical structure mainly consist of dental unit, electric dental chair and seat. The dental unit mainly consist of spray gun, oral lights, light arms and film watching lights, instrument trays, aspirator assembly, strong absorption components, medical foot switch, tank, water purification systems, etc. Used for dental diagnosis, therapy. Reference standards: YY/T 0058 Dental patient chair, YY 0055 Dentistry—Powered polymerization activators, YY/T 1147 General techonlogy condition for electric dental eengine,	II
378	6855	Equipment and appliance for department of stomatology		It is hydraulic drive. Used to support patient sitting position for dental examination, treatment and/or monitoring surgical procedure. The height is usually adjustable to facilitate operations. Mainly consist of headrest and handrail. The deck chair back can be reclining from vertical position to a horizontal position with a rotation function; Some types of dental chair can also be programmed several standard posture. Dental examination and/or treatment devices can be fixed as components of fixed dental chairs or mounted separately. Reference standard: YY/T 0058 Dental patient chair	II
379	6855	Equipment and appliance for department of stomatology		Can be devided into quartz tungsten halogen lamp and light emitting diode (LED) lights according to different light resource. The power supply section of quartz tungsten halogen lamp mainly consist of transformers, power rectifiers, electronic switching circuit while the light resource section of quartz tungsten halogen lamp mainly consist of halogen bulb, light filters, optical fiber tube, cooling fans, timing device, trigger switch, etcShall be with a light blocking device. LED lights network power and rechargeable battery mainly consist of host, batteries, light guide rods, goggles, rechargeable power supply switch, charging base; Alternating current series mainly consist of LED lights, control circuit board, host handles, power adapter, light guide rods, goggles. Reference standard: YY 0055-2002 Dentistry—Powered	II
380	6855	Equipment and appliance for department of stomatology	Dental medium/high capacity aspirator and Accessories	Active device. Mainly consist of vacuum aspirator, aspiration drill. Can be accessories of dental unit. Can be devided into various specifications according to aspiration type, flow (high flow and high flow), etc.  Used for producing negative pressure airflow to remove patient droplets, saliva, food debris, blood, etc  YY/T 0629 Dental equipment—High-and medium-volume suction systems	II
381	6855	Equipment and appliance for department of stomatology	*	Mainly consist of handle and working end. Can be devided into various specifications according to texture, type, size, etc of the handle and headend. Used for drilling teeth in dental therapy. Reference standard: YY 0761.1 Dentistry. Diamond rotary instrument. Part 1:Dimensions,requirements,marking and packaging, YY 0302.1 Dental rotary instruments—Burs—Part 1:Steel and carbide burs, YY 0302.2 dental rotary instruments bur Part 2: polished steel and carbide burs.	II

382	6856	Equipment and appliance for ward nursing	Medical gas pipeline systems-oxygen system	Mainly consist of central oxygen supply station, monitoring and alarming systems and piping distribution system with several terminals. Can be devided into various specifications according to different types of central oxygen supply station. Used for medical institutions with concentrated oxygen supply. Reference standard: YY 0801-2010 Terminal units for medical gas pipeline systems, YY/T 0799-2010 Low-pressure hose assemblies for use with medical gases, ISO 10083: 2006 medical gas pipeline systems with oxygen concentrator supply system, YY/T 0187 General technical requirements for oxygen supply system in	II
383	6856	Equipment and appliance for ward nursing	Medical oxygen supply	Mainly consist of oxygen bottle, flow gauge, pressure gauges, pressure reducer, carts, etc Used for oxygen supply in medical emergencies or medical spot.	II
384	6856	Equipment and appliance for ward nursing	Single-use nasal oxygen tube	Can be devided into various specifications eg.nose frame type, single nasal type, headband type, ear hook type according to different types. The nose frame type mainly consist of taper joints, shunt tube, extension tube, double orifice nose frame, tees and adjusting ring. The headband type mainly consist of earrings hook, rings, connectors. The ear hook type mainly consist of connectors, fine catheter, nasal congestion, hook. The adjusting ring and earrings are made of polyethylene plastic, while the other parts are made of PVC; The product should sterility. Connectted with the oxygen supply system for oxygen inhaling.	II
385	6856	Equipment and appliance for ward nursing		Mainly consist of humidification bottle, humidification liquid and nasal oxygen tube. The bottle body of humidification bottle is made of polypropylene resin while the cover is made of ABS resin. The nose oxygen tube pipe, and nasal congestion joints are made of soft PVC material; The humidification liquid is made of injection water which conforms to "Pharmacopoeia of the People's Republic of China" (2010 version). Can be devided into various specifications according to design, technical parameters, nasal oxygen tube, etc Used with oxygen supply device for patient moist and oxygen transport.	II
386	6856	Equipment and appliance for ward nursing	Sleep apnea treatment mask	Mainly made of polymer material. Mainly consist of mask and fixed band. Can be with pipeline, gas line interface and anti-asphyxia valve, etc Do not include oral appliance or other special purpose functional accessories; Can be sterile state, whiel can be reusable by a single patient. Used for sleep apnea therapy. Reference standard: YY 0671.2-2011 Sleep apnoea breathing therapy—Part 2:Masks and application	II
387	6856	Equipment and appliance for ward nursing	Infant oxygen hoods	Mainly consist of oxygen catheter, locking sets, adjusting plate, cover, cover body. Used with oxygen source, oxygen flowmeter. Used for infants oxygen therapy.	II
388	6856	Equipment and appliance for ward nursing	Infant oxygen- inspiration mask	Mainly made of PVC and other suitable material. Can be devided into various specifications according to texture, design, size, etc Can be sterile state; Used for infant oxygen inhaling.	II
389	6856	Equipment and appliance for ward nursing	Medical gas pipeline systems-vacuum system	Mainly consist of central vacuum station, monitoring and alarming system and pipeline distribution system with various terminals. The function of this system can be light and sound alarming when beyond the negative pressure limit. Used for vacuum suction in medical institutions. Reference standard: YY 0801-2010 Terminal units for medical gas pipeline systems—Part 1:Terminal units for use with compressed medical gases and vacuum, YY/T 0799-2010 Low-pressure hose assemblies for use with medical gases, YY/T 0186 General technical requirements for Suction system in medical center	II

390	6856	Equipment and appliance for ward nursing	Electric sickbed	The power supply can be net power supply or inner power supply or combined electric-driven. Mainly consist of bed surface, bed frame, electronic control part, infusion stand, etc Can be devided into various specifications according to functional configuration. Used for bearing and nursing patients. Reference standard: YY 0571-2005 Medical electrical equipment? Part 2: Particular requirements for the safety of	II
391	6856	Equipment and appliance for ward nursing	Manual wheelchairs	Driven by manpower. Mainly consist of frame, front wheel, rear wheel, seat, back pad, handrails, hitching leg, foot brake, pedals, etc Can be devided into various specifications according to driven means, wheelchairs texture, configuration, function, size, suitable range, etc Used for the disabled or patients or the elderly and infirm walking. Reference standard: GB / T 13800-2009 manual wheelchair.	II
392	6856	Equipment and appliance for ward nursing	Electric wheelchairs	Driven by one or more motors. The moving speed is controlled by motor. The direction is controlled by user or accompanied staff or electrically controlled; Can be devided into various specifications according to texture, function, attachments, and other technical parameters, etc Used for the disabled walking.  Rreference standard: GB 12996-1991 Electric wheelchairs and GB/T 18029 Wheelchairs Electrically	II
393	6856	Equipment and appliance for ward nursing	Nipple inversion retraction device	Mainly consist of cylindrical tube, core, etc Used for nipple suction reduction via the negative principle; Used for nipple retraction therapy.	II
394	6856	Equipment and appliance for ward nursing	Medical anti-bedsore cushion	Mainly consist of airbags, electric air pump, controller, massager motors, bedspreads; Can be devided into various specifications according to texture, design, technical parameters, inflatable model, etc. Used for bedsores prevention.	II
395	6857	Equipment and appliance for disinfection and sterilization	Large-scale steam sterilizers (manual type)	Killing microorganisms by vapor. The main technical parameters such as pressure, temperature, sterilization time are set manually, usually do not have a pre-vacuum or pulsating vacuumizing function. Mainly consist of container, gates, piping and control systems, etc The inner material are mainly SUS304 or SUS316L stainless steel with a more than 60L internal volume; Can be devided into various specifications according to intended use or load, structure type, sterilization inner room size, etc.; Used for medical device or hygienic material moist heat sterilization. Reference standard: YY 0731-2009 Large steam sterilizers—	II
396	6857	Equipment and appliance for disinfection and sterilization	Large steam sterilizer (automatic type)	Killing microorganisms by vapor. The main technical parameters such as pressure, temperature, sterilization time are set manually, usually do not have a pre-vacuum or pulsating vacuumizing function. Mainly consist of container, gates, piping and control systems, etc The inner material are mainly SUS304 or SUS316L stainless steel with a more than 60L internal volume; Can be devided into various specifications according to intended use or load, structure type, sterilization inner room size, etc.; Used for medical device or hygienic material moist heat sterilization. Reference standard: GB 8599-2008 Technical requirements for large steam sterilizers - Automatic type. Similar product names are medical sterilizers, Steam Sterilizers,	II
397	6857	Equipment and appliance for disinfection and sterilization	Small steam sterilizers	Killing microorganisms by vapor. The main technical parameters such as pressure, temperature, sterilization time are set manually, usually do not have a pre-vacuum or pulsating vacuumizing function. Mainly consist of container, gates, piping and control systems, etc The inner material are mainly SUS304 or SUS316L stainless steel with a more than 60L internal volume; Can be devided into various specifications according to intended use or load, structure type, sterilization inner room size, etc.; Used for medical device or hygienic material moist heat sterilization. Reference standard: YY 0646-2008 Small steam sterilizers—Automatic type. Similar products names are desktop sterilizer, cassette sterilizer, desktop steam sterilizers,	II

