



Hangzhou CIRS Co., Limited (CIRS China)
 11F,1# Building Dongguan High Tech Zone, 288# Qiuyi Road,
 Binjiang District, Hangzhou, Zhejiang, China
 Tel: 0086 571 87206541 Fax: 0086 571 87206533
 Email: Edwin.wen@cirs-group.com
 More info.: www.cirs-md.com

Catalogue of Medical Devices Exempted from Clinical trials in China

Prepared by CIRS latest update: April 1st 2015

No.	Code/编码	分类	Category Name	产品名称	Product name	产品描述	Product description	Class
1	6801	基础外科手术器械	Basic Surgical Operation Instruments	医用缝合针	Medical suture needle	医用缝合针通常采用不锈钢丝制成，不带线，按针的形状（如圆形、正三角、反三角、短刃三角、三角半弯等）、弧度（直形、1/2弧、3/8弧等）、针孔（普通孔、弹机孔）等不同分为若干型式，每种型式按针径、弦长等不同又分为若干规格；以无菌或非无菌形式提供；供缝合内脏、软硬组织、皮肤用。产品性能指标采用下列参考标准中的适用部分，如：YY 0043-2005医用缝合针。	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 be divided 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	基础外科手术器械	Basic Surgical Operation Instruments	一次性使用手术刀片	single-use scalpel blade	一次性使用手术刀片采用碳素工具钢或合金工具钢等适合制作刀片材料制成，可含刀柄；刀片根据型式不同分为若干种，每种可按配合刀柄和刀片尺寸等不同分为若干规格；产品以无菌形式提供；供切割软组织用。产品性能指标采用下列参考标准中的适用部分，如：YY 0174-2005手术刀片，GB 8662—2006手术刀片和手术刀柄的配合尺寸	Can be made of carbon tool steel or alloy tool steel; can contain a blade holder; The blade can be divided into various kinds according to different types, while each kind can be divided 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	II
3	6801	基础外科手术器械	Basic Surgical Operation Instruments	一次性使用脐带剪夹器	single-use umbilical Scissors	一次性使用脐带剪夹器通常由高分子材料（如聚乙烯等）和金属材料（如用奥氏体不锈钢制作刀片）制成，可由脐带夹剪器、留置脐带夹及附属部件等构成，以无菌形式提供，供切断并封闭新生儿脐带残端用。	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	基础外科手术器械	Basic Surgical Operation Instruments	一次性使用手术电极清洁片	single-use surgical electrodes clean tablet	一次性使用手术电极清洁片可由（海绵）基层、（SiO ₂ 等）精细磨料层、压敏胶层、（钡线）显影线、（硅油）隔离纸构成，按形状、尺寸等不同分为若干规格；以无菌形式提供；供手术时清洁高频手术电极上的烧焦组织及其他附着物用。	Mainly consist of (sponge) basal layer, (SiO ₂ , etc.) fine abrasive layer, pressure-sensitive adhesive layer (barium line) developing lines, (silicone oil) release paper; Can be divided into various specifications according to shape and size; Sterile; Used for clean the burnt tissues and other attachment on the high frequency	II

5	6801	基础外科手术器械	Basic Surgical Operation Instruments	一次性使用手指操作手术器械	single-use surgical instruments for finger operating	一次性使用手指操作手术器械由聚碳酸酯套管和不锈钢末端执行器组成, 可按设计、技术参数和预期用途等不同分为若干型号和规格; 以无菌形式提供; 用于结肠直肠、泌尿、妇科等腹腔镜手术(HALS)和开放式手术中, 进行抓取、移动、分离、切割及缝合组织用。	Consist of polycarbonate sleeve and stainless steel end effector; Can be divided into various specifications according to design, 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	II
6	6802	显微外科手术器械	Microsurgical Operation instrument	一次性手术用冲洗针	single-use surgical flushing needle	一次性手术用冲洗针采用适用的高分子材料和金属材料制成, 由针座和平头针管组成, 可按材质、容量及针径等不同分为若干型号和规格; 以无菌形式提供; 与注射器配套使用, 供显微外科、眼科、口腔科、整形外科等手术中冲洗创口用。	Made of polymer material and metal material, consist of needle seat, flat needle tube; Can be divided 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	神经外科手术器械	Neurological Surgical Devices	脑内用剪	IntraIntracerebral Scissors	脑内用剪由金属制成, 由手柄与头部组成, 单关节, 刀头部可设计成直、上下弯等, 柄与头部可成一定的二维或三维角度, 以适应不同解剖位置的操作, 刀头末端可为尖或钝头, 表面光滑, 不损伤周围组织; 可按材质、设计、技术参数、预期用途等不同分为若干型号及规格; 通常为可重复器械; 供脑内手术时剪除病骨或坏死神经/脑组织用。	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 divided into various specifications according to texture, design, technical parameters, intended use etc.. Generally be reusable; Used for cutting off the diseased bone or necrotic nerve / brain tissue in brain surgery.	II
8	6803	神经外科手术器械	Neurological Surgical Devices	脑内用钳	Intracerebral Pliers	脑内用钳由金属制成, 由柄与头部组成, 单关节, 钳头可设计成直、左右弯等, 柄与钳头可成一定的二维或三维角度, 以适应不同解剖位置的操作, 钳头末端可为圆或卵圆形或其他形状, 表面光滑, 不损伤周围组织; 可按材质、设计、技术参数、预期用途等不同分为若干型号及规格; 通常为可重复器械; 供脑内手术时夹取颅内肿瘤和包膜用。	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 divided into various specifications according to texture, design, technical parameters, intended use etc.. Generally be reusable; Used for gripping intracranial tumors	II
9	6803	神经外科手术器械	Neurological Surgical Devices	脑内用镊	Intracerebral Forceps	脑内用镊由金属制成, 由柄与头部组成, 头部尖端可设计成尖细或圆形, 柄与头部可成一定的二维角度, 柄上有防滑凹凸设计, 表面光滑, 不损伤周围组织; 可按材质、设计、技术参数、预期用途等不同分为若干型号及规格; 通常为可重复器械; 供脑内手术时夹取敷料、脑内细软组织等用。	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 improve skid resistance, the surface shall be smooth to avoid damaging tissues around; Can be divided into various specifications according to texture, design, technical parameters, intended use etc.. Generally be reusable; Used for gripping dressings, soft tissue in brain surgery.	II

10	6803	神经外科手术器械	Neurological Surgical Devices	脑内用钩	Intracerebral Hook	脑内用钩由金属制成，由柄与头部组成，头部尖端可设计成半圆形弧状或光滑过渡的钩状，柄与头部可成一定的二维或三维角度，柄上可有防滑设计，表面光滑，不损伤周围组织；可按材质、设计、技术参数、预期用途等不同分为若干型号及规格；通常为可重复器械；供脑内手术时牵拉神经或脑内组织等用。	Made of metal, consist of handle and head part; The head tip can be half 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 divided into various specifications according to texture, design, technical parameters, intended use etc..Generally be reusable; Used for pulling nerves or brain tissue in brain surgery.	II
11	6803	神经外科手术器械	Neurological Surgical Devices	脑刮匙	Intracerebral curette	脑刮匙由金属制成，由柄与头部组成，头部尖端可设计成匙状，柄与头部通常共轴，柄可有防滑设计，头部表面光滑，不损伤周围组织；可按材质、设计、技术参数、预期用途等不同分为若干型号及规格；通常为可重复器械；供脑内手术时刮除病骨及坏死组织用。	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 divided into various specifications according to texture, design, technical parameters, intended use etc..Generally be reusable; Used for necrotic tissue and diseased bone curettage in brain surgery.	II
12	6803	神经外科手术器械	Neurological Surgical Devices	脑室液抽吸管	ventricular fluid sucker	脑室液抽吸管用金属制成，由管身与鲁尔接头组成，管身为细长管状，头部可有端孔或侧孔，可按材质、设计、技术参数等不同分为若干型号及规格；通常为可重复器械；供脑内手术时抽吸脑室液作检验或引流脑室液用。	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 divided into various specifications according to texture, design, technical parameters, intended use etc..Generally be reusable; Used for sucking ventricular fluid for inspection or ventricular fluid drainage in brain surgery.	II
13	6803	神经外科手术器械	Neurological Surgical Devices	脑内剥离器	Intracerebral dissector	脑内剥离器由金属等制成，由柄与头部组成，头部尖端可设计成宽窄不一的各种形状，柄与头部通常共轴，柄可有防滑设计，头部表面光滑，不损伤周围组织；可按材质、设计、技术参数等不同分为若干型号及规格；通常为可重复器械；供脑内手术时剥离脑膜用。	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 divided into various specifications according to texture, design, technical parameters, intended use etc..Generally be reusable; Used for	II
14	6804	眼科手术器械	Ophthalmic operation instruments	一次性使用眼科手术用刀	single-use ophthalmic scalpel	一次性使用眼科手术用刀由刀柄（聚碳酸酯）与刀片（不锈钢）组成，可按材质、设计、技术参数、预期用途等不同分为若干型号与规格；以无菌形式提供；供显微眼科手术用。	Consist of shank (polycarbonate) and blade (stainless steel); sterile; Can be divided into various specifications according to texture, design, technical parameters, intended use etc..Sterile state; Used for microscopic eye surgery.	II
15	6804	眼科手术器械	Ophthalmic operation instruments	一次性使用眼科穿刺系统	single-use ophthalmic puncture system	一次性使用眼科穿刺系统可包括穿刺刀、穿刺套管、手柄、保护帽、自闭阀及灌注管头端，可分别用不锈钢、聚碳酸酯、聚丙烯、硅树脂等材料制成；可按材质、设计、技术参数等不同分为若干型号及规格；产品以无菌形式提供；供玻璃体切割术等眼科手术中，在巩膜平坦部建立器械通道用。	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 divided into various specifications according to texture, design, technical parameters, intended use etc..Sterile state; Used for eye surgery, such as vitrectomy, establish instrument	II

16	6804	眼科手术器械	Ophthalmic operation instruments	一次性使用折叠式人工晶状体推注器	single-use foldable IOL implantatio	一次性使用折叠式人工晶状体推注器可采用聚丙烯等适用材料制成,可由推进器、植入器两部分组成;可按材质、设计、技术参数等不同分为若干型号;以无菌形式提供;供人工晶状体植入术中推注折叠式人工晶体用。	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 etc..Sterile state; Used for injecting	II
17	6807	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical Instruments	无损伤动/静脉阻断钳	scatheless artery/vein vascular clamps	无损伤动/静脉阻断钳用金属制成,单关节,由柄与头部组成,钳头可设计成直、上下弯等,柄与钳头可成一定的二维或三维角度,以适应不同解剖位置的操作,钳头内侧可有半硬性嵌入物,以增加钳夹稳定性与无损伤性,钳可锁止,可按材质、设计、技术参数、预期用途等不同分为若干型号及规格;通常为可重复器械;供涉及大血管手术时动静脉阻断用。	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 etc..Generally be reusable; Used for arteriovenous blocking when it comes to major	II
18	6807	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical Instruments	血管打孔器	Vascular puncher	血管打孔器分为一次性使用和反复使用两类。一次性使用血管打孔器用不锈钢和ABS等适用材料制成,以无菌方式提供;反复使用血管打孔器用符合ASTM F899的不锈钢材料制成,非无菌方式提供;两类产品均可按材质、设计、技术参数、适用血管等不同分为若干型号与规格;供外科手术时在动脉/静脉血管壁上打一个圆形开口,以便后续血管移植/吻合等用。	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	II
19	6807	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical Instruments	二尖瓣扩张器	Mitral dilator	二尖瓣扩张器用适用的金属材料制成,由带撑开杆的手柄、器身和扩张器头部组成,扩张宽度可调节,可按材质、设计与技术参数等不同分为若干型号与规格;通常可反复使用;供心脏手术时扩张二尖瓣用。	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 surgery.	II
20	6807	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical Instruments	心内吸引头	Intracardiac Aspirators	心内吸引头用金属制成,由头端、管身和接头组成,头端可有多种角度与形状设计,以适应不同解剖位置的吸引,可按材质、设计与技术参数等不同分为若干型号与规格;可反复使用;与吸引器配套,供心脏手术时吸引心包/心内液体用。	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	II
21	6807	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical Instruments	血管冲洗/吸引管	Vascular flushing / suction tube	血管冲洗/吸引管用不锈钢等金属材料制成,由头端、管身和接头组成,可按材质、设计、技术参数等不同分为若干型号与规格;可反复使用;冲洗装置配套,供外科手术中灌注/吸引、冲洗在体或离体血管用。	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	II

22	6807	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical Instruments	缝线推结器	Suture knot pusher	缝线推结器用金属等材料制成，由头端和把柄组成，头端有缝线穿入孔，可按材质、设计、技术参数等不同分为若干型号及规格；胸腔手术中，用于将体外缝线结推到体表面或胸腔内。	Made of metal and other materials, consist of head part and handle part, the head end has suture penetration hole; Can be divided 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	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical Instruments	肋间软组织牵开器	Intercostal soft tissue retractor	肋间软组织牵开器由牵开环、牵开壁和胶带组成。牵开环可用聚酯等弹性材料,牵开壁可用聚醚聚氨酯等适用材料制成,胶带的背衬为无纺布,胶粘层为丙烯酸粘胶；可按材质、设计、技术参数等不同分为若干型号与规格；以无菌形式提供；心脏外科手术中放入肋间，牵开组织形成手术操作口。	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 divided 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	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical	瓣叶开合测瓣器	Heart Valve Sizer	瓣叶开合测瓣器用医用硅橡胶制成，用于检测机械心脏瓣膜瓣叶的灵活性。	Made of medical silicone rubber. For the detection of mechanical heart valve leaflets flexibility.	II
25	6807	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical	心脏瓣膜安装工具套件	Heart valve installation kit	心脏瓣膜安装工具套件由推结器、瓣膜探测针、瓣膜安置器组成。推结器用于体外缝线结推到体表面或胸腔内；瓣膜探测针用于检验机械瓣膜瓣叶的灵活性；安置器用于放置机械瓣膜。	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	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical	心房牵开器	Atrial retractor	心房牵开器由不锈钢制成，由三角支架、牵开叶片和镊子组成。用于瓣膜手术中，牵开右心房前壁以暴露二尖瓣，便于观察内部和外部心脏结构。	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	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical	瓣膜手术用钳	Plier for valve surgery	瓣膜手术用钳用不锈钢制成，用于瓣膜手术中抓取和移除心脏结构上的硬物质，如钙化物质和纤维组织。	Made of stainless steel, used for grabbing or removing hard substances on cardiac structure in valve surgery, such as calcified material and fibrous tissue.	II
28	6807	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical Instruments	微创心外科手术用镊	tweezers for minimally invasive heart	微创心外科手术用镊用不锈钢制成，在微创心外科手术中用于夹捏和操作心脏结构。	Made of stainless steel, Used for pinching and operations on heart surgery in minimally invasive cardiac structure .	II

29	6807	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical Instruments	一次性使用心表稳定板	single-use ECG stable board	一次性使用心表稳定板由稳定板（中式、左式、右式，塑料）、手臂（不锈钢）、锁定支架、锁定支架旋钮（ABS）、底座和手臂调节旋钮组成，可按材质、设计、技术参数等不同分为若干型号及规格；以无菌形式提供；供心脏不停跳搭桥手术时稳定局部心表，为冠脉吻合术提供条件。	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 divided 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	II
30	6807	胸腔心血管外科手术器械	Thoracic and Cardiovascular Surgical Instruments	一次性使用心脏固定器	single-use Heart Stabilizer	用于心脏搭桥手术时，在心脏的目标血管处建立一个固定的手术区域。分为Stable-V1（吸引固定型）和Stable-M1（机械固定型）两种，通过固定头的压力和负压吸引力或仅通过固定头的压力固定手术区域。一般由调节手柄、固定卡座、万向支撑臂、吸盘、负压吸引管组成，也可由压脚叶（或吸脚固定座、吸脚）、负压连接管、三通阀、定向夹头组件、调节臂、固定座、调节手柄、旋柄、内穿拉紧钢丝组件组成，以无菌形式提供。产品不进入血液循环。	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	腹部外科手术器械	Abdominal Surgical Operation	一次性使用管型吻合器	single-use tube-type anastomat	一次性使用管型吻合器中吻合钉多用金属钛或钽制成，其余部分可分别用金属、高分子材料等制成；通常由钉砧、器身和组件（钉仓、推钉片和吻合钉）组成，可按材质、设计、技术参数、预期用途等不同分为若干型号与规格，如分体式与联体式，可调式与固定式等；以无菌形式提供；通过机械传动装置将预先放置在组件中，呈两排或数排互相平行错位排列的吻合钉击入已经对合好、需要吻合在一起的组织内，将两层组织永久性钉合在一起，主要用于消化道重建手术中的端端、端侧和侧侧吻合。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0245-	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 divided 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 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	腹部外科手术器械	Abdominal Surgical Operation	重复使用管型吻合器	Reusable tube-type anastomat	重复使用管型吻合器中吻合钉多用金属钛或钽制成，其余部分可分别用金属、高分子材料等制成；通常由钉砧、器身和组件（钉仓、推钉片和吻合钉）组成，可按材质、设计、技术参数、预期用途等不同分为若干型号与规格；器身为金属制，可重复使用，组件以无菌形式提供；通过机械传动装置将预先放置在组件中，呈两排或数排互相平行错位排列的吻合钉击入已经对合好、需要吻合在一起的组织内，将两层组织永久性钉合在一起，主要用于消化道重建手术中的端端、端侧和侧侧吻合。产品性能指标采用下列参考标准中的适用部分，如：YY/T0245-2008吻合（缝）	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 divided 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 stapler.	II