398	6857	Equipment and appliance for disinfection and sterilization	Vertical steam sterilizer	Killing microorganisms by vapor. The main technical parameters such as pressure, temperature, sterilization time are set manually, usually do not have a pre-vacuum or pulsating vacuumizing function. Mainly consist of container, gates, piping and control systems, etc The inner material are mainly SUS304 or SUS316L stainless steel with a more than 60L internal volume; Can be devided into various specifications according to intended use or load, structure type, sterilization inner room size, etc.; Used for medical device or hygienic material moist heat sterilization. Reference standard: YY 1007-2010 Vertical mode steam	II
399	6857	Equipment and appliance for disinfection and sterilization		Killing microorganisms by vapor. The main technical parameters such as pressure, temperature, sterilization time are set manually, usually do not have a pre-vacuum or pulsating vacuumizing function. Mainly consist of container, gates, piping and control systems, etc The inner material are mainly SUS304 or SUS316L stainless steel with a more than 60L internal volume; Can be devided into various specifications according to intended use or load, structure type, sterilization inner room size, etc.; Used for medical device or hygienic material moist heat sterilization. Reference standard: YY 0646-2008 Small steam sterilizers—Automatic type.Similar products names are desktop sterilizer, cassette sterilizer, desktop-pressure steam	II
400	6857	Equipment and appliance for disinfection and sterilization	Sterilizer	Mainly consist of handle, sterilization chamber body, steam generator and control system. Can be devided into various specifications according to heating mode, structure type, sterilization chamber volume, control means, precision, additional functions, etc Used for medical device sterilization in clincal institution.  Reference standard: YY 0504-2005 Portable Mode Steam Sterilizers	II
401	6857	Equipment and appliance for disinfection and sterilization	Ethylene oxide sterilizers	Mainly consist of sterilized box, heating and thermal cycle apparatus, vacuum apparatus, dosing and gasification apparatus, humidifying device, sealing device, residual gas treating apparatus, monitoring and control device, etc Can be devided into various specifications according to sterilization chamber volume, monitoring and control capabilities, additional functions, etc Used for medical device ethylene oxide sterilization. Reference standard: YY 0503-2005 Ethylene oxide sterilizer	II
402	6857	Equipment and appliance for disinfection and sterilization	temperature steam	The sterilization media can be formaldehyde vapor or gas. Mainly consist of sterilizing chamber body, doors, sterilizer pipeline systems, electrical systems, control systems and steam generator. Can be devided into various specifications according to cavity structure, door type, cavity volume, vacuum capability, additional procedures/functions, etc Used for medical products low temperature formaldehyde vapor sterilization. Reference standard: YY 0679-2008 Sterilizers for medical purposes-Low temperature steam	II
403	6857	Equipment and appliance for disinfection and sterilization	Low-temperature plasma hydrogen peroxide sterilizers	Mainly consist of sterilization bin, sterilization items frame, hydrogen peroxide vapor generator, plasma electrode, high-frequency generator and control unit; Can be devided into various specifications according to types, structures, sterilization capacity, technical parameters, additional auxiliary functions, etc Used for sterilization for high temperature and humidity sensitive items via plasma state steam or gas microorganism	II
404	6857	Equipment and appliance for disinfection and sterilization	Medical ozone water generator	Mainly consist of water/air input system, ozone generator, ozone water and gas mixing system, control system, may also include ozone monitoring/decomposition system; Can be devided into various specifications according to ozone generation principle, unit ozone output, additional auxiliary functions, etc Used to disinfect with ozone water for medical products such as surgical instruments. Be not used in	II

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405	6857	Equipment and appliance for disinfection and sterilization	EOW generator	Mainly consist of power supply, closed diaphragm electrolytic cell, sodium chloride solution storage/demineralized water supply system, acid/base potential water storage system, monitoring system; Used for patient wounds, skin and mucous membranes or surgical instrument sterilization with acid oxidation potential water generated by 0.1% sodium chloride solution electrolysis. Reference standard: GB 28234-2011 Safety and sanitation standard of acidic electrolyzed-oxidizing water generator	II
406	6857	Equipment and appliance for disinfection and sterilization	Medical endoscope cleaning and disinfecting equipment	Mainly consist of primary launder, enzyme launder, second enzyme launder, immersion disinfection launder, end launder, drying units, control console, without disinfectant, can be equipped with a heating function; Can be devided into various specifications according to design, technical parameters, additional auxiliary functions, etc. Used with disinfectant for medical endoscope cleaning and disinfection.	II
407	6857	Equipment and appliance for disinfection and sterilization	Breathing circuit sterilizer	Mainly consist of ozone generators, hydrogen peroxide atomizing device, pump, filter, ozone detection devices, cooling fans, control systems, etc Can be devided into various specifications according to design, type, technical parameters, additional auxiliary functions, etc Connected with breathing pipeline for ventilator, anesthesia machine inner loop disinfection with ozone and hydrogen peroxide mixed gas.	II
408	6857	Equipment and appliance for disinfection and sterilization	Dry Heat Sterilizers	It is an equipment for sterilization by hot-air or hot inert gas, usually an electric drive device. Mainly consist of sterilization chamber, door, control system, display system, etc Can be devided into various specifications according to sterilizer cavity structure, volume, types of doors, control type and control parameters, additional features. Used for dry heat sterilization for medical devices and products. Reference standard: YY 0602-2007 Safety requirements for electrical equipment for measurement control and laboratory use - Part 2-043:Particular requirements for dry heat sterilizers using either hot air or hot inert	II
409	6857	Equipment and appliance for disinfection and sterilization	Ultrasonic disinfection equipment	It is an electric drive equipment. Mainly consist of multi-slot assembly line for ultrasonic cleaning, ultrasonic rinsing, electric drying wind, etc Can be devided into various specifications according to structure and composition, technical parameters, additional function, etc Cleaning-related parameters can be process controlled. Used with cleaning agents and disinfectants. Used for medical devices cleaning,	II
410	6857	Equipment and appliance for disinfection and sterilization	Dental Cassette Steam Sterilizer	Electric drive equipment. Mainly consist of electric heating module, cassette sterilization boxes, control/display module and annexes. Can be devided into various specifications according to structure and composition, sterilization box volume, technical parameters and additional procedures/ functions, etc Used for rapid sterilization for dental reusable devices.	II
411	6858	Medical cold therapy, low temperature, cold storage equipment	Medical cryogenic refrigerator	Electric drive equipment. Mainly consist of liner, incubator body, refrigerating system, control(with alarm function) /display system. Can be devided into various specifications according to refrigeration working mechanism, incubator layer and liner texture, efficient refrigeration volume, refrigeration parameters and precision, additional function, etc The temperature can reach -86 °C. Used for samples, blood, drugs,	II
412	6858	Medical cold therapy, low temperature, cold storage equipment	Refrigerators for conserved blood	Electric drive equipment. Mainly consist of refrigerating system, temperature control/display system and tank shell. Can be devided into various specifications according to refrigeration working mechanism, incubator layer and liner texture, efficient refrigeration volume, refrigeration parameters and precision, additional function, etc Used for storage blood and other products. Reference standard: YY/T 0168 Blood	II

		Medical cold		Electric drive equipment, can also be passive device. Mainly consist of refrigerating system or ice	
		therapy, low		media,temperature control/display system and tank shell. Can be devided into various specifications	
413	6858	temperature, cold	( )rgan refrigeration limit	according to refrigeration working mechanism, incubator layer and liner texture, efficient refrigeration	II
		storage equipment		volume, refrigeration parameters and precision, additional function, etc The temperature range is about of	
		Medical cold		Remove water by sublimation from plasma which is frozen into solid to store plasma. Electric drive	
1,,,	c0.50	therapy, low	Freeze-dried plasma	equipment. Mainly consist of refrigerating system, vacuum system, heating system, gauge control system,	***
414	6858	temperature, cold	machine	etc Can be devided into various specifications according to structure and composition, technical	II
		storage equipment		parameters, additional functions, etc Used for freeze-dried plasma.	
		Medical cold		Remove water by sublimation to store substances. Electric drive equipment. Mainly consist of refrigerating	
415	C050	therapy, low		system, vacuum system, heating system, gauge control system, etc Can be devided into various	TT
415	6858	temperature, cold	vacuum freeze drier	specifications according to structure and composition, technical parameters, additional functions, etc Used	II
		storage equipment		for freeze-dried blood, biological samples or active substances, etc.	
		Medical cold		Mainly consist of heating tanks, thawing tank, circulation pipes, inlet pipe, drains, electrical control box,	
116	6858	therapy, low	Thaw box for frozen	etc Can be with alarming function. Can be devided into various specifications according to structure and	$_{ m II}$
1710	0030	temperature, cold	plasma	composition, the maximize thawing amount, thawing time, additional function, etc Used for thawing frozen	11
		storage equipment		plasma.	
		Medical cold	refrigerated Recycle	Mainly consist of box body, aluminum cooling box, trolleys, plastic lock, etc; Can be with the function of	
417	6858	therapy, low		temperature monitoring; The energy storage bag can be put into the box. Used for insulation refrigeration	II
111		temperature, cold		blood in transportion, storage for short time.	11
		storage equipment		order in anispersion, storage for the same	
		Medical cold	refrigerated Recycle t	Mainly consist of case (including insulation layer), refrigerated plate, flat plate carts etc; May have	
418	6858	therapy, low		temperature monitoring display; The energy storage bag can be put into the box. Used for insulation	II
		temperature, cold		refrigeration blood in transportion, storage for short time.	
-		storage equipment			
		Medical cold	M. P. of a C. on A.	Mainly consist of box body, liner, door, crew, control systems, shelves, handles, casters, etc Can be	
419	6858	therapy, low	Medical refrigeration	devided into various specifications according to design, technical parameters, and other auxiliary functions,	II
		temperature, cold	refrigerator	etc Used for human samples, medicines, vaccines, biologicals, reagents, etc. storage.	
		storage equipment  Medical cold	4444		
		therapy, low		Mainly consist of host, blankets and temperature sensors. Used for controlling blanket temperature to	
420	6858	temperature, cold	Warming Blankets	regulate human body temperature by in vitro physical temperature rising. Can be devided into various	II
		storage equipment		specifications according to design, technical parameters, and other auxiliary functions, etc	
		Medical cold			
		therapy, low		Mainly consist of host, blankets and temperature sensors. Used for controlling blanket temperature to	
421	6858	temperature, cold	Cooling blankets	regulate human body temperature by in vitro physical cooling. Can be devided into various specifications	II
		storage equipment		according to design, technical parameters, and other auxiliary functions, etc	
Ь		storage equipment			

422	6863	dental material	Customized fixed denture	Mainly consist of retainers, pontic and connector. Can be metal baked-porcelain-veneer crown, metal baked porcelain pontic, metal crown, metal pontic, all-ceramic crowns, all-ceramic pontic; Metal baked-porcelain-veneer crown, metal baked porcelain pontic are made of dental Ni-Cr casting alloys and high-temperature ceramic powder or low-temperature ceramic powder, etc Metal crown, metal pontic are made of dental nickel-based casting alloys and other suitable materials. Used for teeth, dentition defect fixed prosthesis	II
423	6863	dental material	Customized removable denture	Can be partial dentures or complete dentures, partial dentures mainly consist of artificial teeth, denture base and snap ring, complete dentures mainly consist of artificial teeth and denture base; Mainly made of dental cobalt-chromium alloys, denture denture base polymer, multi-colored synthetic resin teeth made of. Used for missing teeth, dentition restoration.	II
424	6863	dental material	Ceramic powder for customized denture	It is I-type ceramics powder to be the raw material for customized denture. Can be devided into various specifications according to component, intended use, etc Used for dyeing, transparent, addition and glazing for tooth nuclear, dentin porcelain/teeth body, teeth enamel, teeth neck. Reference standard: YY 0716-2009	II
425	6863	dental material	Dental casting alloys	It is customized denture materials which shall comply with YY 0621-2008 Metal-ceramic dental restorative systems. Precious metals shall be consistent with YY 0620-2008 Dentistry—Casting gold alloys and GB/T 17168-2008 Dental casting precious metal alloys; Including casting alloys for metal full mouth bracket, denture bracket and clasp, eg. nickel-chromium-based alloys, cobalt-chromium alloys, titanium and titanium	II
426	6863	dental material	All-ceramic dental zirconia ceramic blocks	The main components are zirconium oxide, yttrium oxide, alumina, and other oxides. Can be divided into different specification according to components, molding, shape, etc Used for making all-ceramic dental crown with CAD/CAM methods. Reference standard: YY 0716-2009 dental ceramics.	II
427	6863	dental material	All-ceramic material for dental ceramic restorations	It is I-type ceramics powder to be the raw material for customized denture. Can be devided into various specifications according to component, intended use, etc Used for dyeing, transparent, addition and glazing for tooth nuclear, dentin porcelain/teeth body, teeth enamel, teeth neck. Reference standard: YY 0716-2009 dental ceramics. Used for making or all-ceramic repairing all-ceramic crown, long pontic and inlay.	II
428	6863	dental material	Orthodontic bracket	Mainly made of stainless steel, ceramic, etc Can be devided into various specifications according to texture, teeth position, technical parameters, applicable sites, etc Used with orthodontic wire for teeth	II
429	6863	dental material	Orthodontic wire	Mainly made of stainless steel or nickel-titanium alloy steel, the surface can be coated with PFA resin coating (stealth). Can be divided into different specification according to texture, elasticity, cross-sectional shapes (circular and rectangular) and size, etc Used with orthodontic brackets for dental orthodontic. Reference standard: YY 0625-2008 dentistry orthodontic products: orthodontic wire.	II
430	6863	dental material	Orthodontic elastomeric attachments	Mainly consist of orthodontic elastic traction circle, orthodontic elastic cord/elastic tubes, orthodontic rubber chain, orthodontic ligature ring, orthodontic separation ring. Made of natural or synthetic rubber. Can be divided into different specification according to texture, shape, size, etc Used with fixed or removable appliance in or out oral cavity for synergistic orthodontic treatment effect.Reference standard: YY 0624-2008 Dentistry -Orthodontic products-orthodontic elastomeric auxiliaries	II
431	6863	dental material	Dental phosphoric acid etching agent	Liquid state. Can be divided into different specification according to prescription, phosphoric acid content, load quantity, etc.; Used for teeth acid corrosion treatment prior to dental filling repair, orthodontic bracket cement, dental caries prevention, etc Reference standard: YY 9769-2009 Dental phosphoric acid etching	II

432	6863	dental material	Plaster impression	Mainly made of hemihydrate calcium sulfate and modifier. Can be divided into different specification according to materials, recipe, technical parameters, etc Used for teeth and oral tissues impression.  Reference standard: YY 0462-2003 dental gypsum products.	II
433	6863	dental material		It is made of reversible gel material. Can be divided into different specification according to consistency.  Can be reusable. Reference standard: YY 0494-2004 Dental aqueous impression materials based on agar	II
434	6863	dental material	Elastomeric impression	It is elastomeric material after plasticity. Such as silicone rubber, polyether rubber. Mainly made of matrix, crosslinking agent, catalyst and filler. Can be divided into different specification according to material, recipe, impression technical parameters, etc. Used for teeth and oral tissues delivery by polymerization reaction. Reference standard: YY 0493-2011 Dentistry—Elastomeric impression materials	II
435	6863	dental material	Dental alginate impression material	Powder state. The appearance is uniform without impurities. The reconciled material shall be uniform, without agglomerate or grain, with a smooth surface. Single-use products. It shall be no oral mucous membrane irritant, non-allergenic toxicity. The main components are alginate, calcium sulfate, diatomaceous earth, talc, etc Can be divided into different specification according to prescription, reconciled time, total working time, curing time. Used for teeth and oral tissues impression. Reference	II
436	6863	dental material	Silicone bite registration material	The main component are silicon dioxide, polydimethylsiloxane. Used for recording occlusion.	II
437	6863	dental material	Teeth desiccant	The main component are ethanol, acetone, distilled water, etc Covered on the teeth surface for rapid cleaning, dying for further diagnosis and treatment.	II
438	6863	dental material	Gingival retraction cord	Made of white cotton thread. Without medicines such as hemostasis medicines. Can be divided into different specification according to texture, thread diameter, length, etc Used for separating gums to reduce injury and drying partial section prior to teeth preparation, impression taking or sticky crown, etc	II
439	6863	dental material	Gingival retraction cream	Mainly made of aluminum chloride, kaolin and supplementary material, paste state. Without medicines such as hemostasis medicines. Can be divided into different specification according to recipe, load quantity, accessories, etc.; Used for separating gums to reduce injury and drying partial section prior to teeth preparation, impression taking or sticky crown, etc. by physical adsorption, filling.	II
440	6863	dental material	Intraoral polishing material	Mainly made of silicon dioxide or sodium bicarbonate and auxiliary material. Can be powder or paste state.  Can be divided into different specification according to recipe, abrasive particle size, load quantity, accessories, etc. Used for polishing teeth tissue or dummy to smooth the surface.	II
441	6863	dental material	Fiber Reinforcement	The main component is polymer material such as polyethylene terephthalate or glass fiber. Can be divided into different specification according to texture, design, physical properties, sizes, etc Used for loose teeth fixation, missing teeth temporary fixation, dentition missing gap maintain, temporary or permanent reinforcement and repair for fixed pontic.	II
442	6863	dental material	Dental Optical dusting	Mainly made of ethanol, fluorinated hydrocarbons, mint flavor. Used in dental prosthesis computer-aided design for spraying on the teeth of patients to aid oral dental camera to obtain a clear 3D images.	II
443	6863	dental material	Protective cap for planting base station	Mainly made of polymethyl methacrylate and plastic polyformaldehyde, cap structure. Used to prevent bacteria from entering the implant and the inner superstructure to cause internal infection and prevent scratching the surface of the implant as well by covering on implant superstructure.	II