33	6808	腹部外科手术器械	Abdominal Surgical Operation	一次性使用直线吻合器	single-use Linear anastomat	一次性使用直线吻合器中吻合钉多用金属钛或钽制成，其余部分可分别用金属、高分子材料等制成；通常由钉砧、器身和组件（钉仓、推钉片和吻合钉）组成，可按材质、设计、技术参数、预期用途等不同分为若干型号与规格，如固定间隙和可调间隙、是否防误击发等；以无菌形式提供；将组织放在组件和钉砧之间，安置好定位针，根据组织厚度标尺设定好适合的厚度，扳动击发手柄，缝钉驱动器即将两排平行错位的缝钉植入组织并弯曲成“B”形，牢固地将两层组织进行直线钉合封闭，吻合器的组件可以更换，但无切割功能；主要用于消化道重建及脏器切除手术中的残端或切口的闭合。用于肺切除手术需提供临床评价报告。产品性能指标采用下列参考标准中的适用部分。	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 divided into various specifications according to texture, design, technical parameters, intended use etc.. Sterile state; Place tissue between components 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	腹部外科手术器械	Abdominal Surgical Operation	一次性使用弧型吻合器	single-use curved anastomat	一次性使用弧型吻合器是直线型吻合器和管型吻合器的结合，吻合钉多用金属钛或钽制成，其余部分可分别用金属、高分子材料等制成；通常由钉砧、器身和组件（钉仓、推钉片和吻合钉）组成，可按材质、设计、技术参数、预期用途等不同分为若干型号与规格，吻合器的组件可以更换；以无菌形式提供；设计主要用于术野显露困难的消化道重建及脏器切除手术中吻合口创建及残端或切口的闭合。	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 divided 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	腹部外科手术器械	Abdominal Surgical Operation	一次性使用直线切割吻合器	single-use linear cutter anastomat	一次性使用直线切割吻合器中吻合钉多用金属钛或钽制成，其余部分可分别用金属、高分子材料等制成；通常由钉砧、器身和组件（钉仓、推钉片和吻合钉）组成，可按材质、设计、技术参数、预期用途等不同分为若干型号与规格，如固定间隙和可调间隙、是否防误击发等；以无菌形式提供；吻合器的组件可以更换；主要用于消化道重建及脏器切除手术中的残端或切口的闭合。用于肺切除手术需提供临床评价报告。产品性能指标采用下列参考标准中的适用部分，如：YY 0876-2013直线型切割吻合器及组件。	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 divided 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 Linear	II
36	6808	腹部外科手术器械	Abdominal Surgical Operation	一次性使用荷包缝合针	single-use purse-string suture needle	一次性使用荷包缝合针用金属和缝线制成，由两根缝针、一根非吸收性缝线（如聚酰胺6或聚酰胺6/6）组成；可按材质、设计、技术参数等不同分为若干型号与规格；产品以无菌形式提供；与缝合钳配合使用，适用于消化道吻合手术中的荷包缝扎。产品性能指标采用下列参考标准中的适用部分，如：YY 0877-2013荷包缝合针。	Made of metal and suture, consist of a non-absorbable suture(polyamide 6, polyamide 6/6) and two needles; Can be divided 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	腹部外科手术器械	Abdominal Surgical Operation	一次性使用自动荷包缝合器	single-use automatic purse string suture	一次性使用自动荷包缝合器采用金属、高分子材料、非吸收外科缝线制成，由夹座、钉座、钉和荷包线组成，按材质、设计、技术参数等不同分为若干型号与规格；以无菌形式提供；供消化道开放手术中作荷包缝合用。	Made of metal, polymer materials, non-absorbable surgical suture, mainly consist of clamp base, nail base, nail and purse suture; Can be divided into various specifications according to texture, design, technical parameters, etc.. Sterile state; Used for gastrointestinal surgery purse string.	II
38	6809	泌尿肛肠外科手术器械	Urinary anorectal surgical instruments	一次性使用肛肠吻合器	single-use anorectal anastomat	一次性使用肛肠吻合器是一次性使用管型吻合器中的一种，其中吻合钉多用金属钛或钽制成，其余部分可分别用金属、高分子材料等制成；通常由钉砧、器身和组件（钉仓、推钉片和吻合钉）组成，可按材质、设计、技术参数、预期用途等不同分为若干型号与规格；以无菌形式提供；通过机械传动装置将预先放置在组件中，呈两排或数排互相平行错位排列的吻合钉击入已经对合好、需要吻合在一起的组织内，将两层组织永久性钉合在一起，主要用于选择性切除直肠齿状线上粘膜和粘膜下组织，恢复直肠下段正常解剖结构，供齿状线上黏膜选择性切除用。产品性能指标采用下列参考标准中的适用部分，如：YY/T	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 divided 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	II
39	6809	泌尿肛肠外科手术器械	Urinary anorectal surgical instruments	重复使用肛肠吻合器	Reusable anorectal anastomat	重复使用肛肠吻合器是管型吻合器中的一种，吻合钉多用金属钛或钽制成，其余部分可分别用金属、高分子材料等制成；通常由钉砧、器身和组件（钉仓、推钉片和吻合钉）组成，可按材质、设计、技术参数、预期用途等不同分为若干型号与规格；器身为金属制，可反复使用；组件以无菌形式提供；主要用于选择性切除直肠齿状线上粘膜和粘膜下组织，恢复直肠下段正常解剖结构，供齿状线上黏膜选择性切除术用。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0245-2008吻（缝）合器通用技术	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 divided 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	II
40	6809	泌尿肛肠外科手术器械	Urinary anorectal surgical instruments	一次性使用包皮切割吻合器	single-use circumcision anastomat	一次性使用包皮切割吻合器采用不锈钢和ABS等材料制成，缝合钉可用不锈钢或适用的金属制成，通常包括环形切割刀、定位弹簧、金属垫片、固定销及活动连片，316L不锈钢为材料的缝合钉，以及以ABS为材料的凹形座、环形刀砧、钉仓保护盖、钉仓、顶体、主体外壳、移动器、主体固定圈、定位调节螺母、主体上下盖、活动手把、保险销。产品应无菌。适用于临床包皮切割缝合手术。	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	泌尿肛肠外科手术器械	Urinary anorectal surgical instruments	一次性使用包皮套扎器	single-use foreskin ligation device	一次性使用包皮套扎器采用金属和塑料等制成, 可由夹紧环、套环(内环、胶垫组成; 内环上可有/无柄)、连接装置(连接杆或导套、螺母、螺钉)组成, 可按材质、设计、技术参数等不同分为若干型号及规格; 以无菌形式提供; 供辅助包皮环切及免缝合用。	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 divided 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	泌尿肛肠外科手术器械	Urinary anorectal surgical instruments	一次性使用无菌瘻管刷	single-use Sterile fistula brush	一次性使用无菌瘻管刷可由刷柄、刷毛和丝线组成, 以无菌形式提供; 供识别、清洁直肠瘻管用。	Mainly consist of brush handle, bristles and silk thread; Sterile; Used for identification, cleaning rectal fistula.	II
43	6809	泌尿肛肠外科手术器械	Urinary anorectal surgical instruments	一次性使用尿道扩张器	single-use urethral dilator	一次性使用尿道扩张器由头部、杆部和手柄组成, 可采用适用塑料制成; 可按材质、设计、技术参数等不同分为若干型号与规格; 以无菌形式提供; 供尿道狭窄时扩张尿道用。	Mainly consist of the head, the rod portion and the handle, can be made of applicable plastic material; Sterile; Can be divided into various specifications according to texture, design, technical parameters, etc.. Used for expansion when the urethra urethral	II
44	6809	泌尿肛肠外科手术器械	Urinary anorectal surgical instruments	一次性使用肛肠套扎器	single-use anorectal ligation device	一次性使用肛肠套扎器可用适用的金属、塑料和硅胶等制成, 可由枪体(内置弹簧)、枪管、硅胶圈、负压吸引接头、绕线轮、套扎器开关和盖帽组成, 可带单个或多个硅胶圈, 可有辅助照明装置, 可按材质、设计、技术参数、预期用途等不同分为若干型号与规格; 以无菌形式提供; 适用于各期内痔及混合痔或直肠良性息肉的套扎治疗。	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	泌尿肛肠外科手术器械	Urinary anorectal surgical instruments	一次性使用输尿管导引鞘	single-use ureter introducer sheath	一次性使用输尿管导引鞘用尼龙、聚四氟乙烯、不锈钢、聚乙烯、聚丙烯等制成, 通常由管身涂有亲水涂层的鞘管和扩张器组成, 也可包含导丝, 鞘管可为单腔或双腔, 可按材质、设计、技术参数等不同分为若干型号及规格; 以无菌形式提供; 供泌尿外科手术中, 建立内窥镜等器械进入泌尿道的通道用。	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 divided into various specifications according to texture, design, technical parameters, etc.. Sterile; Used in urological surgery, such as the establishment of an endoscopic instrument channel by entering the	II
46	6810	矫形外科(骨科)手术器械	Orthopedic surgery (orthopedic) surgical instruments	椎骨咬骨钳	Vertebral rongeur	椎骨咬骨钳用适用的金属材料制成(如钳头采用40Cr13、32Cr13Mo或40Cr13Mo, 钳柄、铈轴螺钉、撑簧及撑簧滑轮采用20Cr13、30Cr13或32Cr13Mo材料制成, 撑簧螺钉采用12Cr18Ni9或06Cr19Ni10制成), 可由钳头、钳柄、铈轴螺钉、撑簧螺钉、撑簧、撑簧滑轮等组成, 可分为单关节、双关节、侧角等若干类, 每类按钳头形式不同分直头、弯头和侧角头等若干种, 也可按钳头的形状可分为圆形和尖形等若干种, 按钳柄型式不同可分为有肩和无肩两种, 按刃口的开档可分为正常开档与打开档两种; 每种按口阔及全长等尺寸不同分为若干规格; 供骨科手术时咬切腐死骨和整修骨骼用(按设计不同可分别咬切颅骨、椎板或鼻中隔等)。产品性能指标采用下列参考标准中的适用部	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	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	髓核钳	Nucleus clamp	髓核钳由钳头、盖板、钳身、左钳柄、支撑弹簧组成，按型式不同分直头和弯头两种，每种按尺寸不同分为若干规格；供骨科手术中咬切髓核等软组织用。	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 divided into various specification according to different size. Used for biting soft tissues such as nucleus pulposus in orthopedic surgery	II
48	6810	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	椎骨骨凿	Vertebral bone chisel	椎体骨凿通常用不锈钢制成，手柄可有其他适用材料，通常为单刃口的手持手动一件式外科器械，远端有成型的锋利刃口，刃口形状可各异；可按材质、设计、技术参数等不同分为若干型号及规格；可使用手术槌或手术锤手动将力从器械的近端传至远端，供手术时凿切、修整、剥离颈椎、腰椎等椎骨并使椎骨成型。	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 divided 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 and	II
49	6810	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	骨水泥填充器套件	Bone cement filler kit	骨水泥填充器套件（一次性使用或重复使用）可由骨水泥胶枪（由金属制手柄、机构螺杆或类似结构组成的枪状）、可分离喷嘴套筒（套筒两端有螺纹等连接结构，可按装在骨水泥胶枪上，套筒可由金属或高分子材料制成）、骨水泥配制容器、骨水泥勺、搅拌棒、套筒座等组成。金属部件通常重复使用，非金属部件通常为一次性使用。套件可以无菌形式提供，供骨科手术中混匀骨水泥，并将骨水泥注入（输送到）骨髓腔填充部位用。包括低粘骨水泥	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 suite can be sterile; Used to stir bone cement and inject it into marrow cavity. Including low viscosity bone cement filling suite.	II
50	6810	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	电池供电骨组织手术设备	Battery-powered bone tissue surgical equipment	电池供电骨组织手术设备由可充电电池供电，可由主机、手机（如钻机、铣机、磨机、锯机等）、各种刀具（可选配）及附件组成（手机与主机可一体也可分离）；设备可按动力、设计、技术参数、附件、预期用途等不同分为若干型号；供手术时对骨组织（如配自停手机可包括颅骨）实施钻、铣、磨、锯等操作。产品性能指标采用下列参考标准中的适用部分，如：YY 0904-2013 电池供电骨组织手术设备。	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 divided 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 0904-2013 Battery power supply surgical equipment for osseous tissue	II
51	6810	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	网电源供电骨组织手术设备	bone tissue surgical equipment with network power supply	网电源供电骨组织手术设备由网电源供电（也可为网电源、充电电池双动力），可由主机、手机（如钻机、铣机、磨机、锯机等）、各种刀具（可选配）及附件组成（手机与主机可一体也可分离）；设备可按动力、设计、技术参数、附件、预期用途等不同分为若干型号；供手术时对骨组织（如配自停手机可包括颅骨）实施钻、铣、磨、锯等操作。产品性能指标采用下列参考标准中的适用部分，	Supply power is network power (can be double-power of network power and battery power), consist of host, phone (such as drilling rigs, etc.), various knife tools and accessories; Can be divided 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/T 0752-2009 Electric surgical	II

52	6810	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	气动骨组织手术设备	Pneumatic bone tissue surgical equipment	气动骨组织手术设备由压缩空气提供动力，可由主机、手机（如钻机、铣机、磨机、锯机等）、各种刀具（可选配）及附件组成（手机与主机可一体也可分离）；设备可按动力、设计、技术参数、附件、预期用途等不同分为若干型号；供手术时对骨组织（如配自停手机可包括颅骨）	Supply power is compressed air, consist of host, phone (such as drilling rigs, etc.), various knife tools and accessories; Can be divided into various specifications according to power, supply, technical parameter, accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, sawing and other	II
53	6810	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	微动力骨组织手术设备	Micro Power bone tissue surgical equipment	微动力骨组织手术设备由网电源供电（也可为网电源、充电电池双动力），可由主机、手机（如钻机、铣机、磨机、锯机等）、各种刀具（可选配）、附件、脚踏开关组成（手机与主机分离）；可配水冷系统；设备可按动力、设计、技术参数、附件、预期用途等不同分为若干型号；供显微手术时对骨组织实施精确钻、铣、磨、锯等操作。	Supply power is network power(can be double-power of network power and battery power), consist of host, phone (such as drilling rigs, etc.), various knife tools and accessories; Can be divided into various specifications according to power supply, design, technical parameter, accessories, intended use, etc.. Used for implementing bone drilling, milling, grinding, sawing and other operations in	II
54	6810	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	微动力气动骨组织手术设备	Micro Power Pneumatic bone tissue surgical equipment	微动力气动骨组织手术设备由压缩气体提供动力，可由主机、手机（如钻机、铣机、磨机、锯机等）、各种刀具（可选配）、附件、脚踏开关组成（手机与主机分离）；可配水冷系统；设备可按动力来源、设计、技术参数、附件、预期用途等不同分为若干型号；供开放或显微手术时对骨组织实施精确钻、铣、磨、锯等操作。	Supply power is compressed air, consist of host, phone (such as drilling rigs, etc.), various knife tools, accessories, foot switch; Can be equipped with water-cooling system. The equipment can be divided into various specifications according to power supply, design, technical parameter, accessories, intended use, etc. Used for implementing bone drilling, milling, grinding, sawing and other operations in open or closed microsurgery.	II
55	6810	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	骨科电动/气动工具配件—磨头	Orthopaedic electric / pneumatic tool accessories - Polishers	骨科电动/气动工具配件—磨头用不锈钢或适用的合金制成，由杆和头部（表面有硬质磨牙）组成；可按头部形状、尺寸等不同分为若干型号与规格；可分别与气动或电动工具配合使用，供骨科手术中骨的切割、雕塑等用。	Made of stainless steel or alloy, mainly consist of the rod and head part; Can be divided into different specifications according to the head shapes or sizes. Can be respectively with pneumatic or electric tools to cut, sculpt in orthopedic surgery	II
56	6810	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	骨科电动/气动工具配件—金刚石磨头	Orthopaedic electric / pneumatic tool accessories - diamond Polishers	骨科电动/气动工具配件—金刚石磨头由不锈钢杆和不锈钢头部（表面有圆粒金刚石牙）组成；可按头部形状、尺寸等不同分为若干型号与规格；可分别与气动或电动工具配合使用，供骨科手术中骨的切割、雕塑等用。	Made of stainless steel or alloy, mainly consist of the rod and head part; Can be divided into different specifications according to the head shapes or sizes. Can be respectively with pneumatic or electric tools to cut, sculpt in orthopedic surgery	II
57	6810	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	骨科电动/气动工具配件—刀片	Orthopaedic electric / pneumatic tool accessories - Blades	骨科电动/气动工具配件—刀片用适用的金属材料如301、420不锈钢和420MODIFIED不锈钢制成，通常刀片上有固定环和边刃，可按刀片材质、形状、尺寸等不同分为若干型号和规格；可分别与气动或电动工具配合使用，供骨科手术中骨的切割、雕塑等用。	Made of applicable metals such as 301、420、420MODIFIED stainless steel; There are fixed collar on the blade; Can be divided into different specifications according to texture, shapes and sizes, etc.. Can be respectively with pneumatic or electric tools to cut, sculpt in orthopedic surgery	II