444	6863	dental material	Denture sealing agent	It is paste state made of sodium carboxymethylcellulose,poly-methyl vinyl ether sodium and calcium salt, shrink-malic acid. Can be divided into various specifications according to prescription, technical parameters, etc. Used for dentures repair by coating in gaps of dentures and gums to prevent infection	II
445	6863	dental material	Calcium hydroxide root canal disinfectant	Can be single-component or double-components powder paste. Single-component mainly contains calcium oxide and excipient while double-components mainly contain calcium hydroxide and aqueous propylene glycol, can be attached with tools; Can be divided into various specifications according to prescription, technical parameters and accessories, etc Used for root canal disinfection in oral cavity.	II
446	6863	dental material	Orthodontic buccal tubes	Mainly consist of main body and drag hook and is made of stainless steel and other suitable material. Can be divided into various specifications according to texture, design and technical parameters, etc Used with orthodontic brackets, orthodontic wire and other facilities, used for orthodontics.	II
447	6863	dental material	Orthodontic ligature wire	Mainly made of stainless steel wire. Can be divided into various specifications according to texture, physical properties, wire diameter/length, etc. Used for orthodontic wire, brackets or other attachment ligation in dental dentition orthodontics to fix and pulling teeth move.	II
448	6863	dental material	Free towing hook	Mainly made of stainless steel wire. Can be divided into various specifications according to texture, physical properties, size, etc Used with orthodontic products for orthodontics.	II
449	6863	dental material	Spiral arch expansion device	Mainly made of stainless steel and consist of screw rod, nut, guiding bar, adjusting rod. Can be divided into various specifications according to texture, design, technical parameters, applicabel sites. Used for dental arch gap expansion for dental arch stenosis.	II
450	6863	dental material	Orthodontic spring	Mainly made of stainless steel and can be divided into various specifications according to texture, design, technical parameters, intended use, etc., e.g. stretching, compressing, rotating spring; Used with other ancillary orthodontic products for oral orthodontic.	II
451	6863	dental material	Front jaw Extraoral traction appliances	Mainly consist of forehead bracket, adjustable bracket, regulators and low jaw pocket. The forehead bracket and low jaw pocket are made of polypropylene resin while the adjustable brackets are made of stainless steel; Can be divided into various specifications according to texture, design, technology parameters, etc Used with orthodontic devices for assisting traction in assist. Does not include intraoral orthodontic	II
452	6863	dental material	Molar propeller	Mainly made of stainless steel, etc.and consist of various supporting rods and springs. Can be divided into various specifications according to texture, design, technology parameters, etc Used with brackets, belt loops, planting nails and other facilities for pushing molars to achieve wrong teeth aligned required gaps. Does not include planting nails, brackets, belt loop.	III
453	6863	dental material	Dental diaphragm	Mainly made of polyethylene, vinyl acetate, edible pigments, etc It is physically stable and has a certain elasticity, compressive strength, easy plastic, single-layer structure. Can be divided into various specifications according texture, shape, size, etc. Used for making movable mouthguard, bracket	III
454	6863	dental material	Glass ionomer cement	Solidified cement produced by reaction of aluminosilicate glass powder and alkenoic acid or reaction of aluminosilicate glass powder/poly acid powder and aqueous tartaric acid. Clinical exempt products shall meet requirements in YY 0271.1 Dentistry—Water-based cements—Part 1:Powder/liquid acid-base cements. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function	III

	6863	dental material	zinc oxide cement without eugenol	Mainly composed of zinc oxide, mineral oil. Used for temporary dental restoration and rebasement. Clinical exempt products shall meet requirements of YY 0272 Dentistry-Zinc oxide/eugenol and zinc oxide/non-eugenol cements. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	III
456	6863	dental material	Retention nails	Used in large area of missing teeth repair and to provide retention in teeth repair. Mainly made of metal.	III
457	6863	dental material	Synthetic resin teeth	Mainly made of acrylic polymers for partial dentures and complete denture preparation. Clinical exempt products shall meet requirements of YY 0300 Dentistry—Artificial teeth for dental prostheses. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	III
458	6863	dental material	Metal post	Used for crown nuclear retention in large area teeth missing reconstruction. Clinical exempt products shall meet requirements of YY/T 0517 Dental prefabricated root post. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action	III
459	6863	dental material	Polymer-based crown and bridge material	Mainly made of polymer materials. Used for dentition defect and missing repair. Clinical exempt products shall meet requirements of YY 1042 Dentistry—Polymer-based restorative materials. Exemption does not include products which use new material, active ingredients, new technique, new design or products with	III
460	6863	dental material	Zinc polycarboxylate cement	Solidified cement produced by reaction of aluminosilicate glass powder and alkenoic acid or reaction of aluminosilicate glass powder/poly acid powder and aqueous tartaric acid. Used for rebasement and lining dentistry cavity. Clinical exempt products shall meet requirements of YY 0272 Dentistry-Zinc oxide/eugenol and zinc oxide/non-eugenol cements. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	III
461	6863	dental material	Zinc phosphate cement	Solidified cement produced by reaction of oxide powder (major component is zinc oxide) and aqueous solution of phosphoric acid. Clinical exempt products shall meet requirements of YY 0271.1 Dentistry—Water-based cements—Part 1:Powder/liquid acid-base cements	III
462	6863	dental material	Calcium hydroxide cement	Mainly composed of calcium hydroxide and chelating agent. Often act as low-intensity bottom materials, lining, indirect lining or pulp capping agent. Clinical exempt products shall meet requirements of 0271.1 Dentistry—Water-based cements—Part 1:Powder/liquid acid-base cements. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action	III
463	6863	dental material	Fiber post	Used for crown nuclear retention in large area teeth missing reconstruction. Clinical exempt products shall meet requirements of YY/T 0517 Dental prefabricated root post. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action	III
464	6863	dental material	Gutta percha	Mainly consist of gutta percha, zinc oxide, barium sulphate. It is filling material for dental root canal. Used with medicines for filling root canal after cleaning the punched disease teeth to treat pulpitis and root apex tussue disease. Clinical exempt products shall meet requirements of YY 0495 Dental root-canal obturating points. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	III

465	6863	dental material	Zinc oxide eugenol cement	Mainly consist of powder and liquid. Powders are mainly zinc oxide, resin, zinc stearate and coarse zinc and other components. Liquid are mainly clove oil, olive oil and other components. Used for dental temporary restoration and bottom lining. Clinical exempt products shall meet requirements of YY 0272 Dentistry-Zinc oxide/eugenol and zinc oxide/non-eugenol cements. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	III
466	6863	dental material	Denture base polymer	Mainly made of methyl methacrylate (MMA) homopolymer or acrylate copolymer and methyl methacrylate monomer, used for making denture base. Clinical exempt products shall meet requirements of YY 0270.1 dentistry denture base polymers - Part 1: Requirements related to denture base polymers. Exemption does not include the use of new materials, active ingredients, new technologies, new design or with a new action mechanism, new features of the product.	III
467	6863	dental material	silver amalgam	Mainly consisting of elements such as silver, tin, copper and small amounts of indium, palladium, platinum, zinc and mercury and other elements. Used for filling cavity in caries therapy. Clinical exempt products shall meet requirements of YY 1026 Dental materials-Alloys for dental amalgam. Exemption does not include products which use new material, active ingredients, new technique, new design or products with	III
468	6863	dental material	Pretreating agent	Mainly made of silane coupling agent, adhesion monomers and volatile monomers. Some are others, such as hydrofluoric acid. Used for improving adhesion between restoration, prosthesises.	III
469	6863	dental material	Temporary Crown and Bridge Resin	Mainly made of polymer materials. Used for temporary crown bridge making. Clinical exempt products shall meet requirements of YY 1042 Dentistry—Polymer-based restorative materials. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	III
470	6863	dental material	powder for synthetic polymer teeth and iquid for synthetic polymer teeth	Mainly made of methyl methacrylate (MMA) homopolymer or acrylate copolymer and methyl methacrylate monomer, used for making dentures. Clinical exempt products shall meet requirements of YY 0270.1 Dentistry-Base polymers. Part 1:Denture base polymers. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or	II
471	6863	dental material	Orthodontic base polymers	Mainly made of methyl methacrylate (MMA) homopolymer or acrylate copolymer and methyl methacrylate monomer, used for making orthodontic denture base. Clinical exempt products shall meet requirements of YY 0270.2-2011 Dentistry—Base polymers—Part 2:Orthodontic base polymers. Exemption does not include products which use new material, active ingredients, new technique, new design or products with	II
472	6864	Medical hygienic materials and dressings	Medical degreasing cotton and related products	Mainly made of pure cotton after opening, cleaning, degreasing, bleaching processes. Can be divided into different specifications according to package weight, non-sterile products. Medical degreasing cotton can made into medical dressing according to sizes, shapes and types, e.g. dressing cotton block or pad. Can be sterile and non-sterile form (pre-sterilized before use), used for clinical trauma care, moinsture absorption. Reference standard: YY 0331-2006 Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze, YY 0594-2006 General requirements for surgical gauze dressings	Π
473	6864	Medical hygienic materials and dressings	Medical sterile liquid paraffin non-woven	Mainly made of non-woven and liquid paraffin. Can be divided into different specifications according to recipe, texture, size, etcSterile form; Used for lubrication on the surface of patient examination parts and devices.	II

480	6864	Medical hygienic materials and dressings	single-use sterile clean clothes	Mainly made of non-woven or coated non-woven, etc. and consist of collar, bodice, sleeves and composition or coat and pants, can contain shoes; cuffs and ankle cuffs is with elastic mouth, waist cuffs can be elastic cuffs, drawstring cuffs or buckle; can be divided into gown style, jumpsuits, fission garments. Can be divided into various specifications according to sizes. Can be sterile state. Used for patients wound infection and to prevent clean area contamination caused by contaminated resouce carried by personnel. Reference standard: YY/T 0506 Surgical drapes gowns and clean air suits for patients clinical staff and	II
479	6864	Medical hygienic materials and dressings	single-use surgical gowns	Mainly made of non-woven or coated non-woven, etc. and consist of collar, bodice, sleeves and composition or coat and pants, can contain shoes; cuffs and ankle cuffs is with elastic mouth, waist cuffs can be elastic cuffs, drawstring cuffs or buckle; can be divided into gown style, jumpsuits, fission garments. Can be divided into various specifications according to sizes. Can be sterile state. The breast and elbows parts can be with strengthen protection. Used to reduce migration of infection source to surgical wound for postoperative wound infection prevention and can also reduce infection source in blood or body liquid to transmit into medical staff.Reference standard: YY / T 0506 patients, staff and equipment with the surgical	II
478	6864	Medical hygienic materials and dressings	Medical protective shoe covers	Made of texure which is with the function of specific liquid obsruction, specific strength, filtration efficiency, flame retardant, anti-static and static decay function, etc The protective shoe can be with elastic cuffs. Can be divided into various specifications according to types, textures, sizes, etc Used to provide protection and obstruction for medical staff who contact patients blood, body liquid, secretion which are	II
477	6864	Medical hygienic materials and dressings	Medical Protective Footwear	Mainly made of polymer material with air holes. Can be divided into different specifications according to texture, type, application subjects, sizes, etc Used in special places (such as operating rooms, intensive care room, etc.) for avoiding blood, waste water or sharp instrument injuries.	II
476	6864	Medical hygienic materials and dressings	Medical single-use protective cap	Made of texure which is with the function of specific hquid obsruction, specific strength, filtration efficiency, flame retardant, anti-static and static decay, etc Protective cap is with elastic mouth shut. Used to provide protection and obstruction for medical staff who contact patients blood, body liquid, secretion	II
475	6864	Medical hygienic materials and dressings	Respirator	Made of texure which is with smaller flow resistance, synthetic blood barrier, specific strength, filtration efficiency, surface moisture resistance, flame retardant etc Can be self-suction. Mainly consist of mask body (including nose clip) and masks band. Can be divided into three grade according to filter efficiency while each level is divided into different specifications according to sizes. Used in medical work environments for filtering particulate matter in the air, blocking droplets, blood, body fluids, secretions, etc Reference standard: GB 19083-2010 Technical requirements for protective face mask for medical use	II
474	6864	Medical hygienic materials and dressings	Medical single-use protective clothing	Made of texure which is with the function of specific liquid obsruction, specific strength, filtration efficiency, flame retardant, anti-static and static decay, etc Mainly consist of hoodies, trousers, etc. The cuffs end and ankle end are with elastic mouth shut. Cap and waist end are with elastic mouth shut, dragging rop shut or agraffe. Can be one-piece or split into two categories. Can be divided into different specifications according to sizes. Used to provide protection and obstruction for medical staff who contact patients blood, body liquid, secretion which are with potential infection Reference standard: GB 19082-2009 Technical requirements for single-use protective clothing for medical use	II

481	6864	Medical hygienic materials and dressings	single-use isolation gowns	Mainly made of non-woven or coated non-woven, etc. and consist of collar, bodice, sleeves and composition or coat and pants, can contain shoes; cuffs and ankle cuffs is with elastic mouth, waist cuffs can be elastic cuffs, drawstring cuffs or buckle; can be divided into gown style, jumpsuits, fission garments. Can be divided into various specifications according to sizes. Generally be non-sterile. Used to prevent personnel who enter into potential pathogens contaminated areas from infection and disease by wearing this products. Reference standard: YY/T 0506 Surgical drapes gowns and clean air suits for patients clinical	II
482	6864	Medical hygienic materials and dressings	single-use medical surgical masks	Mainly made of non-woven or non-woven composite materials, can be two or three-tier structure, may be with plasticity nose clip, masks band is elastic or non-elastic. Can be with the funtion of particulate matter and bacteria filteration. Can be divided into various specifications according to types, sizes, etc Sterile form. Used for wearing in clinical invasive operation to cover the user's mouth, nose and jaw, in order to provide a physical barrier to avoid pathogenic microorganisms, particulate matter penetrating	II
483	6864	Medical hygienic materials and dressings	single-use sterile surgical drapes	Mainly made of non-woven or coated non-woven, etc Can be divided into various specifications according to types and sizes. Sterile state. Used for covering on patient, surgical drapes or surgical film to reduce migration of infection source from wound surface skin to surgical wound for postoperative wound infection prevention. Can also be with the function of surgical waste collection. Reference standard: YY/T 0506 Surgical drapes gowns and clean air suits for patients clinical staff and equipment	II
484	6864	Medical hygienic materials and dressings	Surgical drapes	Mainly made of non-woven or coated non-woven, etc Can be divided into various specifications according to types and sizes. Sterile state. Used to reduce migration of infection source from wound surface skin to surgical wound for postoperative wound infection prevention by covering on the surgical skin wound	II
485	6864	Medical hygienic materials and dressings	single-use sterile surgical membrane	Made of natural rubber latex (can be without medical pressure-sensitive adhesive coating) or polyurethane, polyethylene substrate coated with hypoallergenic adhesive, release paper is placed onto the top surface. Can be divided into various specifications according to texture, shape, size, etcSterile state; Used to simplify skin care prior to operation and to prevent wound infections in contacting and migrating surgery. Reference standard: YY 0852-2011 Sterile surgical films for single use	II
486	6864	Medical hygienic materials and dressings	Medical masks (non- surgical)	Mainly made of non-woven or non-woven composite materials, can be two or three-tier structure, may be with plasticity nose clip, masks band is elastic or non-elastic. Can be with the funtion of particulate matter and bacteria filteration. Can be divided into various specifications according to types, sizes, etc Sterile form. Used for wearing in clinical non-invasive operation to cover the user's mouth, nose and jaw, in order to provide a physical barrier to avoid pathogenic microorganisms, particulate matter penetrating directly.	II
487	6864	Medical hygienic materials and dressings	Single-use sterile dressing	Mainly made of polyurethane/polyethylene composite membrane or non-woven fabric coated with medical pressure-sensitive adhesive. Can be with dressing-core e.g. gauze, woodiness cotton, carbon fiber, hydrocolloid. Without drugs. Can be divided into various specifications according to texture, layers, shapes, sizes, etc Sterile state; Used for application in surgical wound, artery, intravenous catheter retention. Can also be used in baby umbilical cord wound protection.	II
488	6864	Medical hygienic materials and dressings	single-use medical hydrogel eye patch	Mainly consist of non-woven base layer, medical polyvinyl alcohol hydrogel and release paper; Can be divided into various specifications according to shape, size, etc. Used to paste on external eyes of general anesthesia or deep coma patients for exposure keratitis prevention by providing a relatively closed humid	II

489	6864	Medical hygienic materials and dressings	Woundplast	Mainly made of polyurethane adhesives or non-woven fabric coated with medical pressure-sensitive adhesive; Do not contain drugs; Can be divided into various specifications according to texture, fold layers, shapes, sizes, etc Sterile form; Used for application in surgical wound, artery, intravenous catheter retention. Can also be used in baby umbilical cord wound protection.	II
490	6864	Medical hygienic materials and dressings	Infant phototherapy protective goggles	Mainly consist of goggles and goggles fixture; The goggles are made of high quality non-woven/blue-black physical recombination cloth. The goggles fixture is made of elastic band or soft Velcro, etc.; Can be divided into various specifications according to texture, design, technical parameters and dimensions, etc Used for eye protection in infants blue light therapy.	III
491	6864	Medical hygienic materials and dressings	Medical Non-woven dressing	Mainly made of non-woven fabric. Can be divided into various specifications according to texture, folded or not, folded layers, size, intended use, etc Used for wound care, moisture absorption, organs protection.	III
492	6864	Medical hygienic materials and dressings	Vaseline/paraffin gauze (gauze)	Mainly consist of medical gauze, vaseline, paraffin oil. The intended use is limited into wound drainage, cover, Vaseline/paraffin gauze for padding.Exemption does not include the following circumstances:  (1)Claim to have the function of wound healing, pain reduction, bleeding stopping, scarring reducing, antiadhesion in indications;(2) Products which are used in in vivo wound; (3) Products contains active component: such as drug/pharmaceutical active ingredients, biologics/biological active ingredient, silver,	II
493	6864	Medical hygienic materials and dressings	Polyurethane foam dressing	Mainly made of polyurethane foam. The intended use is limited into wound covering, wound exudate obsorption. Exemption does not include the following circumstances: (1)Claim to have the function of epithelialization promotion, guided tissue regeneration, wound healing, pain reduction, bleeding stopping, scarring reducing, anti-adhesion in indications;(2) Claims that the products can be used for in vivo wound, third-degree burns, wound infection, wound with much necrotic tissue, wound sepsis; (3) Products contains active ingredient; such as drug/pharmaceutically active component, biological products/bioactive ingredient,	II
494	6865	Medical suture materials and adhesives	Non-absorbable surgical sutures	Can be made of natural silk, polyamide 6/66, Polyethylene terephthalate, polypropylene, stainless steel wire, nickel-titanium memory alloy wire, etc. Can be with or without a needle. Can be divided into various specifications according to texture, strands/weaving, coating, with or without a needle, beam/group, wire diameter, applicable sites, etc Used for suturation and ligation. Reference standard: YY 0167-2005 non-absorbable surgical suture, YY 0166-2002 Non-absorbable surgical suture	II
495	6865	Medical suture materials and adhesives	Single-use skin stapler	Mainly consist of push piece (12Cr18Ni9/06Cr10Ni10), shell(ABS), handle (PA/ABS), suturing nails (022Cr17Ni12Mo2), can be with an optional Staple Extractor; Can be divided into various specifications according to design, suturing nail numbers, dimensions of suturing nails, etc Sterile state. Used for suturing skin in trauma or surgical incision.	II
496	6866	Medical polymer materials and products	Single-use sterile vaginal dilator	Made of polypropylene and other suitable polymer materials. Mainly consist of upper vane, lower vane and handle. Can be divided into various specifications according to texture, type, size, etc Sterile form; Used for vaginal examination in gynecology. Reference standard: YY 0336-2002 Sterile vagina dilator for single	II