58	6810	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	气动咬骨钳	Pneumatic rongeur	气动咬骨钳由工作杆(接触人体部分为不锈钢)，减压阀，气动手柄，一次性通气管等组成；一次性通气管用塑料制成，需以无菌形式提供，一次性使用；咬骨钳可按材质、设计、技术参数、适用部位、预期用途等不同分为若干型号和规格；供开放或显微手术中咬除腐骨、软骨和组织等	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 divided into various specifications according to texture, design, technical parameters, applicable sites, intended use, etc.. Used for biting rotten bones, cartilage and tissue, etc. in	II
59	6810	矫形外科（骨科）手术器械	Orthopedic surgery (orthopedic) surgical instruments	骨科外固定支架	Orthopedic external fixator	骨科外固定支架可用适用的材料（不锈钢/铝合金/碳纤维）制成，可由多个支架、固定部件组合而成，可为单臂或环形，可有万向结构，可按材质、设计、技术参数、适用部位、预期用途等不同分为若干型号及规格；与骨钉配套，供四肢长骨或骨盆骨折等外固定用。	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 divided 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	妇产科用手术器械	Obstetrical and Gynecological Surgical Operation Instruments	一次性使用胚胎移植导管	single-use embryo transfer catheter	一次性使用胚胎移植导管由导引导管、带鲁尔接头的移植导管和护套等组成；导引导管用聚氯乙烯材料制成，移植导管由304不锈钢管、聚碳酸酯、硅胶材料制成；可按材质、设计、技术参数等不同分为若干型号及规格；以无菌形式提供；与注射器配合，经阴道向子宫内转移经过体外受精(IVF)的胚胎或受精卵用。	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 divided into various specifications according to texture, design, technical parameters, etc.. Sterile state; Used with syringe to transfer in vitro fertilization (IVF) embryos or fertilized	II
61	6812	妇产科用手术器械	Obstetrical and Gynecological Surgical Operation Instruments	一次性使用带鞘胚胎移植管	single-use embryo transfer tube with sheath	一次性使用带鞘胚胎移植管由保护套管、导引导管和移植导管组成。导引导管由导管(聚四氟乙烯)、导管座(聚乙烯)、保护套管(聚乙烯)组成；移植导管由导管(聚氨酯)、导管座(聚氨酯)、管芯(304不锈钢)、Echotip尖端(304不锈钢)组成；可按材质、设计、技术参数等不同分为若干型号及规格；以无菌形式提供；与注射器配合，经阴道向子宫内转移经过体外受精(IVF)的胚胎或受精卵用。	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 divided 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	妇产科用手术器械	Obstetrical and Gynecological Surgical Operation Instruments	一次性使用胎头吸引器	single-use fetal head vacuum aspirator	一次性使用胎头吸引器采用聚丙烯等适用高分子材料制成，由手柄和吸盘组成；可按材质、设计、尺寸等不同分为若干型号和规格；可以无菌形式提供；当产妇因种种原因不能正常分娩时，通过吸盘对胎头头皮产生的负压吸引以辅助经阴道或剖腹产分娩。不包括气动负压泵式胎头吸引器。	Made of applicable polymer materials such as polypropylene, consist of a handle and a sucker; Can be divided 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 pump fetal aspirator.	II
63	6815	注射穿刺器械	Puncture Injection Equipment	全玻璃注射器	All-glass syringes	全玻璃注射器采用硅硼铝玻璃材料制成，由锥头、外套和芯子组成，可分为中头式和偏头式两种，每种按公称容量不同分为若干规格；装上注射针头，供人体进行皮下、肌肉、静脉注射药液或抽取液体等用。产品性能指标采用下列参考标准中的适用部分，如：YY 1001.1-2004玻璃注射器 第1部分：全玻璃注射器。	Mainly made of aluminoborosilicate glass material, consist of conical head, sleeving and core; Can be metriocranic and unsymmetric; Each kind can be divided into various specifications according to nominal 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	II

64	6815	注射穿刺器械	Puncture Injection Equipment	蓝芯全玻璃注射器	Blue core all-glass syringes	蓝芯全玻璃注射器采用硅硼铝玻璃材料制成，由锥头、外套和芯子（蓝色实心玻璃）组成，通常为中头式，按公称容量不同分为若干规格；装上注射针头，可供人体进行生化试验、皮下试验。注射疫苗、口腔麻醉用，也可供注射其他药液用。产品性能指标采用下列参考标准中的适用部分，如：YY 1001.2-2004玻璃注射器 第2部分：蓝芯全玻璃注射器。	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 syringes with all-glass	II
65	6815	注射穿刺器械	Puncture Injection Equipment	金属注射针	Metal injection needle	金属注射针可用铜基镀铬（针座）和高等级不锈钢材料（针管）制成，由针座（有标准鲁尔接头）和针管构成，通常针管的公称外径为0.4mm—1.6mm，针管长度为10mm—100mm,针管管壁可分为正常壁和薄壁两种，与注射器配套，供人体用于皮下、皮内、肌肉、口腔等部位注射药液、疫苗、麻醉剂或静脉输液、输血用，可重复使用。产品性能指标采用下列参考标准中的适用部分，如：YY/T	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 syringe for subcutaneous, intracutaneous, muscle, oral cavity liquid injection. Reference standard: YY/T 0282-2009 Svringe needle	II
66	6815	注射穿刺器械	Puncture Injection Equipment	金属腰椎穿刺针	Metal Spinal needle	金属腰椎穿刺针可用铜基镀铬（针座、衬芯座）和高等级不锈钢材料（针管、衬芯）制成，可由衬芯座、定位销、针座（有标准鲁尔接头）、衬芯、针管构成，通常针管的公称外径为0.4mm—1.6mm，针管长度为25mm—200mm,针管管壁可分为正常壁和薄壁两种；与注射器配套，供人体蛛网膜下腔阻滞（腰椎麻醉）穿刺，注射药液或抽取脑脊液用，可重复使用。产品性能指标采用下列参考标准中的适用部分，如：YY/T 1148—2009 腰椎穿刺针。	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 syringe for subarachnoid space puncturation or liquid injection or cerebrospinal fluid drawing. Can be reusable. Reference standard: YY/T 1148—	II
67	6815	注射穿刺器械	Puncture Injection Equipment	一次性使用腹腔镜用穿刺器	single-use laparoscopic puncture outfit	一次性使用腹腔镜用穿刺器可用合适的金属材料和高分子材料制成，典型结构可包括穿刺针、穿刺套管、注气阀、阻气阀、密封帽构成；可按材质、设计及技术参数等不同分为若干型号及规格；产品以无菌形式提供；供腹腔镜检查和手术过程中，对人体腹壁组织穿刺，建立腹腔手术的工作通道用。产品性能指标采用下列参考标准中的适用部分，如：YY 0672.1-2008内镜器械 第1部分 腹腔镜用穿刺	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	II
68	6815	注射穿刺器械	Puncture Injection Equipment	一次性使用配药用注射器	single-use syringe for dispensing	一次性使用配药用注射器采用符合YY 0242的聚丙烯或对人体无毒副作用的其他高分子材料制成，可由护帽、配药针、外套管、芯杆和活塞组成，可按公称容量不同分为若干规格，可配侧孔或斜面配药针；产品以无菌形式提供；供抽取或配制药液用。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0821一次性使用配药用注射器。	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	注射穿刺器械	Puncture Injection Equipment	一次性使用配药针	single-use dispensing needle	一次性使用配药针用聚丙烯和高等级不锈钢材料制成，由针座、针管和护帽组成，可按型式不同分为侧孔和斜面两种，按针管外径不同分为1.2mm和1.6mm两种规格；产品以无菌形式提供；与一次性使用配药用注射器配套，供抽取和配制药液用。产品性能指标采用下列参考标准中的适用部分，如：YY/T0821一次性使用配药用注射器。	Made of polypropylene and high-grade stainless steel; Mainly consist of needle seat, needle tubing and protection cap. Can be side opening and bevel. Use with single-use syringe for dispensing for liquid extraction or preparation. Reference standard: YY/T0821 single-use syringe for dispensing	II
70	6815	注射穿刺器械	Puncture Injection Equipment	金属胸腔穿刺针	Metal needle used in thoracentesis	金属胸腔穿刺针可用铜基镀铬（针座等）和高等级不锈钢材料（针管）制成，可由针座（有标准鲁尔接头）、三通、定位装置和有刻度针管构成，通常针管的公称外径为1.2mm或1.6mm，针管长度可为65mm—65mm或更长；与注射器配套，供胸腔穿刺，建立通道，抽取胸腔积液等用，可重复使用。	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.	II
71	6815	注射穿刺器械	Puncture Injection Equipment	一次性使用牙科平头冲洗针	single-use dental rinsing needle with flat head	一次性使用牙科平头冲洗针采用高分子材料和高等级不锈钢材料制成，由针座（带标准鲁尔接头）和平头针管、护帽组成，按针管型式不同可分为直型和弯型两类；以无菌形式提供；与注射器配套使用，用于口腔科诊疗术后口腔压力冲洗用。	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 syringe for oral cavity pressure washing in department of stomatology.	II
72	6815	注射穿刺器械	Puncture Injection Equipment	一次性使用无菌点刺针	single-use sterile needle	一次性使用无菌点刺针采用适用的不锈钢制成，由扁平的柄部和三角形针尖两部分组成；供速发型超敏反应皮肤测试时点刺刺破皮肤，使皮肤上的抗原液渗入皮下用。不包括针内含抗原液的点刺针。	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	注射穿刺器械	Puncture Injection Equipment	笔式胰岛素注射器	Insulin pen-syringe	笔式胰岛素注射器由剂量调节钮(ABS)、笔身(聚碳酸酯)、释放按钮(共聚甲醛)、引导螺杆(尼龙)、笔芯架(PBT)、笔帽(ABS)组成，不包括药物和注射针头，所有部件不与药液接触；须与特定的胰岛素和注射针或标准注射针配套，供胰岛素皮下注射用。	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 syringe needle or standard syringe needle for insulin	III
74	6815	注射穿刺器械	Puncture Injection Equipment	环甲膜穿刺针	Thyrocrico centesis needle	环甲膜穿刺针可采用不锈钢等金属材料制成，由带止位结构的套管和匹配的锥形穿刺针组成，可按材质、设计、技术参数等不同分为若干型号及规格；供环甲膜穿刺，建立人工气道，缓解上呼吸道阻塞用。	Made of metal material such as stainless steel, consist of lockable sleeve and the cone puncture needle. Can be divided into various specifications according to texture, design, technical parameters, etc.. Used to establish artificial airway in thyrocrico centesis to	III
75	6815	注射穿刺器械	Puncture Injection Equipment	穿刺针		由穿刺针管和管座组成。采用Seldinger术，建立有助于血管内器械的经皮进入通路。Seldinger术多指数字减影血管造影术中的血管穿刺术。	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	注射穿刺器械	Puncture Injection Equipment	导引套管		由导管和导管座（可选）组成。采用Seldinger术，建立有助于血管内器械的经皮进入通路。Seldinger术多指数字减影血管造影术中的血管穿刺术。	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	注射穿刺器械	Puncture Injection Equipment	一次性动静脉穿刺针/器（内瘘针）		产品一般由采血针保护套、采血针、针柄、夹具、采血管、内圆锥接头、接头保护套组成。适用于临床上血液透析时的血管穿刺。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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 hemodialysis. 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	注射穿刺器械	Puncture Injection Equipment	一次性使用腹腔穿刺针	Enterocoeli a puncture needle	组成仅限于由针管、针座、连接管组成腹腔穿刺针，用于对人体作腹腔穿刺用。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	注射穿刺器械	Puncture Injection Equipment	一次性使用活检针	single-use biopsy needle	组成仅限于包括穿刺针和针芯的活检针，材料符合GB 18457的要求，通过直接进行人体组织器官穿刺以获取病理组织，不包括与内窥镜系统、负压吸引装置等配合使用或需超声、X线等影像设备引导下操作的活检针。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	III
80	6815	注射穿刺器械	Puncture Injection Equipment	一次性使用静脉采血针	single-use Venous Blood Lancet	该产品一般由管塞穿刺针、护套、导管、采血针组成，配套一次性使用静脉血样采集容器用于人体静脉采集血样。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	注射穿刺器械	Puncture Injection Equipment	一次性使用静脉留置针	single-use intravenous indwelling needle	性能、结构、组成、用途等属于即将发布的行业标准《一次性使用静脉留置针》可完全涵盖的产品。产品一般由导管组件和针管组件两部分组成，导管组件是由导管、导管座、延长管（如果有）和任何一体的接头组成的装配件，针管组件是由针管和针座和/或其他一体的附件组成的装配件。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	III

82	6815	注射穿刺器械	Puncture Injection Equipment	一次性使用静脉输液针	One-time use of intravenous infusion needle	性能、结构、组成、用途等属于GB 18671一次性使用静脉输液针可完全涵盖的产品，一般由针管（公称外径0.36—1.2mm）、针柄、软管、连接座和保护帽组成，与输液器、输血器配套使用，用于建立外周静脉通路。如产品具有特殊性能或结构（如自毁、过滤、防针刺）、新材料（除主材外，还包括含避光剂、增塑剂等添加剂）等不能豁免临床。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	III
83	6815	注射穿刺器械	Puncture Injection Equipment	一次性使用麻醉穿刺针	single-use anesthesia needle	性能、结构、组成、用途等属于YY 0321.2 一次性使用麻醉用针可完全涵盖的产品。产品一般由衬芯座、针座、针管和衬芯等组成，在麻醉时进行穿刺、注射药物。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	III
84	6815	注射穿刺器械	Puncture Injection Equipment	一次性使用乳腺定位丝及其导引针	single-use breast and guided needle localization wire	性能、结构、组成、用途等属于YY/T 0880 一次性使用乳腺定位丝及其导引针可完全涵盖的产品，导引针针管应使用GB 18457中的材料制成，定位丝宜使用不锈钢或其他合金材料制成，临床上使用本产品为了便于手术切除乳腺局部微小病灶，在X射线或超声下用乳腺定位丝及其导引针对病灶进行定位，给临床手术医生以明确的引导，以缩小切口，减少手术损伤。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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 new action	III
85	6815	注射穿刺器械	Puncture Injection Equipment	一次性使用无菌注射器	single-use sterile syringes	性能、结构、组成、用途等属于GB 15810一次性使用无菌注射器可完全涵盖的产品，一般由注射器外套、活塞、密封圈、芯杆、按手、锥头组成，是供抽吸液体或在注入液体后立即注射用的手动注射器。如产品具有特殊性能或结构（如自毁、防针刺等）等不能豁免临床。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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 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	III