497	6866	Medical polymer materials and products	Natural rubber latex condoms	Made of natural rubber latex. Can be planar model, floating-point type, screw type, etc Can add different ingredient. Can be various specifications according to nominal width. Add food grade pigment into the color type; Add food flavors into flavor type; Add silicone oil into lubricated wet type; Nominal width, model differences and added ingredients can be combined. Used for contraception and transmitted diseases prevention for males. Reference standard: GB 7544-2009 Natural latex rubber condoms—Requirements and	II
498	6866	Medical polymer materials and products	Polyisoprene synthetic rubber condoms	Mainly made of polyisoprene rubber. Can be planar model, floating-point type, screw type, etc Can add different ingredient. Can be various specifications according to nominal width. Add food grade pigment into the color type; Add food flavors into flavor type; Add silicone oil into lubricated wet type; Nominal width, model differences and added ingredients can be combined. Used for contraception and transmitted diseases prevention for males. Reference standard: GB 7544-2009 Natural latex rubber condons.—Requirements and	II
499	6866	Medical polymer materials and products	Polyurethane female condom	Mainly consist of inner ring, outer ring and polyurethane film. The inner ring is closure while the inner and outer surfaces are coated with dimethicone. Can be divided into various specifications according to design, technical parameters, etc Used for contraception and transmitted diseases prevention for females.	II
500	6866	Medical polymer materials and	Pessary	Mainly made of silicone rubber and suitable materials. Be a ring. Can be divided into various specifications according to texture, shape, size, etc Used to release pain and complications caused by uterus backward,	II
501	6866	Medical polymer materials and products	Single-use catheter	Mainly made of polyvinyl chloride, natural rubber latex, silicone rubber, rubber, etc. and consist of tube body and connector. Can be divided into various specifications according to application subjects, use texture, lumen number, with or without a balloon, diameter and length, etcSingle use. Sterile form except rubber catheter part. Used for clinical routine catheterization. Excluding microwave, multi-cavity catheter for radio frequency therapy/treatment. Reference standard: YY 0325-2002 Single urethral catheter for single	II
502	6866	Medical polymer materials and products	Single-use biliary drainage tube	Mainly made of silica gel and consist of spiral drainage end, tube body and connectors, etc Can be divided into various specifications according to texture, design and technical parameters, etc Sterile form; Used for biliary drainage in endoscopic biliary stones or gallbladder removal surgery.	II
503	6866	Medical polymer materials and products	single-use surface drainage ball/tube	Mainly made of silicone rubber, latex and other suitable materials. Can be various shapes, tube body is with side holes, can be connected with negative pressure ball. Can be divided into various specifications according to texture, design, diameter, suitable sites, etc Sterile form; Used for surface wound or incision	II
504	6866	Medical polymer materials and products	Single-use Enteral giving device	Mainly made of polymer materials and consist of nutrition bottles/bags, infusion tubing (including flow, flow control device), stomach/intestinal nutrition catheter connection device, stomach/intestinal nutrition catheters. Can be divided into various specifications according to texture, design, technical parameters, scope, intended use, etc Sterile state; Used with enteral nutrition infusion/pump for enteral nutrition delivery. Reference standard: YY 0483-2004 single-use enteral feeding catheters, bowel supplies and its connection design and test methods, YY / T 0817-2010 Enteral feeding catheters and enteral giving sets for	II
505	6866	Medical polymer materials and	single-use lacrimal drainage tube	Made of silicone rubber. Can be divided into various specifications according to texture, design, size, etc  Sterile form. Used for flushing and drainage in lacrimal duct stenosis, occlusion, fracture treatment.	II
506	6866	Medical polymer materials and products	single-use J-type catheters	Mainly made of polyurethane, J-type terminal has a plurality smooth side holes and end holes. Can be divided into various specifications according to diameter, length, etc Sterile form; Used for minimally invasive intervention or open surgical imbedding into renal pelvis and bladder, used for supporting and drainage. The residence time is less than 30 days.	II

507	6866	Medical polymer materials and	single-use ureteral drainage tube	Mainly made of polyurethane, can be straight, the tube body is with side holes; Can be divided into various specifications according to diameter, length, etc Sterile state; Used for ureteral support and drainage.	II
508	6866	Medical polymer materials and products	single-use bladder fistula	Mainly consisto of fistula (soft PVC, polyurethane, silicone rubber and other applicable materials), guide pins (stainless steel) and connecting tube (made of medical soft PVC). Can be divided into various specifications according to diameter, length, whether with a balloon or not. Sterile state; Used for clinical temporary urinary diversion, urine drainage in pubis bladder puncture ostomy	II
509	6866	Medical polymer materials and products	single-use urethral dilator	Mainly consist of pipe, connector and guide wire. Can be divided into various specifications according to texture, design, diameter/length, etc Can consist of single or several models in one set. Sterile state; Used for urethral stricture dilation in urinary surgery to relieve urethral obstruction.	II
510	6866	Medical polymer materials and products	single-use bladder irrigator	Mainly made of PVC plastics, etc. Mainly consist of puncture, protective cover, pipe clamps, pipe, drip chamber, flow regulator, catheter connector. Can be divided into various specifications according to texture, design, technical parameters, etc Used for flushing bladder, urinary tract, surgical instruments, etc.in	II
511	6866	Medical polymer materials and products	Suction catheter for respiratory tract	Mainly consist of catheter with side-hole and plug connector; The catheter is made of polyvinyl chloride, natural rubber latex, silicone rubber, rubber material, the plug connector is made of polyvinyl chloride, silicone rubber or MD-type polyvinyl chloride; Can be divided into various specifications according to texture, diameters, etcSterile form. Can be connected to vacuum systems or equipment for respiratory sputum suction, etc. Do not include multi-lumen airway catheter without side-hole. Reference standard: YY 0339-2009 Suction catheter for use in the respiratory tract. Can also be named single-use sputum suction	II
512	6866	Medical polymer materials and products	single-use trachea cannula	Mainly consist of intubation tube, inflatable tube, cuff, connector and pneumatic valve; The intubation tube, inflatable tube and cuff are made of polyethylene plastic; The connector and pneumatic valve are made of polyethylene and other materials; Tracheostomy tube can be ordinary with/without cuff cannulation and reinforced with/without cuff cannulation. Can be divided into various specifications according to applicable crowd, nominal diameter, cuff capacity, etc Sterile form; Used for artificial airway establishment in clinical first <sub>z</sub> aid. Reference standard: YY 0337-2002 endotracheal intubation. Does not include bronchial intubation.	II
513	6866	Medical polymer materials and products	single-use tracheostomy tube	Mainly consist of tracheostomy tube (patient end has rounded tip, ramps and fixed balloon), standard outer conical connector (machine-end), integrated indicating balloon/valve assembly and fixed wing; The tube body, inflatable tube, cuff of tracheostomy tube is made of polyethylene plastic, rubber and other suitable materials, while fittings, pneumatic valves can be made of polyethylene and other materials; Tracheostomy tube can be ordinary with/without cuff cannulation and reinforced with/without cuff cannulation. Can be divided into various specifications according to applicable crowd, nominal diameter, cuff capacity, etc  Sterile form; Used for artificial airway establishment in clinical first-aid. Reference standard:YY 0338-2002	II
514	6866	Medical polymer materials and products	single-use Medical Laryngeal Mask	Mainly made of silicone rubber and consist of cuff, inflatable tubes, laryngeal mask intubation, machine end, connectors, and indicating balloon, etc Laryngeal mask intubation can be metal reinforced. Can be divided into various specifications according to texture, design, technical parameters, and other auxiliary functions, etc Used to establish short-term artificial artificial airway in general anesthesia or	II
515	6866	Medical polymer materials and products	single-use mouth/nasopharyngeal airway	It is a breathing tube with a flange end and made of polymer material. Can be divided into various specifications according to texture, design, insertion site diameter/length, etc Sterile state. Used for mouth/nasopharyngeal airway to prevent airway obstruction caused by tongue falling.	II