86	6815	注射穿刺器械	Puncture Injection Equipment	一次性使用无菌注射针	single-use sterile needles	性能、结构、组成、用途等属于GB 15811一次性使用无菌注射针可完全涵盖的产品，由针座、连结部、针管、护套组成，用于人体皮内、皮下、肌肉、静脉注射或抽取药液。如产品具有特殊性能或结构（如自毁、防针刺等）等不能豁免临床。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	II
87	6815	注射穿刺器械	Puncture Injection Equipment	一次性使用胸腔穿刺针	single-use needle thoracentesis	组成仅限于由针管、针座、连接管组成胸腔穿刺针，用于对人体作胸腔穿刺用。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	普通诊察器械	General examination equipment	玻璃体温计	Glass thermometer	玻璃体温计用玻璃制成，具有测温留点结构，感温液为汞或其他金属液体，按型式可分为三角型棒式、新生儿棒式、元宝型棒式、内标式，每种按尺寸等不同可分为若干规格，通常的测量范围：35—42℃，温度最小分度值为0.1℃，可供临床或个人测量体温用。产品性能指标采用下列参考标准中的适用部分，如：GB 1588-2001体温计。	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 divided 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	普通诊察器械	General examination equipment	医用电子体温计	Medical electronic thermometer	医用电子体温计为间歇接触式监控患者体温的电子装置，可由塑胶外壳、电路板、温度测量部件、显示屏、电源等组成；可按设计、技术参数、附加辅助功能、预期用途等不同分为若干型号，供测量人体体温或女性监测排卵周期等用，不包括预测模式，也不包括医用红外体温计。产品性能指标采用下列参考标准中的适用部分，如：GB/T 21416-2008 医用电子体温计。	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	II
90	6820	普通诊察器械	General examination equipment	耳腔式医用红外体温计	Ear cavity medical infrared thermometer	耳腔式医用红外体温计可由塑胶外壳、电路板、温度测量部件、显示屏、电源、隔离膜等组成；可按设计、技术参数、附加辅助功能、预期用途等不同分为若干型号；通过热辐射显示被测人体耳腔体温。需提供临床准确度与临床重复性报告。产品性能指标采用下列参考标准中的适用部分，如：GB/T 21417.1-2008 医用红外体温计 第1部分：耳腔式。	Mainly consist of plastic shell, circuit boards, temperature measurement unit, display screen, power supply, isolation film; Can be divided into various 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 Clinical infrared thermometers - part	II

91	6820	普通诊察器械	General examination equipment	汞柱式血压计	Mercury sphygmomanometer	汞柱式血压计可有台式、立式和挂式等型式，基本参数：测量范围：0—40kPa（0—300mmHg），儿童血压计0—20kPa（0—150mmHg）；采用双刻度标尺，最小分度值为0.5 kPa（2 mmHg）；示值允许误差为±0.5kPa（±3.75 mmHg）；袖带可根据气囊尺寸不同分为多个规格；小儿用参数可调整；供测量人体血压用。产品性能指标采用下列参考标准中的适用部分，如：GB 3053-1993 血压计和血压表。	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 according to balloon size; Children sphygmomanometer is with adjustable parameters; Used for measuring blood pressure. Reference standard: GB 3053-	II
92	6820	普通诊察器械	General examination equipment	机械弹性元件式血压表	Mechanical elastic element blood pressure meter	机械弹性元件式血压表采用双刻度，成人用测量范围0—40kPa（0—300mmHg），最小分度值分别为0.5kPa和2mmHg，允许误差为±0.5kPa（±3.75mmHg），袖带可根据气囊尺寸不同分为多个规格；小儿用参数可调整，可按型式、技术参数及适用对象不同分为若干型号；供测量人体血压用。产品性能指标采用下列参考标准中的适用部分，如：GB 3053-1993 血压计和血压表。	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 ± 0.5kPa (± 3.75mmHg), Cuffs can be divided into various specifications according to balloon sizes; Children sphygmomanometer is with adjustable parameters; Can be divided into various specification according to type, technical parameters and application objects; Used for blood pressure measurement.	II
93	6820	普通诊察器械	General examination equipment	简易肺活量计	Simple spirometer	简易肺活量计多为台式，由底座、水槽、浮筒、标尺和螺纹管等组成，可按设计、技术参数、适用对象等不同分为若干型号；供测量人体肺活量用。	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	普通诊察器械	General examination equipment	泪液分泌检测滤纸	Schirmer detection filter paper	泪液分泌检测滤纸由带有荧光素钠标示线的滤纸裁切而成，供临床用于各种泪液分泌障碍的检测。	Mainly made of filter paper with sodium fluorescein labeled line, used for detecting in various tear paracrisis.	II

95	6821	医用电子仪器设备	Medical electronic equipment	心电图机	ECG machine	心脏在机械收缩之前, 首先产生电激动, 心肌激动所产生的微小电流可经过身体组织传导到体表, 使体表不同部位产生不同的电位, 对这种心脏动作电位的可见记录就是心电图。心电图机利用体表放置的通过患者电缆联接到设备的两个电极, 按照心脏激动的时间顺序, 依次记录并经过处理后输出或显示体表两点间的电位差。心电图机一般为台式或手提式, 由主机、患者电缆和电极组成, 电极也可分为可重复使用和一次性使用两种形式。记录方式可采用热笔式或热线阵记录方式等。有些产品具有信号输入或信号输出端口, 可按技术参数和功能不同分为若干型号, 如可按同步测量心电导联数不同分为单道、双道、多道等, 也可将采集的心电信号输入计算机进行处理(如高频信号处理等), 但不包括辅助分析和诊断功能。产品性能指标采用下列参考标准中的适用部分, 如: YY 1039-2013心电诊断设备; 单道和多道心电图机, YY 0782-2010医用电气设备 第2-51部分: 记录和分析型单道和多道心电图机安全性能基本性能专用要求。	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 hand-held. 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,	II
96	6821	医用电子仪器设备	Medical electronic equipment	动态心电图记录仪	Dynamic ECG Recorder	动态心电图记录仪通常由移动式记录器和导联线组成, 也可包括数据管理软件和附件(导联线、充电器、USB线等), 可按导联数、技术参数、预期用途、附加辅助功能等不同分为若干型号; 供人体24小时动态心电监测用。不包括自动分析诊断功能。产品性能指标采用下列参考标准中的适用部分, 如: YY 0885-2013 医用电气设备 第2部分: 动态心电图系统安全和基本性能专用要求。	Mainly consist of portable recorder and leadwires, can include data management software and accessories (ECG cable, charger, USB cable, etc.); Can be divided 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	医用电子仪器设备	Medical electronic equipment	胎儿心电图机	Fetal ECG machine	胎儿心电图机主要由主机、导联线、电极组成, 可包括数据管理软件、打印设施及附件; 可按导联数、技术参数、预期用途、附加辅助功能等不同分为若干型号; 供胎儿心电图检查、监测用, 但不包括辅助分析和诊断功能。	Mainly consist of host, lead wair, electrode, can contain data management software, print facility; Can be divided 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	医用电子仪器设备	Medical electronic equipment	一次性使用心电电极	Single-use ECG Electrodes	一次性使用心电电极是心电图采集设备附件，由传感元件和电解质组成，可带或不带连接导线。电极可由基衬材料、导电膏、电极扣等组成，基衬材料可用透气纸、水刺布、无纺布、发泡纸、棉布或PE等加涂医用压敏胶制成，并按其形状不同分为圆形、椭圆型、方形等，并按其尺寸大小不同分为若干规格；配合仪器，供心电检测、监测用。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0196—2005一次性使用心电电极。	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	II
99	6821	医用电子仪器设备	Medical electronic equipment	脑电图机	EEG (electroencephalograph)	脑电图机可由放大器输入盒、计算机、显示器、专用软件、电极组成，也可包括闪光灯、闪光控制器、打印机等，可按设计、型式、技术参数、附加辅助功能等不同分为若干型号，供人体脑电生理信号检测、处理、显示和储存等用。产品性能指标采用下列参考标准中的适用部分，如：YY 9706.25-2005医用电气设备第2部分：脑电图机安全专用要求。	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 human physiological signal. Reference standard: GB 9706.25-2005 Medical electrical equipment-Part 2: Particular requirements for	II
100	6821	医用电子仪器设备	Medical electronic equipment	脑电地形图仪	BEAM (Brain electrical activity mapping)	脑电地形图仪主要由主机、显示器、放大器、打印机、键盘、鼠标等组成，可按设计、型式、技术参数、附加辅助功能等不同分为若干型号；供人体脑电生理信号数据定量处理、分析功能，不包括自动诊断部分。	Mainly consist of host, display screen, amplifiers, printer, keyboard, mouse; Can be devided into various specifications according to different design, type, technical parameters, additional auxiliary functions, etc. Used for EEG physiological signals data processing, analysis, but without a automatic diagnosis function.	II
101	6821	医用电子仪器设备	Medical electronic equipment	肌电图机	EMG (electromyography)	肌电图机主要由主机、刺激电极组成，也可包括计算机、专用数据管理软件及打印机，可按设计、型式、技术参数、附加辅助功能等不同分为若干型号；供人体肌电信号及神经传导数据采集、处理、分析用，不包括自动诊断部分。产品性能指标采用下列参考标准中的适用部分，如：YY 0896-2013医用电气设备第2部分：肌电及诱发反应设备安全专用要求。	Mainly consist of host, stimulating electrodes, may also include computer, dedicated data management software and printer; Can be devided into various specifications according to different design, type, technical parameters, additional auxiliary functions, etc.Used for human EMG and nerve conduction data acquisition, processing, analysis, does not include automatic diagnosis section. Reference standard: YY 0896-2013 Medical electrical equipment. Part 2: Particular requiremetns for the safety of electromyograohs and	II
102	6821	医用电子仪器设备	Medical electronic equipment	纯音听力计	Pure tone audiometer	纯音听力计可由电源、声卡、功率放大器、控制器、电声换能器件(气导耳机、骨导耳机)、操作软件、患者应答器组成，可按设计、型式、技术参数、附加辅助功能等不同分为若干型号；供有应答能力者听阈检测用。产品性能指标采用下列参考标准中的适用部分，如：GB/T 7341.1—2010电声学 测听设备 第1部分：纯音听力计。	Mainly consist of power supply, sound card, power amplifier, controller, electro-acoustic transducer devices (air conduction headphones, bone conduction headphones), operating software, patient responses composed; Can be devided into various specifications according to different design, type, technical 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	II

103	6821	医用电子仪器设备	Medical electronic equipment	多参数监护仪	Multi-parameter monitor	多参数监护仪主要由主机和附件组成，附件可以包括心电导联电缆、血压袖带、血氧探头、体温探头、呼吸末二氧化碳气体测量组件、麻醉深度外接配件等，可按设计、型式、技术参数、附加辅助功能等不同分为若干型号；供患者的心电、无创血压、脉搏、血氧饱和度、体温、呼吸、呼气末二氧化碳、麻醉深度指数监测用。需提供无创血压系统整体有效性和血氧准确度人体评估报告。产品性能指标采用下列参考标准中的适用部分，如：YY 1079-2008心电监护仪、YY 0670-2008无创自动测量血压计，YY 0784-2010医用电气设备——医用脉搏血氧仪设备基本安全和主要性能专用要求，YY 0785-2010临床体温计——连续测量的电子体温计性能要求等。	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 divided into various specifications according to different design, type, technical parameters, additional auxiliary functions, etc.. Used for monitoring patient's ECG, noninvasive blood pressure, pulse, oxyhemoglobin saturation, body temperature, respiration, end-tidal carbon dioxide, 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	II
104	6821	医用电子仪器设备	Medical electronic equipment	多参数中央监护系统	Multi-parameter central monitoring system	多参数中央监护系统分有线和无线两类。有线监护系统是由中央主机和床边多参数监护仪组成，无线监护系统由中央主机、发射机和床边多参数监护仪组成；可按设计、技术参数、辅助功能等不同分为若干型号；供医疗机构对患者多种生理参数进行集中监护、管理等。需提供无创血压系统整体有效性和血氧准确度人体评估报告。产品性能指标采用下列参考标准中的适用部分，如：YY 1079-2008心电监护仪、YY 0670-2008无创自动测量血压计，YY 0784-2010医用电气设备——医用脉搏血氧仪设备基本安全和主要性能专用要求，YY 0785-2010临床体温计——连续测量的电子体温计性能要求等。	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 divided into various specifications according to different design, technical parameters, auxiliary functions, etc.. Used in medical institutions for varieties of physiological parameters monitoring and management. 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 equipment for medical use, YY 0785-2010 Clinical thermometers—Performance of electrical	II

105	6821	医用电子仪器设备	Medical electronic equipment	母亲/胎儿多参数监护仪	Mother/fetus multi-parameter monitor	母亲/胎儿多参数监护仪主要由主机和附件组成，附件可以包括心电导联电缆、血压袖带、血氧探头、体温探头、超声探头、宫缩压力探头、标记手柄等，可按设计、型式、技术参数、附加辅助功能等不同分为若干型号；供母亲的心电、无创血压、脉搏、血氧饱和度、体温、呼吸、宫缩压力以及胎儿胎心率、胎动监测用。需提供无创血压系统整体有效性和血氧准确度人体评估报告。产品性能指标采用下列参考标准中的适用部分，如：YY 1079-2008心电监护仪、YY 0670-2008无创自动测量血压计，YY 0784-2010医用电气设备——医用脉搏血氧仪设备基本安全和主要性能专用要求，YY 0785-2010临床体温计——连续测量的电子体温计性能要求等。	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 equipment for medical use, YY 0785-2010 Clinical thermometers—Performance of	II
106	6821	医用电子仪器设备	Medical electronic equipment	睡眠呼吸监测仪		睡眠呼吸监测仪可由主机、软件和附件组成，可按设计、型式、技术参数、附加辅助功能等不同分为若干型号；分别通过对患者睡眠条件下口鼻气流、血氧和/或胸腹运动等相关生理信号的监测与分析，供睡眠呼吸暂停低通气综合征诊断或筛查用。不包括自动分析诊断软件。	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 diagnosis software.	II
107	6821	医用电子仪器设备	Medical electronic equipment	红外乳腺检查仪		红外乳腺检查仪由探头(卤素灯探头、激光探头)、摄像机、主机(包含显示器、打印机、计算机、软件)组成，可按设计、型式、技术参数、附加辅助功能等不同分为若干型号；供乳腺疾病的红外光检查用。产品性能指标采用下列参考标准中的适用部分，如：YY 0324-2008红外乳腺检查仪。	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	医用电子仪器设备	Medical electronic equipment	医用脉搏血氧监测仪	Medical pulse oximeter monitor	医用脉搏血氧监测仪通常由主机（包括控制、数据处理/显示模块）和与之相联的血氧探头组成，可按设计、型式、技术参数、附加辅助功能等不同分为若干型号；通过建立光辐射与人体组织血氧饱和度关系，供临床无创估算监测人体动脉血氧饱和度和脉率用。需提供血氧准确度人体评估报告。产品性能指标采用下列参考标准中的适用部分，如：YY 0784-2010医用电气设备——医用脉搏血氧仪设备基本安全和主要性能专用要求。	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	医用电子仪器设备	Medical electronic equipment	多导睡眠诊断分析系统	Polysomnographic diagnosis and analysis system	多导睡眠诊断分析系统由生理信号采集模块、处理模块、数据显示、记录/存储模块及附件等组成，可以包括专用软件。可按设计、技术参数、功能及辅助功能等不同分为若干型号；分别通过对患者睡眠条件下脑电、眼动、肌电、胸腹运动、心电、口鼻气流、鼾声、血氧、体位等睡眠有关生理信号的监测与分析，综合评估人的睡眠呼吸状况，用于睡眠呼吸暂停低通气综合征以及睡眠相关疾病的诊断。不包括自动分析诊断软件。	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	II
110	6821	医用电子仪器设备	Medical electronic equipment	电动吸鼻器	Electric sucking foreign matter in nose	电动吸鼻器由吸头、主机、电池组成。使用时，吸头接触儿童鼻孔外缘，由主机产生吸力。利用负压原理吸除儿童鼻腔分泌物。	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 sucked out by making use of negative pressure.	II
111	6821	医用电子仪器设备	Medical electronic equipment	电子尿量计量仪	Electronic urine meter	电子尿量计量仪由主机（含显示终端）、配套尿袋、托架等组成（不含导尿管）；仪器可按技术参数、附加功能等不同分为若干型号；通过测量尿袋内尿液的重量和体积，计算尿量相关参数。	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	II
112	6821	医用电子仪器设备	Medical electronic equipment	压缩式雾化器	Compressor nebulizer system	压缩式雾化器由往复活塞微型压缩机、连接软管、汽雾手动开关和喷嘴、软管、面罩组成；可按技术参数、附加功能等不同分为若干型号；通过压缩气体产生的气流雾化药物并将其输送到呼吸道，供呼吸道雾化药物吸入治疗用。	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	医用电子仪器设备	Medical electronic equipment	心肺功能测试系统		心肺功能测试系统可由主机、心肺功能测试跑台及附属部件组成，可按设计、技术参数、预期用途等不同分为若干型号，供不同运动负荷下心肺功能评估用。	Mainly consist of host, cardiopulmonary treadmill testing and ancillary components; Can be divided into various specifications according to different design, technical parameters, intended use etc; Used for cardiopulmonary function assessment under different	II
114	6821	医用电子仪器设备	Medical electronic equipment	心肺功能测试系统配套跑台		心肺功能测试系统配套跑台由一条无接头的、可以一定的速度与高度持续运行的履带（通常是绕在滚轮上的可吸收冲击的橡胶带）、电动马达和控制模块组成。跑台也可将前面与侧面扶手一体化以保证测试者的安全；为心肺功能测试系统组件之一，电动设备，可按设计、技术参数等不同分为若干型号；供被测者在跑台运动履带上原地步行、慢跑或快跑来体现不同的运动量，以评估被测者一定的运动负荷下的生理状况（如心肺功能失常/功能）。	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	医用电子仪器设备	Medical electronic equipment	神经和肌肉刺激器用电极	Nerve and muscle stimulator electrodes	神经和肌肉刺激器用电极由电极片（导电塑料及金属镀层）、导线和设备接插件组成，可按材质、技术参数、尺寸等不同分为若干型号及规格；可一端与神经和肌肉刺激器连接，一端与人体完好皮肤连接；产品可以无菌形提供，单个病人一定时间内可以重复使用；供向人体无创传输神经和肌肉刺激器刺激电信号用。产品性能指标采用下列参考标准中的适用部分，如：YY 0868-2011神经和肌肉刺激器用电极。	Mainly consist of electrode sheet (conductive plastic and metal coating), guide wires and equipment connectors; Can be divided 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	II
116	6821	医用电子仪器设备	Medical electronic equipment	医用导电膏	Medical conductive paste	医用导电膏通常为水基质高分子凝胶，内含生物相容性较好且稳定的电解质，用于心电检查和电疗电极耦合用。	Generally be water-based polymer gel, containing good biocompatible and stable electrolyte; Used for ECG examination and electrotherapy electrode coupling.	II
117	6821	医用电子仪器设备	Medical electronic equipment	一次性使用无创脑电电极	Single-use non-invasive EEG electrodes	一次性使用无创脑电电极由电极片（导电塑料及金属镀层）、导线和设备接插件组成，可一端与脑电诊断/监护设备连接，一端与人体头部皮肤连接，供采集、传输脑电生物信号用。单个病人短时间内可以重复使用。	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 single	II
118	6821	医用电子仪器设备	Medical electronic equipment	无创医用传感器	Non-invasive medical sensors	包括温度、压力、重力、角度等医用传感器。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0781-2010 血压传感器等。有特别要求的按特别要求处理。	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 to special requirements.	II

119	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	内窥镜用组织拉钩	Endoscope tissue retractor	内窥镜用组织拉钩采用不锈钢和铝等材料制成, 由工作端(拉杆)、器械杆、握把等组成, 可按材质、设计、技术参数等不同分为若干型号; 以无菌形式提供; 供各种内窥镜手术过程中组织的暂时性牵拉。	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 texture, design and technical parameters, etc. Sterile form; Used for tissue temporary traction in endoscopic surgical procedures.	II
120	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	裂隙灯显微镜	Slit lamp microscope	裂隙灯显微镜是一种眼科双目(也可为三目)显微镜, 仪器把一个高亮的窄缝投射到眼睛里, 用可移动的显微镜从侧面观察其反射光, 从而对反射表面进行观察和/或测量。典型结构由显微镜和能产生裂隙(窄缝)的旋转照明系统组成, 可以是手持式的, 也可是台式, 显微镜可以是连续变倍或非连续变倍; 若配备照相机和计算机, 也可用软件管理图像, 可因设计与技术参数的不同分为若干型号; 供检查眼前节及其他眼内部病变用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0065-2007眼科仪器裂隙灯显微镜。	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 equipped with cameras and computers; Can be divided into different specifications according to different design or technical parameters; Used for anterior segment or other eye disease examination; Reference standard: YY 0065-2007 Ophthalmic instruments—Slit-	II
121	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	直接检眼镜	Direct ophthalmoscope	直接检眼镜由照明系统和观察系统(由透视镜和光阑组组成), 产生正向或不翻转的图像, 使检查者可以清晰观察视网膜细节和其他结构/介质(角膜、房水、晶状体及玻璃体), 多为手持式, 电池供电(也可由网电源供电), 典型结构由一个安装在内部的光源、一面反光镜和一个拨盘组成, 光源方向可由检查者进行改变, 通过瞳孔照亮眼球内部, 反光镜中间有一个圆孔, 检查者可通过其进行观察, 拨盘上有补偿透镜和辅助镜片, 检查时可进行选择, 用于检查眼底病变、屈光介质的异常及视网膜的定位等。产品性能指标采用下列参考标准中的适用部分, 如: YY 1080-2009 眼科仪器 直接检眼镜。	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	II
122	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	间接检眼镜	Indirect ophthalmoscope	间接检眼镜由一个聚光镜(手持式或整体式)来产生一个可被目视观察的中间实像, 通常由一个用于照亮眼球内部的主光源、一个镜片及滤片系统, 以及一个用于减少反光的照明光束组成, 可分为手持式或头戴式, 可以是内部电源供电, 也可由网电源供电; 供眼内介质及眼底检查用。产品性能指标采用下列参考标准中的适用部分, 如: YY0633-2008 眼科仪器 间接检眼镜。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	检影镜	Retinoscope	检影镜通常由折光镜、中心通光反射镜的投射系统、观察系统和电源组成，可分为带状光（矩形截面光束，焦距和方位可调）检影镜和点状光检影镜（近圆截面光束，像焦点可调）两类，每类按电源、技术参数、辅助功能等不同分为若干型号；供眼屈光不正客观评估和视网膜反射交叉越过瞳孔时的位移观察用。产品性能指标采用下列参考标准中的适用部分，如：YY 0718-2009眼科仪器 检影镜。	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 Ophthalmic instruments—Retinoscopes	II
124	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	验光镜片	Optometry lens	验光镜片主要由正、负球镜验光镜片，正、负柱镜验光镜片，棱镜验光镜片，辅助验光镜片（马式杆片、裂隙片、针孔片、黑片、磨砂片、平光片、十字片、红色滤光片、绿色滤光片、偏振片、交叉柱镜片、翻转镜等组合而成，按验光镜片的数量、种类不同可分为若干型号或种类，可附验光镜架，供检查人眼的屈光状态（远视、近视、老视、散光）和斜视及眼科其他方面的疾病用。产品性能指标采用下列参考标准中的适用部分，如：GB 17342—2009眼	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	压陷式眼压计	Indentation ophthalmotonometer	压陷式眼压计通常由固定砝码、压针、锤弓和指针组成；可按型式（手持或台式）等不同分为不同型号；通过仪器手动向眼睛施加了一个外力，通过压针测量出眼角膜内陷的程度，并通过换算间接测量眼内压力。产品性能指标采用下列参考标准中的适用部分，如：YY 1036-2004压陷式眼压计。	Generally consist of fixed weights, pressure pin, hammer bow and pointers; Can be divided 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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	医用光学硬管内窥镜（检耳镜、膀胱镜、子宫镜、直肠镜、羊水镜）	Medical Optical rigid endoscopes (Otoscope, cystoscopy, hysteroscopy, rectoscope, amniotic fluid)	医用光学硬管内窥镜（检耳镜、膀胱镜、子宫镜、直肠镜、羊水镜）通常由手持部分、刚性插入部分、光学部分（含观察端）及头端（患者端）组成，解剖图像通过透镜光学元件中继传输给操作者，可重复使用装置，可按结构型式、技术参数、附加功能、预期用途等不同分为若干型号，通过人体自然腔道，供诊查、治疗等用。产品性能指标采用下列参考标准中的适用部分，如：YY 0068 医用内窥镜 硬性内窥镜系列，YY 1075-2007硬性宫腔内窥镜。	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 divided 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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	医用内窥镜用冷光源	Medical endoscope cold light resource	医用内窥镜用冷光源为医用内窥镜的辅助设备，通常由冷光源、控制电路及光源输出部分组成，可含导光束，可按光源种类、技术参数等不同分为若干型号，可与医用内窥镜有电气连接，供临床窥镜内视或手术深部照明等用。产品性能指标采用下列参考标准中的适用部分，如：YY 1081-2011医用内窥镜 内窥镜功能供给装置 冷光源。	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—	II
128	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	生物显微镜	Biological Microscope	生物显微镜通常由观察系统、照明系统、载物台及附件组成。观察系统是具有目镜、高倍物镜的短工作距的体视光学显微系统，可外接图像采集显示系统；附件包括相衬装置、荧光装置、偏光装置、显微摄影装置、暗场照明装置、微分干涉装置、显微描绘器、显微光度计、垂直照明装置等；生物显微镜可按结构、配置与功能、技术参数等不同分为若干型号，供临床实验室利用显微放大原理观察微小细胞、组织等样本用。产品性能指标采用下列参考标准中的适用部分，如：GB/T 2985-2008生物显微镜。	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:	II
129	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	微循环显微镜检查仪	Microcirculation microscope tester	微循环显微镜检查仪可由微循环显微镜、光源（LED光源/冷光源）、CCD（黑白/彩色）、显示器（监视器）等组成，可包括图像管理软件，可按结构组成、技术参数、预期用途、附加辅助功能等不同分为若干型号；供人体末梢微循环（如甲襞）检查用，以此评估人体微循环状况。产品性能指标采用下列参考标准中的适用部分，如：YY 0067-2007微循环显微镜。	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-	II
130	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	数码显微镜	Digital Microscope	数码显微镜是CCD与光学显微镜相结合的产品，通过在光学显微镜目镜上加装CCD摄像头，可将光学显微镜下的显微图像采集并直接传输、显示在各种显示器上（如电视机、电脑等）直接观察；可按显微镜的型号、采集图像相关的技术参数、附加辅助图像管理功能等不同分为若干型号；供临床检验，观察血液等体液标本中血细胞等有形物质用。	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 cells	II

131	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	手术显微镜	Surgical microscope	手术显微镜由光学系统、机架、照明系统、电气装置四个基本部分组成，也可包括照相/摄像系统及图像管理系统，可按结构组成、技术参数、预期用途、附加辅助功能等不同分为若干型号；供外科显微手术放大、照明、图像管理等用。参教标准 GB 11239.1-2005手术显微镜 第1部分。	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	II
132	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	数码电子阴道镜	Digital electronic colposcope	数码电子阴道镜可由彩色摄像仪、LED光源、计算机主机、软件及显示器等组成，可按结构、组成、技术参数、附加辅助功能等不同分为若干型号，供外阴、阴道、宫颈疾病的非接触性观察和影像记录用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	一次性使用内窥镜气腹穿刺套管针	Single-use endoscope pneumoperitoneum puncture needle sets	一次性使用内窥镜气腹穿刺套管针用适用的ABS等高分子材料制成，由外套管及可配套锁止的穿刺内芯组成；可按材质、设计、尺寸等不同分为若干型号及规格；为内窥镜配套用手术器械，通过在腹壁穿刺并固定，供形成气腹注气通道和腹腔镜或其他手术器械的工作通道用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	一次性使用内窥镜用取样刷	Single-use endoscope sampling brush	一次性使用内窥镜用取样刷由刷柄、管鞘、牵引丝和刷子组成，可用聚甲醛、聚四氟乙烯、聚酰胺、不锈钢等适用材料制成；可按材质、设计、技术参数、适用部位等不同分为若干型号及规格；以无菌形式提供；供内窥镜检查时从人体中提取组织样本用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	一次性使用防污样本刷	Single-use antifouling samples brush	一次性使用防污样本刷由管路组件、刷头组件、聚乙二醇和保护塞组成，可按材质、设计、技术参数、适用部位、预期用途等不同分为若干型号及规格；以无菌形式提供；供内窥镜下刷取患者病变部位细胞组织或分泌物用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	一次性使用内窥镜标本取物袋	Single-use endoscopic specimen Pouch	一次性使用内窥镜标本取物袋可由多重套管、张开装置、结扎绳、纳物袋组成，其中套管和纳物袋可由高分子等适用材料制成，张开装置可由不锈钢等材料制成；可按材质、设计、技术参数、适用部位、预期用途等不同分为若干型号及规格；应以无菌形式提供；供临床微创窥镜手术下收集人体组织标本/异物并取出体外用。	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 collecting tissue samples/ foreign matters to fetch them out of human body.	II
137	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	一次性使用内窥镜取石篮	single-use endoscopic stone extraction baskets	一次性使用内窥镜取石篮通常由带鲁尔接头的手柄、带软鞘导丝杆（或套管）和远端的360°金属丝制自展篮组成，可按材质、设计、技术参数、适用部位、预期用途等不同分为若干型号及规格；以无菌形式提供；供消化、泌尿等诊疗时在内窥镜下抓住、操控和取出结石以及其他异物用。	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 grabbing, operating and fetching stones in digestion, urinary, etc. diagnosis under endoscope.	II
138	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	内窥镜下机械碎石/取石辅件	Endoscopic mechanical lithotripsy/ stone fetching accessories	内窥镜下机械碎石/取石辅件用金属和高分子材料制成，由外鞘管、碎石手柄、冲洗延长管、接头组成；可按材质、设计、技术参数、适用部位、预期用途等不同分为若干型号及规格；可以灭菌/非灭菌状态提供，可重复使用；供其他内窥镜取石方法失败的情况下进行机械性胆道碎石/取石用。	Mainly made of metal and polymer materials; Mainly consist of outside sheath, lithotripsy handle, extension tube, connector; Can be divided into different specifications according to texture, design, technical parameters, applicable sites, intended use, etc. Can be aseptis or non-aseptis, can be reused; Used for mechanical biliary gravel stone fetching when failed in endoscope stone fetching	II
139	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	一次性使用内窥镜用钳	Single-use endoscopic forceps	一次性使用内窥镜用钳采用金属和高分子材料制成，由钳头、鞘管和控制手柄组成，钳头可有多种设计，具有咬切、抓取等多种功能，可按材质、设计、技术参数、适用部位、预期用途等不同分为若干型号及规格；以无菌形式提供；供内窥镜下抓取、咬切组织或异物用。	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, grabbing function; Can be divided into different specifications according to texture, design, technical parameters, applicable sites, intended use, etc. Sterile state; Used for endoscopic grabbing, biting tissue or foreign matters.	II
140	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	一次性内窥镜用软管式活组织取样钳	Single-use flexible pipe type endoscopic biopsy samples forceps	一次性内窥镜用软管式活组织取样钳主要由钳头部分、弹簧外管和操作柄部分组成，可有定位针，可按材质、设计、尺寸等不同分为若干型号及规格；以无菌形式提供；供消化道、呼吸道等内窥镜下活组织取样或钳取和清除异物用。产品性能指标采用下列参考标准中的适用部分，如：YY/T1076—2004内窥镜用软管式活组织取样钳。	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 specifications	II