516	6866	Medical polymer materials and products	single-use anesthesia mask	Mainly made of silicone rubber, etc. and consist of face cup, air bags, valve core (valve core valve spool, seals, springs and bottom cover) and fixed ring. Can be divided into various specifications according to texture, design, technical parameters, intended use, auxiliary function, etc Used for clinical anesthesia	II
517	6866	Medical polymer materials and products	single-use fiber optic laryngoscope	Mainly consist of plastic handle and laryngoscope blade with anti-fog CCD camera and optical fiber wires blade. The other end of the handle can be connected to display. Handle and laryngoscope blade can be detachable. Can be divided into various specifications according to applicable crowds, texture, design, technical parameters, laryngoscope blade size, etc Sterile form; Used for guiding medical workers for airway intubation in anesthesia or emergency accurately or for oral cavity examination, treatment. Used for upper respiratory tract observation and examination and assisting intubation tube insertion.	II
518	6866	Medical polymer materials and products	single-use anesthesia laryngoscope	Mainly consist of laryngoscope blade and lens cones. Laryngoscope blade can be direct lighting and fiber optic lighting and is made of PVC material. The lens cones are made of high density polyethylene resin; Can be divided into various specifications according to applicable subjects, type, size, etc The laryngoscope blade is sterile form. Used with anesthesia throat handle for assisting intubation tube in clinical larynx examination, first aid and anesthesia. Reference standard: YY 0499-2004 General	II
519	6866	Medical polymer materials and products	Breathing circuit for anesthesia machine and ventilator	Mainly made of polyvinyl chloride and consist of anesthesia machine piping and ventilator piping. The anesthesia machine piping consists of Y type connector, bellows, rotary elbows. These two piping can be combined with each other. Can be with optional storage balloon, masks. Can be divided into various specifications according to texture, design, assembles, applicable subjects(adult / child), technical parameters, optional accessories. Sterile form, Used for pipe connection of anesthesia machines, ventilators and oxygen mask. Reference standard: YY 0461-2003 Breathing tubes intended for use with aneasthetic	II
520	6866	Medical polymer materials and products	single-use stomach tube	Mainly made of polyvinyl chloride, silicone rubber, natural rubber latex, rubber and other materials and consist of catheter and conical connector. Can be divided into various specifications according to texture, diameter size, etc. Sterile form; Used for cleaning, filling, emptying stomach by inserting into it. Do not	II
521	6866	Medical polymer materials and products	single-use nasogastric tube	Mainly made of polyvinyl chloride, silicone rubber, natural rubber latex, rubber and other materials and consist of catheter and conical connector. Can be divided into various specifications according to texture, diameter size, etc. Sterile form; Used for clinical nasal feeding by inserting into stomach from the nasal	II
522	6866	Medical polymer materials and products	single-use rectal catheter	Mainly consist of connector, catheters. The catheter is made of polyvinyl chloride, silicone rubber, natural latex, rubber; the connector is made of polyethylene, silicone rubber, etc Can be divided into various specifications according to texture, design, type, diameter, whether with a balloon or not. Sterile state. Used for cleaning, filling, emptying intestinal tract. Reference standard: YY 0488-2004 Sterile rectal catheters for	II
523	6866	Medical polymer materials and products	single-use parenteral nutrition infusion pipe	Mainly consist of bag by bag connector and infusion pipe and made of polyvinyl chloride. Can be divided into various specifications according to design, bag capacity, etc Sterile form; Used with nasogastric tube or stomach tube for transporting nutrients to patients intestines and stomach. Reference standard: YY 0483-2004 Enteral feeding catheters and enteral giving sets for single use and their connectors Design and	II
524	6866	Medical polymer materials and products	Single-use sterile rubber surgical gloves	Mainly made of natural rubber latex or thermoplastic colloid. Can be divided into pockmarked or smooth surface, surface with or without powder according to surface type. Can be divided into straight glove and gloves with fingers bent to palm side according to different designs. Can be divided into different specifications according to different sizes. Sterile state. Reference standard: GB 7543-2006 Single-use	II

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525	6866	Medical polymer	single-use Cervical	Mainly made of polyethylene plastic and can be divided into different specifications according to outside	П
0_0	0000	materials and	dilatation rod	diameters. Sterile form. Used for dilating uterine cervix during clinical obstetrics and gynecology uterine	
526	6866	Medical polymer	single-use uterine tissue	Mainly made of polyethylene plastic and consist of handle and tube body. Can be divided into different	П
320	0000	materials and	suction tube	specifications according to pipe diameter. Sterile form, used with aspirator for intrauterine tissue absorbtion.	11
		Medical polymer	single-use abortion	Made of PVC and consist of pipes body and connector. The suction tube is with a scale and can be cannula.	
527	6866	materials and	suction tube	Can be devided into various specifications according to texture, design and technical parameters, etc	II
		products	suction tube	Sterile form; Used with aspirator for termination of pregnancy by clinical attraction.	II
		Medical polymer	simale was utonine covity	Mainly made of silicone rubber and other polymer materials and consist of balloons, catheters, inflatable	
528	6866	materials and	single-use uterine cavity	connector, and liquid instillations connector. Can be devided into various specifications according to	II
		products	fluid imaging tubes	texture, outer diameter of the lumen, etc Sterile state. Used for clinical human uterine liquid instillations	
				Mainly made of plastic, stainless steel wire, etc. and consist of elbow guiding catheter, guiding rod, inner	
				catheter, guidewire; Can also be made of silicone and plastic, etc. and consist of catheter (single or dual-	
<b>72</b> 0	-0	Medical polymer	single-use	chamber), catheter seat(may contain valves and tees), balloon; The catheter can be with a X-ray non-	**
529	6866	materials and	salpingography catheter	penetration mark. Can be devided into various specifications according to texture, design, technical	Ш
		products		parameters (such as diameter, balloon pressure), etc Sterile state; Used for injecting pigment liquid or	
				contrast agent to assess tubal patency by inserting into tubal through hysteroscope passageway or uterus	
		Medical polymer		Made of polymer materials. Can be devided into various specifications according to texture, design, and	
530	6866	materials and	single-use Sterile	other technical parameters, etc Sterile form; Used for umbilical cord stump closure. Does not include	П
	0000	products	umbilical cord clamp	umbilical cord scissors.	11
		Medical polymer		Made of polypropylene or suitable materials. Mainly consist of handle and fine rod like probe with scale.	
531	6866	materials and	single-use uterine probe	Can be devided into various specifications according to texture, with or without a X-ray non-penetration	П
001	0000	products	singre use uterine proce	mark, needle diameter, length, etc Sterile state; Used for detect uterus uterine direction and depth.	11
		•		Made of injection molded plastic. Mainly consist of body pipe and connectors. Can be devided into various	
İ		Medical polymer	  single-use gynecological	specifications according to texture, technical parameters (such as length, diameter, etc.). Sterile state; Used	
532	6866	materials and		to connect to washing or flushing handle of medical ozone treatment instrument. Used to establish	II
		products		intravaginal passage for ozone gas or liquid delivery.	
		Medical polymer		Made of PVC and other suitable materials. Can be single tube or cannula tube. There are smooth hole on	
533	6866	materials and	single-use intracranial	tube tip and side tube. Can be devided into various specifications according to types ,tube diameters, etc.	II
333	0800	products	suction tube	Sterile state; Used for body fluids, blood, flushing fluid suction in brain surgery.	11
		Medical polymer		Mainly made of polystyrene resin or polyacetal, U-shaped structure, two blades connected with each other	
524	6866	materials and	single-use sterile scalp	can be biting together. Can be placed manually or via scalp clamp, non-implanted devices; Products are	П
334	0000		clip	sterile. Used for scalp fixation and hemostasis in clinical surgery.	11
		products	single was sin fly	, , , , , , , , , , , , , , , , , , ,	
535	6866	Medical polymer	single-use air-flow	Used in breathing apparatus and connect with oxygen at one end. Used to atomize medicament by oxygen	II
		materials and	nebulizer	pressure for patients inhalation.	