141	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	腹腔镜线结推送器	Laparoscopic knot pusher	腹腔镜线结推送器采用不锈钢等材料制成，由线结固定槽、推送杆和手柄组成，头端有缝线穿入孔，可按材质、设计、技术参数等不同分为若干型号及规格；用于将体外打结缝线放入腹腔镜术区中。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	内窥镜摄像系统	Endoscopic camera system	内窥镜摄像系统由控制主机、摄像头、适配器组成，可按设计、技术参数、辅助功能等不同分为若干型号；供内窥镜手术时，将体内手术区域视频放大成像。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	重复使用内窥镜手术器械	Reusable endoscopic surgical instruments	重复使用内窥镜手术器械用不锈钢制成，由手柄、钳口、剪刀头等组成；可按材质、设计、技术参数、工作部位、预期用途等不同分为若干型号及规格；非灭菌提供，可重复使用；配合宫腔镜、胸腹腔内窥镜、肾镜及膀胱镜等，通过自然或手术通道进行抓取、咬切、分离组织或异物等用。	Mainly made of stainless steel; Mainly 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 grabbing, biting, separating tissues or foreign matter via natural or surgical channel.	II
144	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	胸腹腔内窥镜用手术器械	Abdominal cavity endoscopic surgical instruments	胸腹腔内窥镜用手术器械为内窥镜下无源组件，用聚砜树脂、不锈钢等材料制成，由管路、穿刺针、穿刺针套管、钳子、打结推杆、肌瘤螺杆、探杆、组织牵开器、棉签施用器、扩张器、手术钩、冲洗装置、封帽、连接器、适配器等组成；可按材质、设计、技术参数、工作部位、预期用途等不同分为若干型号及规格；可以以灭菌/非灭菌形式提供；与胸腹腔内窥镜配合使用,用于患者胸腹腔疾病的诊断和治疗。	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	II
145	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	腹腔镜气腹机	Laparoscopic pneumoperitoneum Insufflator	腹腔镜气腹机由气体过滤、温控、压力控制、处理\显示及附件（如脚踏开关）等组成，可按设计、技术参数、附加辅助功能等不同分为若干型号；产品用于腹腔镜微创手术时向腹腔内充气形成气腹，提供手术的空间和视野。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	腹腔镜加压冲\吸仪	Laparoscopic pressurized punch\suction device	腹腔镜加压冲\吸仪由主机（含控制单元）、气路、液路及气液转换针等附件组成，可按设计、技术参数、附加辅助功能等不同分为若干型号；供腹腔镜手术时对手术部位充气、冲洗和液体吸引用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	内窥镜用异物钳	Foreign body forceps for endoscope	内窥镜用异物钳用不锈钢和塑料等制成，由钳头、外套管、连杆、钳柄组成，钳头类型分为鳄嘴头、锯齿头、麦粒头、取珠式、新锯齿头、杯型头、取笔套式、反二爪、花生米式、三爪等，可按材质、设计、技术参数等不同分为若干型号及规格；可以灭菌或非灭菌状态提供；可与气管镜、食管镜及喉镜等配套，供气管或上消化道等钳取异物用。	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	II
148	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	光学硬管镜用摄像系统	Camera system for optical rigid tube lens	光学硬管镜用摄像系统由相机控制器、镜头、电缆等组成，可以包括图像处理软件；可按设计、技术参数、适用光学镜等不同分为若干型号；与光学内窥镜和摄像系统配合，提供目标区域的视频图像用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	一次性使用内窥镜给药管	single-use endoscope drug administration tube	一次性使用内窥镜给药管由不锈钢和聚乙烯、ABS等制成，通常由喷洒头、导管、接头等组成，可包括导丝，可按材质、设计、技术参数、适用部位、预期用途等不同分为若干型号与规格；以无菌形式提供；与内窥镜配合，用于灌洗、喷洒药液、造影、移动胆石/胆砂等用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	一次性使用内窥镜用先端帽	Tip cap for single-use endoscope	一次性使用内窥镜用先端帽用硅橡胶等制成，可按材质、技术参数、适用内窥镜等不同分为若干种；无菌状态提供；安装于内镜先端部，以保持适当的内镜视野。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	一次性使用内窥镜用结扎线剪	Ligature wire cutting scissors for single-use endoscope	一次性使用内窥镜用结扎线剪用聚氯乙烯、聚苯砵、不锈钢等制成，通常由手柄、管身、刀头/剪刀收纳部组成；可按材质、设计、技术参数、适用部位等不同分为若干型号及规格；可以灭菌或非灭菌形式提供；与内窥镜配套，供剪断结扎线头等用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	内窥镜弯针持针器	Endoscopic Curved Needle Drivers	内窥镜弯针持针器采用不锈钢、硅胶和树脂等制成，由持针槽、推送杆、控制手柄组成，可按材质、设计、技术参数等不同分为若干种；可以无菌形式提供；供腹腔内窥镜手术中缝合操作作用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	一次性使用内窥镜用套扎器	Single-use endoscope loop ligature	一次性使用内窥镜用套扎器主要由套筒（PC、硅橡胶）、触发拉线（PE纤维、PS）、控制手柄（ABS、Y1Cr18Ni9、硅橡胶）、冲洗接头（ABS、PU）、装载导管（POM、Y1Cr18Ni9）、套圈（天然橡胶）组成，可按材质、设计、技术参数等不同分为若干型号及规格；以无菌形式提供；与内窥镜配套，用于食道静脉曲张的血管结扎。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	一次性使用导光束	Single-use guide beam	一次性使用导光束由光纤和不锈钢头端组成，可按材质、设计、技术参数等不同分为若干种；以无菌形式提供；供脊柱微创手术束式照明用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	带灯医用放大镜	Illuminated Medical Magnifier	带灯医用放大镜由LED灯、物镜、目镜、控制按钮、可充电锂电池和系带组成，可按光源、光学技术参数等不同分为若干种；通过光学放大，用于患者皮肤病变组织的诊查。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	非血管腔道导丝-泌尿道用	Non-vascular cavity guidewire for urinary tract	非血管腔道导丝-泌尿道用由导丝和推管组成，导丝的材质和形状各异：如金属导丝、金属弯头导丝、PE导丝、PTFE导丝、PTFE弯头导丝、PTFE涂覆导丝、PTFE涂覆弯头导丝等，导丝可涂覆亲水涂层；可按产品材质、设计、技术参数、预期用途等不同分为若干型号及规格；以无菌形式提供；内窥镜下与J型导管和微创扩张引流套件配套使用，起支撑、引导作用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	食道贲门狭窄扩张器	Esophageal cardia stricture dilator	食道贲门狭窄扩张器由扩张条（有X射线显影标志）、导引钢丝、安全软弹簧等组成，扩张条采用软聚氯乙烯塑料制成，导引钢丝采用镍钛合金制成，可按材质、设计、直径/长度等不同分为若干型号和规格；可以以灭菌/非灭菌形式提供；供内窥镜下食道、贲门狭窄扩张治疗用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	视野计	perimeter	视野计主要由背景屏、刺激点显示装置、颌托、额托、瞳孔监测装置、反应装置、非独立升降台、控制电路/计算机主机等组成，可按设计、技术参数、附加辅助功能等不同分为若干型号；用于对视路疾病的判断和诊断，如青光眼、眼底病等。视野随诊还能用以判断某些疾病的发展状况，用于指导治疗。产品性能指标采用下列参考标准中的适用部分，如：YY 0676-2008眼科仪器 视野计。	Mainly consist of background screen, stimulate point display device, jaw mold, forehead mold, pupil monitoring devices, reactor, non-independent elevator, control circuit/mainframe, etc..Can 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 Ophthalmic instruments—	II
159	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	手动角膜曲率计	Manual keratometry	手动角膜曲率计为手动估读式，由曲率计部件、运动底座、仪器台、电箱、头架五部分组成，可按设计、技术参数、附加辅助功能等不同分为若干型号；供检查角膜的曲率及散光轴位测量用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	角膜曲率计	Keratometry	角膜曲率计由主机(光学系统、观察系统和控制系统)、可移动工作台和头托构成；可按设计、技术参数、附加辅助功能等不同分为若干型号；供测量患者角膜和角膜接触镜的中心曲率和子午方向用。产品性能指标采用下列参考标准中的适用部分。如：YY 0579-2005角膜曲率计。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	角膜地形图仪	Corneal topography instrument	角膜地形图仪由数据采集单元, 数据校正/处理单元及附件组成, 可包括计算机及专用软件, 可按工作原理、设计、技术参数、附加辅助功能等不同分为若干型号; 通过非接触方式测量人眼角膜表面形状, 获得角膜曲率及屈光力等参数用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0787-2010眼科仪器 角膜地形图仪。	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 Ophthalmic instruments—	II
162	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	眼底照相机	Fundus Camera	眼底照相机主要由大物镜系统、照明系统、图像系统、显示系统、控制器组成, 也可包括计算机及数据管理专用软件, 可按设计、技术参数、附加辅助功能等不同分为若干型号; 适用于在无需散瞳的情况下, 对患者眼底进行观察、拍摄, 获取视网膜图像用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0634-2008眼科仪器 眼底照相机。	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	II
163	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	压平眼压计	Flatten ophthalmotonometer	压平眼压计为光学压平式, 由压重控制箱、双像棱镜、测量臂、测量旋钮、安装组件和校准组件组成, 可按与裂隙灯显微镜的连接方式等不同分为若干型号; 供人眼内压测量用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	回弹式眼压计	Springback ophthalmotonometer	回弹式眼压计由探针、测量系统、显示系统组成, 可按设计、技术参数、附加辅助功能等不同分为若干型号; 供人眼内压测量用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	非接触式眼压计	Non-contact ophthalmotonometer	非接触式眼压计由显示系统、喷气、测量光路系统及三维运动系统组成, 可按设计、技术参数、附加辅助功能等不同分为若干型号; 供人眼内压测量用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	非血管腔道导丝-消化道、气道用	Non-vascular cavity guidewire-digestive tract, airway	非血管腔道导丝-消化道、气道用由导丝杆、弹簧软头和导丝芯组成；弹簧软头可由聚氨酯等材料制作、导丝杆和导丝芯由镍钛合金制成，头部不透X线，导丝可有覆亲水涂层，可按产品材质、设计、技术参数、预期用途等不同分为若干型号和规格；应以无菌状态提供；与内窥镜配套，供消化系统或气道引导或导入其他器械用。	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	III
167	6822	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	鼻窦照明系统	Sinus lighting system	鼻窦照明系统由光缆连接器、含导丝的柔性管以及远端和近端光学透镜组成，可按设计、技术参数等不同分为若干种；柔性管以无菌形式提供；与适配光源配套，供临床用于鼻和鼻窦结构内照明/透照。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	电子上消化道内窥镜	Electronic upper gastrointestinal endoscopes	电子上消化道内窥镜为软性电子内窥镜，一般由头端部、弯曲部、插入部及电气和光源连接的部分组成。头端部的CCD将接收到的光学信号转换为电信号，通过摄像系统在显示器上观察。通过视频监视器提供影像供上消化道（不包含十二指肠）的观察、诊断、摄影用。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	高频内窥镜手术器械	High frequency endoscopic surgical instruments	用于在内窥镜下完成手术操作的高频电极，属于高频手术设备的应用部分；在内窥镜手术下，通过内窥镜器械孔道或其他器械通道进入人体；在内窥镜手术中用于对人体组织进行常规的切割和凝血。	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	医用光学器具、仪器及内窥镜设备	Medical optical equipment, instruments and endoscopic equipment	硬性光学腹腔镜	Rigid Optical abdominal endoscopes	硬性光学腹腔镜一般由光学成像系统和照明系统组成。光学成像系统由物镜系统、转像系统、目镜系统三大系统组成。照明系统一般为光学纤维。被观察物经物镜所成的倒像，通过转像系统将倒像转为正像，并传输到目镜，再由目镜或摄像系统放大用于观察。用于腹部微创手术中观察成像用。	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	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	超声机械扫描探头	ultrasonic mechanical scanning probe	超声机械扫描探头通常由超声换能器和/或超声换能器阵元组, 声透镜、壳体、电缆线等组成, 换能器阵元平面或凸阵排列, 可以按结构、型式、技术参数和功能等不同分为若干型号, 与超声设备配套, 经完好的皮肤、腔道粘膜 (如阴道、直肠, 不包括经食道超声探头、上下消化道超声内窥镜的超声部分) 实现包括生物信息采集、组织成像等预期功能。产品性能指标采用下列参考标准中的适用部分, 如: GB 10152-2009 B型超声诊断设备。	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	II
172	6823	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	电子线阵探头	Electronic linear array probe	电子线阵探头通常由超声换能器和/或超声换能器阵元组, 声透镜、壳体、电缆线等组成, 换能器阵元平面排列, 可以按结构、型式、技术参数和功能等不同分为若干型号, 与超声设备配套, 经完好的皮肤、腔道粘膜 (如阴道、直肠, 不包括经食道超声探头、上下消化道超声内窥镜的超声部分) 实现包括生物信息采集、组织成像等预期功能。产品性能指标采用下列参考标准中的适用部分, 如: GB 10152-2009 B型超声诊断设备。	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	II
173	6823	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	电子凸阵探头	Electronic convex array probe	电子凸阵探头通常由超声换能器和/或超声换能器阵元组, 声透镜、壳体、电缆线等组成, 换能器阵元凸阵排列, 可以按结构、型式、技术参数和功能等不同分为若干型号, 与超声设备配套, 经完好的皮肤、腔道粘膜 (如阴道、直肠, 不包括经食道超声探头、上下消化道超声内窥镜的超声部分) 实现包括生物信息采集、组织成像等预期功能。产品性能指标采用下列参考标准中的适用部分, 如: GB 10152-2009 B型超声诊断设备。	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	II
174	6823	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	超声脉冲回波成像设备	Ultrasonic pulse echo imaging equipment	超声脉冲回波成像设备利用超声脉冲回波原理, 完成人体器官组织成像的超声系统。通常由探头 (线阵、凸阵、相控阵、机械扇扫等)、超声波发射/接收、信号处理和图像显示等部分组成; 可按机型、成像性质 (模拟与数字)、探头配置、技术参数、附加辅助功能、软件处理、预期用途等不同分为若干型号; 供腹部器官和部分浅表组织器官的超声成像用。产品性能指标采用下列参考标准中的适用部分, 如: GB 10152-2009 B型超声诊断设备等。	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	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	超声脉冲多普勒成像设备	Ultrasound Pulsed Doppler imaging equipment	超声脉冲多普勒成像设备利用超声多普勒技术和超声脉冲回波原理, 同时进行采集血流运动信息和人体器官组织成像的超声系统。通常由探头(相控阵、线阵、凸阵、机械扇扫、三维探头、内窥镜探头等)、超声波发射/接收电路、信号处理和图像显示等部分组成; 可按机型、成像性质(模拟与数字)、探头配置、技术参数、附加辅助功能、软件处理、预期用途等不同分为若干型号; 主要用于心脏、腹部器官的超声成像与血流运动信息采集。产品性能指标采用下列参考标准中的适用部分, 如: GB 10152-2009 B型超声诊断设备等。不包括彩色血流成像部分。	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:	II
176	6823	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	医用超声雾化器	Medical ultrasonic nebulizer	医用超声雾化器可由主机(含雾化及控制部分)及雾化输送附件组成, 可按结构、组成、技术参数、附加辅助功能等不同分为若干型号, 雾化药物供治疗用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0109-2003超声雾化器。	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	II
177	6823	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	超声多普勒血流分析仪	Ultrasonic doppler blood flow analyzer	超声多普勒血流分析仪利用超声多普勒频移原理, 用来探查、测量非胎儿的血流的运动信息。通常由探头(一般采用单元探头)、超声波发射/接收电路、信号处理和显示等部分组成; 可按机型、成像性质(模拟与数字)、探头配置、技术参数、附加辅助功能、软件处理、预期用途等不同分为若干型号; 主要用于经颅、颈部和外周血管的血流测量, 不包括分析诊断功能。YY 0593-2005 超声经颅多普勒血流分析仪等。	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	II
178	6823	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	超声多普勒胎儿监护仪	Ultrasonic Doppler fetal monitor	超声多普勒胎儿监护仪利用超声多普勒原理, 在围产期对胎儿进行连续监护, 并在出现异常时及时提供报警信息的超声仪器。通常由超声探头(一般采用梅花式探头)、宫缩压力传感器及与之相连的主机组成; 可按机型、探头配置、技术参数、附加辅助功能、软件处理、预期用途等不同分为若干型号; 主要用于围产期胎儿心率和孕妇宫缩压力等的连续监护。	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	II

179	6823	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	超声多普勒胎儿心率仪	Ultrasonic Doppler fetal heart rate meter	超声多普勒胎儿心率仪根据多普勒原理从孕妇腹部获取胎心运动信息的超声仪器。通常由探头（一般采用单元探头）、超声波发射/接收电路、信号输出部分组成。可按机型、探头配置、技术参数、附加辅助功能、软件处理、预期用途等不同分为若干型号；供胎儿心率测量用。产品性能指标采用下列参考标准中的适用部分，如：YY 0448-2009超声多普勒胎儿心率仪。	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	II
180	6823	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	超声多普勒脐带血流分析仪	Ultrasonic Doppler umbilical cord blood flow analyzer	超声多普勒脐带血流分析仪由主机和超声多普勒探头组成，可按设计、技术参数、辅助功能等不同分为若干型号及功能；采用多普勒超声技术，对围产期胎儿脐带血流进行检测/监护用。	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	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	超声内窥镜专用水囊	Ultrasonic Endoscopic dedicated bladders	超声内窥镜专用水囊用天然胶乳/硅胶和聚四氟乙烯等材料制成，由水囊和水囊外套管组成，水囊外套管由插入部、连接部构成；安装于超声内窥镜前端，注无菌生理盐水膨胀后作为超声传导介质；可按材质、容量、形状、使用部位等不同分为若干种；以无菌形式提供（接头可为非无菌）；供超声内窥镜检查时探头与被检查部位皮肤/粘膜间的耦合用。	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	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	超声洁牙机	Ultrasonic scaler	超声洁牙机将超声能量通过手柄尖端作用于牙齿，去除牙齿上的结石沉积等；通常由超声波发生器、手柄、与手柄相配接的各种作用头（尖端）组成，可有冲洗部分；可按设计、技术参数、是否带工作头、附加辅助功能等不同分为若干型号；供临床去除牙垢用。产品性能指标采用下列参考标准中的适用部分，如：YY 0460-2009超声洁牙设备。	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	II
183	6823	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	超声引导宫腔手术监视仪	Ultrasound-guided uterine surgery Monitor	超声引导宫腔手术监视仪由主机、专用凸阵探头和监视器组成，超声成像部分可以是模拟或数字化成像，主机可以包括人流用负压吸引系统和相关专用附件，设备可按设计、技术参数、辅助功能、附件等不同分为若干型号；供人工流产、取放节育环等妇产科手术的实时监测及腹部超声检查等用。	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	II

184	6823	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	无菌超声探头穿刺支架	Sterile ultrasound probe puncture bracket	无菌超声探头穿刺支架可由钛合金、不锈钢或适用的高分子材料制成，可由探头固定部分与穿刺针固定部分组成，固定部分可分别有一定的调节范围，可按支架材质、设计、调节范围、固定探头、穿刺针种类不同分为若干型号；以无菌形式提供；可与腔内或体外各类超声探头配套，用于固定超声探头或穿刺针用。	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 ultrasonic probe or puncture	II
185	6823	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	消毒型医用超声耦合剂	Disinfection medical ultrasound coupling agent	消毒型医用超声耦合剂可由消毒剂（如三氯羟基二苯醚）、丙二醇、丙三醇（甘油）、三乙醇胺、卡波姆（交联聚丙烯酸树脂）组成；可按配方、技术参数、适用部位、装量等不同分为若干型号及规格；供超声诊断或治疗操作中，充填或涂敷于皮肤-黏膜与探头（或治疗头）辐射面之间，用于透射声波的中介媒质，用于改善探头与患者皮肤/粘膜之间的超声耦合效果，并具有消毒皮肤、粘膜功能。	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	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	腔道用医用超声耦合剂	Medical ultrasound coupling agent for cavity	腔道用医用超声耦合剂由博克-DP（三氯羟基二苯醚）、丙二醇、丙三醇三乙醇胺、卡波姆（交联聚丙烯酸树脂）组成；可以以无菌形式提供；涂布与腔内超声探头头端，供提高腔内粘膜与探头的超声耦合用。	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	医用超声仪器及有关设备	Medical ultrasound equipment and related equipment	眼科专用超声脉冲回波设备	Ultrasonic pulse echo equipment special for ophthalmology	包括眼科A超、B超和A/B超由主机和探头组成，其探头标称频率一般在10MHz以上，利用超声脉冲回波原理，完成眼科诊断信息采集、显示、测量。专用于眼科的超声诊断设备，可实现眼球及眼眶的超声成像、角膜厚度测量、眼轴长度测量等功能。	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 length measuring.	II
188	6824	医用激光仪器设备	Medical laser equipment	医用激光光纤	Medical laser fiber	医用激光光纤由设备接头、光纤管、病人端及塑料盘管组成；可按接头、管长等不同分为若干型号或规格；可以以无菌形式提供；与医用激光治疗仪配套，传输激光器产生的能量，供激光手术用。	Consist of the connectors, optical fibre, patient end and plastic coiler; Can be divided into different specifications according to connector, tube length, etc..Sterile state; Use with laser therapeutic instrument to transmit energy for laser surgery.	II
189	6824	医用激光仪器设备	Medical laser equipment	一次性使用鼻腔内照射光纤头	Single-use nasal irradiation fiber head	一次性使用鼻腔内照射光纤头由接头、光纤管、塑料盘管组成，病人端为U型，可按接头、管长等不同分为若干型号或规格；与适用的激光器配套，利用光纤的光导原理，将激光导入鼻腔，供对鼻腔内的毛细血管进行照射用。	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	医用高频仪器设备	High-frequency medical equipment	高频电灼器	High-frequency electrocautery	高频电灼器由主机、多种治疗器、附件组成，通常额定频率、输出功率远低于高频手术设备，可按设计、型式、技术参数、预期用途等不同分为若干型号；可分别供腋下汗腺、直肠痔疮、妇科外阴、宫颈、五官科等体表、浅表自然腔道局部病变组织的凝固、汽化用。	Mainly consist of host, therapeutic 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, etc..Used for coagulation, vaporization the localized lesions of underarm sweat glands, rectal hemorrhoids, gynecological vulva, cervix, ENT and other surface, superficial	II
191	6825	医用高频仪器设备	High-frequency medical equipment	一次性使用高频手术设备用阴极板	Single-use cathode plate for high frequency surgical equipment	一次性使用高频手术设备用阴极板通常由隔离纸、导电胶、铝箔、基衬（如聚乙烯发泡或无纺布涂丙烯酸压敏胶）和电极导线组成，按照导电介质（金属电极导电/离子导电胶导电）、使用人群（成人型/儿童型）、电极数量（单极/双极）及形状（方型/椭圆型）、是否带导线等分为不同的型号和规格；连接人体和高频手术设备，提供低电流密度的高频电流回路，防止人体灼伤用；双极中另一极供高频手术设备报警回路用。产品性能指标采用下列参考标准中的适用部分，如：GB 9706.4医用电气设备 第2-2部分：高	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 Of high frequency surgical equipment	II
192	6825	医用高频仪器设备	High-frequency medical equipment	高频手术电极（电刀笔、电凝钳、电凝剪、电凝镊）	HF surgical electrodes (electric knife pen, coagulation forceps, coagulation scissors, coagulation)	高频手术电极是高频手术设备的附件，通常由设备端高频插头、高频导线、手持工作端（可含手柄、手控开关/也可另配脚踏踏板和单/双极金属电极头端，还可附带降温供水系统）组成，附件可按工作原理、降温等附加功能、技术参数、预期功能等不同分为若干类别、型号和规格；可以以灭菌/非灭菌形式提供；与高频手术设备配套，供临床各类外科手术中分别用于组织切割、分离、血管夹闭止血、组织凝固等。产品性能指标采用下列参考标准中的适用部分，如：GB 9706.4医用电气设备 第2-2部分：高频手术设备安全专用要求。	It is a assessor 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 cutting, isolating, vascular occlusion hemostasis, tissue coagulation. Reference standard:GB 9706.4 Medical electrical equipment - Part 2-2: Particular requirements for the safety Of high frequency surgical equipment	III
193	6825	医用高频仪器设备	High-frequency medical equipment	无菌管路高频连接仪	Aseptic pipeline high-frequency connection device	无菌管路高频连接仪采用高频辐射加热方法使两个高分子制无菌管路实施无菌连接；仪器通常由高频发生器、输出和控制器组成，借助模具，可热合不同管径的无菌管路；供临床现场热合输液管路等无菌管路用。	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	医用高频仪器设备	High-frequency medical equipment	高频手术设备	High frequency surgical equipment	通常包括高频发生器主机及其他相关附件（脚踏开关、手术电极、中性电极等）；利用高频电流（频率范围200k—5MHz）直接流经人体产生热效应从而对人体组织进行常规切割和凝血；用于传统电外科手术中对人体组织进行常规切割和凝血。高频发生器频率范围应仅限于GB 9706.4中所规定范围200k—5MHz；适用范围仅限于常规的组织切割和凝血手术（普通外科、耳鼻喉科、神经外科、妇科、腹腔镜手术等）；某些特殊临床应用或使用方式不建议豁免临床	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	医用高频仪器设备	High-frequency medical equipment	射频消融用针状电极	Radiofrequency ablation needle shape	射频消融用针状电极通常配合穿刺针、套管等成套使用，属于射频消融设备的应用部分。消融针上含有测温传感器；把射频发生器产生的高频电流传递至指定的人体组织，从而实现对其消融/凝固/坏死等目的；与射频发生器（射频控制器）配合使用，用于人体组织的消融。	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/necrosis, etc.; Use with RF generator for human tissue ablation.	II
196	6825	医用高频仪器设备	High-frequency medical equipment	氩气控制器	Argon controller	包括控制器和氩气喷笔等附件；通过气体减压阀及氩气控制模块将高纯氩气瓶中的高压氩气转化为工作需要的可调节低流量氩气，与高频刀合用成为氩气刀；与高频电刀配合使用，在电外科手术中实现氩气环境下的凝血。	Mainly consist of controllers and airbrush argon; The high purity argon can be transmitted 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 electric surgery.	II
197	6826	物理治疗及康复设备	Physiotherapy and rehabilitation equipment	足托	Foot Orthosis	足托为无源器械，由L形夹板、鞋垫内衬、水垫、防旋转条、魔力贴、聚氯乙烯磨砂搭扣和安全粘脚板保护垫等组成；用于保持足、踝关节的生理体位，预防和治疗因各种原因引起或可能引起的足下垂及其继发病。	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	物理治疗及康复设备	Physiotherapy and rehabilitation equipment	关节持续被动活动仪（CPM仪）	Joint continuous passive motion device (CPM instrument)	关节持续被动活动仪（CPM仪）为有源设备，通常由主机、控制部分和关节固定部分组成，可按固定关节、技术参数、附加功能等不同分类若干型号；通过电动机械结构使患者相应关节反复被动屈伸，持续被动运动可以刺激关节，使其生理性关节液产生良性循环，减轻关节肿胀，可防止或治疗因创伤或运动不足等原因导致或可能导致的关节运动幅度减小，关节僵硬和静脉栓塞等。	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 lack of exercise.	II
199	6826	物理治疗及康复设备	Physiotherapy and rehabilitation equipment	电动牵引床	Electric traction bed	电动牵引床由床体、牵引动力系统、控制系统及附属部件构成，可按设计型式、技术参数、适用部位、预期用途等不同分为若干型号，可分别供颈、腰椎适应症的牵引治疗，不包括快牵牵引床。产品性能指标采用下列参考标准中的适用部分，如：YY 0697-2008电动牵引床。	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, etc..Used for cervical, spinal traction treatment. Does not include quick pulling traction bed. Reference standard: YY 0697-2008 Dynamoelectric traction-table	II

200	6826	物理治疗及康复设备	Physiotherapy and rehabilitation equipment	电动颈椎牵引装置	Electric cervical traction device	电动颈椎牵引装置由牵引动力系统、控制系统及附属部件构成, 可按设计型式、技术参数、适用部位、预期用途等不同分为若干型号, 可供颈椎适应症的牵引治疗。不包括快牵装置。	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, etc..Used for cervical indications traction treatment. Does not include quick pulling traction	II
201	6826	物理治疗及康复设备	Physiotherapy and rehabilitation equipment	振动叩击排痰机	Tapping vibration expectoration machine	振动叩击排痰机主要由主机、传动软轴和多种叩击头组成, 叩击头转速、叩头频率、强度可调、叩击模式、工作时间可调, 可有多路输出, 可按设计、技术参数、适用对象等不同分为若干型号。通过振动叩击,改善患者肺部血液循环状况、协助排出呼吸道分泌物。	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 secretions.	II
202	6826	物理治疗及康复设备	Physiotherapy and rehabilitation equipment	熏蒸仪	Fumigation instrument	熏蒸仪由药液箱、进/出液管路、加热装置、温度/液位等控制单元、显示单元、治疗头等组成 (不包括药物), 可按设计、技术参数、适用部位、预期用途、辅助功能等不同分为若干型号; 可配合药液, 用于人体局部熏蒸治疗。	Mainly 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	物理治疗及康复设备	Physiotherapy and rehabilitation equipment	熏蒸床	Fumigation bed	熏蒸床可由床体、控制单元、药槽、温度控制器、液位控制器、加热装置、液晶显示屏等组成 (不包括药物); 可按设计、技术参数、适用部位、预期用途、辅助功能等不同分为若干型号; 可配合药液, 用于人体躯干等部位熏蒸治疗。	Mainly 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 other parts	III
204	6826	物理治疗及康复设备	Physiotherapy and rehabilitation equipment	加压氧舱	Pressurized oxygen chamber	一般由舱体、供排氧系统、空调系统和控制系统组成。加压介质为医用氧气, 最高工作压力不大于0.2MPa, 进仓人数为1人。旨在供需要按照处方规定进行高浓度辅助供氧的成人患者使用, 用于缺血、缺氧性疾病的辅助治疗。将病人暴露于高压氧环境中, 使其呼吸高压氧, 达到治疗疾病的目的。供需要按照医师处方进行辅助供氧的治疗的成人患者使用, 用于缺血、缺氧性疾病的辅助治疗。	Mainly 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	II

205	6826	物理治疗及康复设备	Physiotherapy and rehabilitation equipment	空气加压舱	Air pressurized cabin	一般由舱体(壳体、舱门、观察窗、安全阀等)、供排气系统、供排氧系统、空调系统、电气系统、水喷淋系统、控制台组成。加压介质为空气，最高工作压力不大于0.3MPa的氧舱。根据舱内治疗人数不同分为单人氧舱和多人氧舱。将病人暴露于高压氧环境中，使其呼吸高压氧，达到治疗疾病的目的。供需要按照医师处方进行辅助供氧治疗的成人患者使用，用于缺血、缺氧性疾病的辅助治疗。	Mainly 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 adjuvant therapy	II
206	6827	中医器械	Traditional Chinese medical equipment	针灸针	Acupuncture needles	针灸针由针体和针柄构成，针体材料可以用奥氏体不锈钢等适用材料制成，针柄可以用不锈钢丝（管）或铜丝（管）或铝丝（管）或聚丙烯等制成，按是否带进针管，针柄型式（如环柄针、平柄针、花柄针、塑柄等）、针体直径及长度等不同分为若干型式和规格；可以灭菌或非灭菌状态提供；供专业人员用于人体体表穴位（含耳穴）不同深度的侵入式刺激用。产品性能指标采用下列参考标准中的适用部分，如：GB 2024-1994 针灸针。	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	II
207	6827	中医器械	Traditional Chinese medical equipment	揸针	press-needle	揸针通常由针体和针盘构成，也可粘贴于适形的敷贴上以方便留置，针体、针座多采用奥氏体不锈钢丝等适用材料经磨抛绕制而成，按预期用途、结构型式、针径、长度等不同分为若干型号和规格；多以非灭菌状态提供；供专业人员用于人体体表穴位（含耳穴）的表浅侵入式刺激。产品性能指标采用下列参考标准中的适用部分，如：YY 0105-1993揸针。	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	中医器械	Traditional Chinese medical equipment	三棱针	three edged needle	三棱针多采用奥氏体不锈钢制成，由柄和棱形头端组成，可按针柄型式、尺寸等不同分为若干型号和规格；供人体末梢采血或穴位点刺等用。产品性能指标采用下列参考标准中的适用部分，如：YY 0104-1994 三棱针。	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	II
209	6827	中医器械	Traditional Chinese medical equipment	皮内针	Intradermal needle	皮内针由针尖和针盘两部分组成，也可粘贴于适形的敷贴上以方便体表留置，多采用奥氏体不锈钢丝等适用材料经磨抛绕制而成，按预期用途、结构型式、针径、长度等不同分为若干型号和规格，可以灭菌和非灭菌状态提供，供专业人员用于人体体表穴位（含耳穴）的表浅侵入式留置刺激。产品性能指标采用下列参考标准中的适用部分，如：YY 0105 揸针。	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	中医器械	Traditional Chinese medical equipment	梅花针	Plum Needle	梅花针，又称七星皮肤针，由针尖、针座和手柄三部分构成，针体采用奥氏体不锈钢丝制成，针座和手柄可采用牛角或珠光塑料制成，可按型式（单、双头）和聚针、散针针径等不同分为若干型号和规格；可以灭菌或非灭菌形式提供；供专业人员用于体表穴位的多针浅表侵入式刺激用。	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	II
211	6827	中医器械	Traditional Chinese medical equipment	小针刀	Small needle-knife	小针刀疗法是一种介于手术方法和非手术疗法之间的闭合性松解术，其操作的特点是在治疗部位刺入深部到病变处进行切割，剥离有害的组织，以达到止痛祛病的目的。小针刀是形状上似针又似刀的一种针灸用具，分手持柄、针身、针刀三部分，通常刀与针同宽，刃口锋利，可按形状和长短等不同分为若干型号和规格；可以以灭菌/非灭菌形式提供，供软组织损伤性病变和骨关节病变非直视下松解	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 cut or isolate injury tissue.	II
212	6827	中医器械	Traditional Chinese medical equipment	负压理疗器	Negative pressure physiotherapy device	负压理疗器通常由手动/动力负压装置和多个负压罐组成，可按负压原理、设计、技术参数、适用部位、预期用途等不同分为若干型号及规格；供体表穴位负压拔罐理疗用。	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	II
213	6830	医用X射线设备	Medical X-ray equipment	乳腺X射线摄影设备	Breast X-ray imaging equipment	乳腺X射线摄影设备一般采用钼或铑等材料制X射线管靶面，配合较低的管电压来形成低能量的X射线束，配有乳腺压迫器，影像分析和显示系统的专用X射线摄影设备；可按设计、技术参数、附加辅助功能等不同分为若干型号；专用于对人体乳腺组织摄影，获取组织影像供临床诊断。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0706-2008乳腺X射线机专用技术条件，YY/T 0741数字化医用X射线摄影系统专用技术条件等。	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. Mainly 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	II
214	6830	医用X射线设备	Medical X-ray equipment	牙科X射线机	Dental X-ray machine	牙科X射线机一般包括组合机头、口内影像接收器、可能有伸缩曲臂等部件，为专用X射线机；可按设计、技术参数、附加辅助功能等不同分为若干型号；专用于对牙齿X射线摄影，获得影像供临床诊断（不包括全景摄影）。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0106-2008医用诊断X射线机通用技术条件，YY/T 0741数字化医用X射线摄影系统专用技术条件，YY/T 0010-2008口腔X射线机专用技术条件等。包括便携设备。	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	II