536	6866	Medical polymer materials and products	single-use sterile liquid transfer device	Can be various designs. Can be with two puncture devices or with a puncture device and a luer connector, while both of them can be connected with each other in different passageway; It can be with a cover or connect with an air filter or a liquid filter; The puncture device can be stainless steel or be plastic, other components may be made of PVC, etc Sterile state. Used for transport liquid from one container to another. Reference standard: YY 0804-2010 Transfer sets for pharmaceutical preparations—Requirements	II
537	6866	Medical polymer materials and products	Synthetic resin prosthetic eye	Mainly made of methyl methacrylate, polymethyl methacrylate, self-condensation of methyl methacrylate, human eye simulation. Can be devided into various specifications according to texture, design, size, etc  Used for filling and supporting by placing into conjunctiva after enucleation.	II
538	6866	Medical polymer materials and products	single-use endoscopic cannula	It is flexible sealed or semi-sealed transparent thin wall sets which made of polyvinyl chloride and other suitable materials. Sterile form; Used for endoscope protection by covering on the endoscope to prevent lens from damage or contamination, can also play a role of fixation.	II
539	6866	Medical polymer materials and products	single-use enterocoelia suction tube	Mainly made of PVC material. Mainly consist of pipe body (straight, curved, bent type) and handle. The pipe body can be casing pipe while the patient terminal end has a side hole and a regulation hole, can be with a negative pressure source connecting pipe. Can be devided into various specifications according to texture, design and technical parameters, etc Sterile state. Used with medical vacuum equipment for body liquid and surgery liquid suction. Reference standard: YY/T 0191-2011 Abdominal suction tube.	II
540	6866	Medical polymer materials and products	single-use chest drainage unit	Mainly made of polymer injection molding. It is a water-sealed type. Mainly consist of fluid chamber, pressure chamber and seal chamber, inlet and outlet and piping composition. Can be devided into various specifications according to texture, design, technical parameters, additional auxiliary functions, etc Sterile state. Used for thoracic close drainage. Reference standard: YY 0583-2005 Chest draining equipments for	II
541	6866	Medical polymer materials and	Nasal paste(without drugs)	Fix a flexible plastic via glue and fabric onto nose bridge part. Used for nostril expansion to release nasal congestion.	II
542	6866	Medical polymer materials and	single-use vaginal drug dispenser	Mainly made of polypropylene. Mainly consist of cartridge and push rod. Sterile form; Can be devided into various specifications according to texture, design, capacity, etc. Used for female vagina drug	II
543	6866	Medical polymer materials and products	Silicone catheter for	Mainly made of silicone. Mainly consist of valve, chamber head, multi-lumen tube and balloon, etc., without electrode; Can be devided into various specifications according to texture, design, technical parameters, intended use, etc Sterile state; Use with drugs and microwave therapy apparatus for drug	II
544	6866	Medical polymer materials and products	Nasal cavity irrigator	Mainly made of plastic. Mainly consist of bottle body, cap and outlet pipe. Without flushing fluid; Can be devided into various specifications according to texture, design, technical parameters, etc Sterile state; Used for nasal irrigation.	II
545	6866	Medical polymer materials and products	single-use funnel for breast augmentation surgery	Mainly made of elastic nylon material. The inner surface is coated with mixture of hydrophilic polyvinylpyrrolidone and polyurethane; Sterile state; Used for putting implant on the device surface which is with hydrophilic lubrication coating, while the implant can enter into predetermined portion easily through a small openings. The incision will be much smaller by using this device.	II
546	6866	Medical polymer materials and	Single-use glans protective sleeve	Mainly made of ABS plastic. Sterile state. Used to avoid glans injury in electric knife circumcision by cover it on glans.	III
547	6866	Medical polymer materials and	Incontinence Anal Plug	Mainly made of polyurethane foam. Mainly consist of expansion embolism, water-soluble film and gauze thread. Used for embolism anal for acathectic patients or flatus incontinence to prolong feces residence	III

548	6866	Medical polymer materials and products	Conventional Infusion sets for single use	Performance, structure, composition, intended use, etc.shall be covered in GB 8368 Infusion sets for single use, gravity feed, while the raw material shall comply with related requirements of GB 15593 Plasticized polyvinyl chloride (PVC) compounds for transfusion (infusion) equipment, etc Mainly consist of bottle stopper puncture device and protective sleeve, inlet with with air filter and plug, fluid passage, dropper, drip bucket, liquid filters, piping, flow regulator, injection parts, outer conical fitting and protective jacket. Used with infusion container, and infusion needle for intravenous infusion. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function. e.g.(1)non-PVC material; (2) products withnon-DEHP plasticizer, light-avoiding Agent, etc(3) with a new structure design function such as auto-liquid stopping, auto-gas releasing or products belongs to YY 0286. (4) products containing active ingredients: such as drug/pharmaceutical	III
549	6866	Medical polymer materials and products	Manifolds	Mainly consist of connector, connecting plate, switch (valve). Used for connecting passageway, establishing passway and providing liquid or contrast agent injection in blood vessel interventional operation. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	III
550	6866	Medical polymer materials and products	single-use peritoneal drainage tube	Mainly made of medical silicone rubber for hydrops abdominis drainage. Silicone rubber materials shall meet the requirements of YY 0334 General specification for surgical implants made of silicone elastomer. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	III
551	6866	Medical polymer materials and products	single-use anesthesia catheter and connector	Performance, structure, composition, intended use, etc.shall be covered in YY 0321.1 Single-use puncture set local anaesthesia. Mainly consist of catheter and catheter connectors. Used with single-use anesthesia needles for anesthesia transfusion. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	III
552	6866	Medical polymer materials and products	single-use anesthesia filter	Performance, structure, composition, intended use, etc.shall be covered in YY 0321.3 Single-use filter for anaesthesia. Mainly consist of upper cover, filtrate membrane, base seat, inner conical connecting protective jacket, outer conical connecting protective jacket. Can be liquid filter and air filter. Exemption does not include products which use new material, active ingredients, new technique, new design or products with	III
553	6866	Medical polymer materials and products	single-use tee (valve)	Mainly consist of shell, protective cover, valves, rotating handle, remarkable plugs, nuts, etc Used with infusion apparatus for connecting and controlling liquid pipeline such as intravenous transfusion, pressure measurement. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	III
554	6866	Medical polymer materials and products	single-use heparin cap for infusion	Performance, structure, composition, intended use, etc.shall be covered in YY 0581 Infusion access adapters—Part 1:Needle access adapters(Heparin plugs). Mainly consist of shell, rubber cap. Used with peripheral trocar catheter. Used for infusing pharmaceuticals into vessels or infusing an appropriate amount of heparin to prevent indwelling catheter coagulation when indwelling catheter is in non-transfusion state. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	III

555	6866	Medical polymer materials and products		Performance, structure, composition, intended use, etc.shall be covered in YY/T 0243 Plunger of sterile syringes for single use. Shall be cylindrical. Mainly made of flexible material. Used with single-use sterile syringe. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	II
556	6866	Medical polymer materials and products	single-use intrathoracic drain	Mainly made of medical silicone rubber. Used for drainage of pleural effusion. The raw materal shall meet the requirements of YY0334 General specification for surgical implants made of silicone elastomer. Exemption does not include products which use new material, active ingredients, new technique, new design or products with new action mechanism or function.	II
557	6870	Software	Diagnostic image processing software	Used for human checkups image processing, including images such as digital X-rays, pathology, microscopy, infrared, ultrasound images and fused images and three-dimensional and dynamic image of original reconstruction images. Does not include automatic diagnosis section.	II
558	6870	Software	Diagnostic data processing software	Used for human checkups data processing, including ECG data, EEG data, EMG data, blood data, maternal and child care data. Does not include automatic diagnosis section.	II
559	6870	Software	Medical imaging, data processing software	Used for human checkups image, data management, view, transport and storage. Does not include automatic diagnosis section.	II
560	6870	Software	Allergen semi- quantitative analysis software	Used with ordinary scanner. Used for reactive strips semi-quantitative detection allergen-specific antibodies and autoimmune antibodies with immunoblotting and immune chromatography method. Does not include automatic diagnosis function.	III
561	6870	Software	Blotting analysis software	Used for scanning bar code to achieve electron images by a plate scanister. Used for bar code location identification to identify band specificity. Does not include automatic diagnosis function.	III
562	6877	Interventional appliances	Catheter sheath	Mainly consist of sheath pipe, pipe seat and side branch. Used for establishing percutaneous access path for endovascular devices by Seldinger technique. It does not have the function of blood vessel inner location or endovascular access path establishment. Seldinger technique refers to a blood vessel paracentesis used in digital subtraction/angiography	Ш
563	6877	Interventional appliances	Guide wire	Mainly consist of core wire, wire wrap, safety wire, jacket. can be coated with a coating. Used for establishing percutaneous access path for endovascular devices by Seldinger technique. It does not have the function of blood vessel inner location or endovascular access path establishment. Seldinger technique refers to a blood vessel paracentesis used in digital subtraction angiography	III
564	6877	Interventional appliances	Dilator	Mainly consist of dilator tubes and seat. Used for establishing percutaneous access path for endovascular devices by Seldinger technique. It does not have the function of blood vessel inner location or endovascular access path establishment. Seldinger technique refers to a blood vessel paracentesis used in digital	III
565	6877	Interventional appliances	Guide wire for Peripheral Vessel	Mainly consist of core wire, wire wrap, safety wire, jacket, With or without a twist control device, can be coated with a coating. Twist control device consists of cap and shaft. Usually connects with distal guide wire for torsion control. It is a flexible instrument for inserting and locating guiding catheter into peripheral vascular. Exemption does not include neurovascular inner applications.	III
566	6877	Interventional appliances	Guide catheter for Peripheral Vessel	Mainly consist of tubular body and seat, can be coated with a coating. Used for vascular access establishment in PTA surgery. Exemption does not include neurovascular inner applications.	III

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567	6977	Interventional	Angiographic Catheter	Mainly consist of tubular body and seat, can be coated with a coating. Used for control media and/or liquids	Ш
567	68//	appliances	for Peripheral Vessel	injection or transfusion. Exemption does not include neurovascular inner applications.	111