215	6830	医用X射线设备	Medical X-ray equipment	X射线透视设备	X-ray perspective equipment	X射线透视设备利用人体不同组织和器官对射线衰减不同的原理, 通过对X射线源的连续加载, 在成像介质上转化为动态影像的通用X射线设备。该类设备具有X射线源, 成像介质包括荧光屏、电视系统等, 还可能带有患者支撑装置等; 可按设计、技术参数、附加辅助功能等不同分为若干型号; 仅用于对患者的透视, 获得连续影像供临床诊断。包括遥控设备及数字化设备。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0106-2008医用诊断X射线机通用技术条件, YY/T 0741数字化医用X射线摄影系统专用技术条件,YY/T 0475-2009遥控透视X射线机专用技术条件等。	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 0475-2009 General technical	II
216	6830	医用X射线设备	Medical X-ray equipment	X射线摄影设备	X-ray radiographic equipment	X射线摄影设备利用从X射线管发射出的X射线穿过患者身体不同组织和器官时, 对射线衰减不同的原理, 将穿过患者且携带足够信息的X射线投射到成像介质上, 转化为可见的平面灰度影像的通用X射线设备。该类设备具有X射线源, 成像介质包括胶片、影像板、数字平板等, 还可能配有患者支撑装置等; 可按设计、技术参数、附加辅助功能等不同分为若干型号; 仅用于对患者的摄影, 获得单幅影像供临床诊断。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0106-2008医用诊断X射线机通用技术条件, YY/T 0741数字化医用X射线摄影系统专用技术条件等	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 specifications for	II
217	6830	医用X射线设备	Medical X-ray equipment	X射线透视、摄影设备	X-ray perspective, radiographic equipment	X射线透视、摄影设备兼具有X射线摄影和透视功能的通用X射线设备。该类设备具有X射线源, 成像介质包括胶片、影像板、荧光屏、电视系统、数字平板等, 还可能带有患者支撑装置等。可按设计、技术参数、附加辅助功能等不同分为若干型号; 用于对患者的摄影和透视, 获得单幅或连续影像供临床诊断。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0106-2008医用诊断X射线机通用技术条件, YY/T 0741数字化医用X射线摄影系统专用技术条件等。	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	II

218	6830	医用X射线设备	Medical X-ray equipment	移动式X射线机	Mobile X-ray machine	移动式X射线机带有滚轮等装置, 在使用中可方便移动的通用X射线设备。该类设备具有X射线源, 成像介质包括胶片、数字平板等; 可按设计、技术参数、附加辅助功能等不同分为若干型号; 用于将X射线机移动至病房、手术室等地对不宜搬动的患者进行摄影或透视使用。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0106-2008 医用诊断X射线机通用技术条件, YY/T 0741 数字化医用X射线摄影系统专用技术条件, YY/T 0707-2009 移动式X射线机专用技术条件、YY/T 0744-2009 移动式C型臂X射线机专用技术条件等。	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	医用X射线设备	Medical X-ray equipment	携带式X射线机	Portable X-ray machine	在使用时或使用的间隔期间, 可由一个人或几个人携着从一个地方移到另一个地方的X射线机, 主要部件包括X射线管头等; 可按设计、技术参数、附加辅助功能等不同分为若干型号; 适用于骨科或野外条件下, 对四肢, 或其他较小、较薄部位进行X射线临床检查。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0106-2008 医用诊断X射线机通用技术条件, YY/T 0741 数字化医用X射线摄影系统专用技术条件等。可按设计、技术参数、附加辅助功	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	医用X射线设备	Medical X-ray equipment	胃肠X射线设备	Gastrointestinal X-ray equipment	使用时一般通过透视动态图像锁定感兴趣区, 而后用较大剂量摄影得到该区域清晰的静态图像。该类设备具有X射线源, 高压发生装置, 图像显示系统, 专用胃肠床, 还可能有压迫器、点片装置等。可按设计、技术参数、附加辅助功能等不同分为若干型号; 专用于临床胃肠道X射线透视及摄影检查, 获得影像供临床诊断。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0106-2008 医用诊断X射线机通用技术条件, YY/T 0741 数字化医用X射线摄影系统专用技术条件, YY/T 0742-2009 胃肠X射线机专用技术条件等。	X-ray radiographic and radioscopy apparatus, lock the interest 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	II

221	6830	医用X射线设备	Medical X-ray equipment	X射线骨密度仪	X-ray bone densitometer	X射线骨密度仪根据不同密度的骨骼和组织对X射线的吸收程度不同, 通过将接收到的带有人体信息的数字信号输入电脑进行分析得出骨密度的结果。该类设备具有X射线源, 探测器, 信息分析和显示系统, 还可能有患者支撑装置; 可按设计、技术参数、附加辅助功能等不同分为若干型号; 通过对人体的X射线衰减测量, 专用于评估患者骨骼及邻近组织的骨密度和矿物质含量, 以供临床诊断。包括数字式X射线骨密度仪。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0724双能X射线骨密度仪专用技术条件。	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	II
222	6830	医用X射线设备	Medical X-ray equipment	车载X射线机	Car X-ray machine	车载X射线机安装在可移动运输工具上的X射线机, 有透视和/或摄影功能。可按设计、技术参数、附加辅助功能等不同分为若干型号; 适用于机动条件下, 在远离医院的现场开展X射线透视、摄影诊断检查。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0106-2008医用诊断X射线机通用技术条件, YY/T 0741数字化医用X射线摄影系统专用技术条件, YY/T 0746-2009车载X射线机专用技术条件等。	Mounted on moving vehicle for perspective or photographic functions. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc.. Car X-ray machine, used in maneuver conditions, carry out X-ray photography diagnostic tests away from the hospital. 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	II
223	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	高压发生器	High voltage generator	高压发生器是X射线机的主要部件, 控制和产生供X射线管工作的电能, 通常由高压变压器组件和高压控制器组成; 可按设计、技术参数、附加辅助功能等不同分为若干型号; 为X射线管组件提供电能, 以产生X射线。	It is the main component of X-ray machine, control and generate electrical energy in the X-ray tube, usually contains high-voltage transformer assembly and high-voltage controller. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc.. Used to provide power to the X-ray tube assembly to produce X-rays.	II
224	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线管	X-ray tube	X射线管是X射线机的主要部件, 通过施加在X射线管阴极和阳极之间的高电压, 使阴极表面上的游离电子撞击阳极, 产生X射线, 通过控制加载时间和电压电流, 达到不同的医疗诊断目的; 可按设计、技术参数、附加辅助功能等不同分为若干型号; 装配于X射线管组件内。	The free electron on the surface of cathode impact the anode by the high voltage applied the cathode and the anode of X-ray tube, generate X-rays by controlling the load time, voltage and current, to the purpose of different medical diagnostic. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc.. Mounted on X-ray tube	II
225	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	固定阳极X射线管	Fixed anode X-ray tube	固定阳极X射线管是医用X射线发生装置, X射线机的主要部件, 阳极固定, 通过施加在X射线管阴极和阳极之间的高电压, 使阴极表面上的游离电子撞击阳极, 产生X射线, 通过控制加载时间和电压电流, 达到不同的医疗诊断目的, 可按技术参数不同分为若干型号。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0197-2007医用诊断X射线管固定阳极X射线管系列。	It is a medical X-rays generating devices with a fixed anode. The free electron on the surface of cathode impact the anode by the high voltage applied the cathode and the anode of X-ray tube, generate X-rays by controlling the load time, voltage and current, to the purpose of different medical diagnostic. Can be divided into different specifications according to technical parameters. Reference standard: YY/T 0197-2007 X-ray tube for medical	II

226	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	旋转阳极X射线管	Rotating anode X-ray tube	旋转阳极X射线管是医用X射线发生装置，X射线机的主要部件，阳极通过旋转以降低温度，通过施加在X射线管阴极和阳极之间的高电压，使阴极表面上的游离电子撞击阳极，产生X射线，通过控制加载时间和电压电流，达到不同的医疗诊断目的，可按技术参数不同分为若干型号。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0197.5-2007医用诊断X射线管XD51-20、40/100和XD51-20	Decrease temperature by rotating anode. The free electron on the surface of cathode impact the anode by the high voltage applied the cathode and the anode of X-ray tube, generate X-rays by controlling the load time, voltage and current, to the purpose of different medical diagnostic. Can be divided into different specifications according to technical parameters. Reference standard:YY/T 0197.5-2007 X-ray tube for medical diagnosis XD51-20、40/100	II
227	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	栅极控制X射线管	grid electrode control X-ray tube	栅极控制X射线管是在X射线管内部阴极和阳极之间增加栅极，通过控制栅极电压从而产生脉冲X射线；可按设计、技术参数、附加辅助功能等不同分为若干型号；一般装配于血管造影X射线设备的管组件内。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0607-2007医用诊断X射线管组件通用技术条件。	Add grid into the internal X-ray tube between the cathode and the anode, produce pulse X-rays by controlling grid voltage. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc.. Generally assembled in X-ray tube assembly of angiographic equipment. Reference standard: YY/T 0607-2007 General specifications of medical	II
228	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	乳腺X射线管	Breast X-ray tube	乳腺X射线管一般靶材采用钼或铑，管电压较低，产生软射线；可按设计、技术参数、附加辅助功能等不同分为若干型号；专用于乳腺摄影设备用X射线管。产品性能指标采用下列参考标准中的适用部分，如：YY/T0607-2007医用诊断X射线管组件通用技术条件。	General material of target is molybdenum or rhodium, tube voltage is low, resulting in a soft rays. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc. It is a dedicated X-ray tube used in mammography equipment.Reference standard: YY/T0607-2007 General specifications of medical diagnostic X-ray tube assemblies	II
229	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	治疗机用X射线管	X-ray tube for therapeutic machine	治疗机用X射线管最高管电压通常在200kV以上，一般配有冷却装置，可长时间连续工作；可按设计、技术参数、附加辅助功能等不同分为若干型号；装配于X射线治疗设备的管组件内。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0747-2009 XZ1-4/250治疗用X射线管等。	Maximum tube voltage is usually above 200kV, generally equipped with a cooling device, can continuous work for a long time. Can be divided into different specifications according to design, technical parameters, additional auxiliary functions, etc. Fitted into X-ray therapy equipment tube assembly. Reference standard: YY/T 0747-2009 XZ1-4/250 Therapy X-ray tube	II
230	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线管组件	X-ray tube assembly	X射线管组件包括X射线管及管套，管套内装满高压绝缘油并密封，实现绝缘和热交换的目的；可按设计、技术参数、附加辅助功能等不同分为若干型号；装配于X射线设备，来自于高压发生器的高压加在X射线管组件上，产生X射线。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0607-2007医用诊断X射线管组件通用技术条件。	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 requirements for the safety of nerve and muscle	II

231	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	医用X射线限束装置	Medical X-ray beam limiting device	医用X射线限束装置，通常由限束页片/限束门和手动/自动控制部分组成；限束门或页片通常用不透X射线材料如铅制成；通过限制X射线初级线束的几何形状以限制设备的辐射野；可按限束方式及技术参数不同分为若干型号。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0129-2007 医用诊断X射线可变限束器通用技术条件	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	II
232	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线源组件	X-ray source assembly	装配于X射线设备，包括X射线管组件及限束器；可按设计、技术参数、附加辅助功能等不同分为若干型号。	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	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线计算机体层摄影设备用X射线管	X-ray tube for X-ray computed tomography equipment	X射线计算机体层摄影设备用X射线管热容量大，可长时间连续曝光，一般配有冷却装置；主要由管芯、管套和高压电路、循环冷却系统等几部分组成（管芯可由杯状阴极灯丝、旋转阳极钨基钨靶、高速轴承、附属散热装置等部件组成），装配于X射线计算机体层摄影设备（CT）的X射线管组件内；可按设计、技术参数、附加辅助功能等不同	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	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线影像增强器	X-ray image intensifier	X射线影像增强器是医用X射线影像接收装置，将携带患者信息的X射线信号转换为可见光图像的光电真空管，广泛应用于各类X射线设备中，可按转换原理及技术参数等不同分为若干型号。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0457-2003医用电气设备 光电X射线影像增强特性系列，YY/T 0093-2013医用诊断X射线影像增强器。	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	II
235	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线影像增强器电视系统	X-ray image intensifier television system	X射线影像增强器电视系统由X射线影像增强器、光学系统、摄像机信号处理系统及影像显示装置组成的将X射线图像转换成相应的可见光影像的系统；可按设计、技术参数、附加辅助功能等不同分为若干型号；装配于X射线诊断系统，将X射线图像转换成可见光图像。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0608-2013医用X射线影像增强器电视系统通用技术条件。	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 system for medical diagnosis	II

236	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	平板探测器及其影像系统	Flat panel detector and imaging system	平板探测器及其影像系统采用特定的光电转换介质将来自人体的X射线信号转化为数字信号, 进入图像处理显示系统。一般配有平板探测器, 图像传输, 处理和显示系统; 可按工作原理、设计、技术参数、附加辅助功能等不同分为若干型号; 装配于X射线诊断系统, 将X射线信号转化为数字信号。	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 transmit the X-ray signal into a digital	II
237	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	CCD、CCD影像系统及其他数字化成像系统	CCD, CCD imaging systems and other digital imaging	CCD、CCD影像系统及其他数字化成像系统将穿过人体的X射线信号转变成可见光信号, 再通过数字化成像装置, 将光信号转换为数字信号的影像接收及处理系统, 如CCD探测器、CMOS探测器等; 可按工作原理、设计、技术参数、附加辅助功能等不同分为若干型号; 一般装配于X射线诊断系统, 将X射线信号转换成数字信号。	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	II
238	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线摄影用影像板成像装置 (CR)	Image plate imaging device for X-ray photography	X射线摄影用影像板成像装置 (CR) 采用影像板对来自人体的X射线信息收集并形成潜影, 通过激光扫描读取存储在影像板中的信息并送入计算机进行存储、处理和显示。一般包括影像板, 激光扫描装置和显示器等; 可按工作原理、设计、技术参数、附加辅助功能等不同分为若干型号; 可配合医疗机构原有的采用胶片成像的X射线机实现数字化图像的采集、存储、显示和传输等。	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 image 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, display and transmission of the digitized image.	II
239	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线图像处理工作站	X-ray image processing workstation	X射线图像处理工作站用于处理X射线影像的计算机及其附件, 包括软件; 可按设计、技术参数、附加辅助功能等不同分为若干型号; 可配合X射线机, 用于处理、传输数字诊断图像。	Used for processing X-ray image computer and its accessories, 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	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线胃肠摄影床	X-ray Gastrointestinal photography bed	X射线胃肠摄影床是医用X射线诊断附属设备, 多由床体、透X射线的平床 (含点片装置)、遥控操作装置和/或近台操作装置等组成, 可实现摄影床的平移、转动等功能, 可按设计、技术参数、附加辅助功能等不同分为不同型号, 供X射线胃肠摄影时支撑患者, 提供软组织摄影体位用。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0743-2009 X射线胃肠诊断床专用技术条件。	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	II

241	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线导管床	X-ray catheter bed	X射线导管床是医用X射线诊断附属设备，可为无骨架构造，在与C臂、U臂等介入手术X射线设备组合进行多方向观察与摄影时，图像视野不受妨碍，多用于普通介入治疗和数字减影血管造影（DSA）。可按设计、技术参数及功能等不同分为若干型号，供实施介入放射诊断及治疗时支撑患者，提供诊疗体位用。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0738-2009医用X射线导管床专用技术条件。	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:	II
242	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	计算机体层摄影系统（CT）用床	Bed for computed tomography systems (CT)	计算机体层摄影系统（CT）用床通常由底座、透X射线的平床和电动平床驱动及控制部分组成，可包括与患者通讯设施，可实现摄影平床的平移等功能，也可可为无骨架结构；可按设计、技术参数、附加辅助功能等不同分为若干型号；患者支撑装置，配合计算机体层摄影系统（CT）使用。产品性能指标采用下列参考标准中的适用部分，如：GB 9706.18-2006医用电气设备 第二部分：X射线计算机体层摄影设备安全专用要求，YY 0310-2005 X射线计算机体层摄影设备通用技术条件等。	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 supporting 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-ray	II
243	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线体层摄影装置	X-ray tomography device	X射线体层摄影装置能清楚地摄取与人体纵轴相平行的某一层或几层组织的影像，又使其他各体层的影像模糊不清的摄片装置；可按设计、技术参数、附加辅助功能等不同分为若干型号；与摄影平床配合，用于对人体进行体层摄影。	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 tomography.	II
244	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线电动摄影平床	X-ray electric photography flat bed	X射线电动摄影平床是医用X射线诊断附属设备，通常由底座、透X射线的平床（含点片装置）和电动平床驱动及控制部分组成，可实现摄影平床的平移、转动等功能，可按设计、技术参数、附加辅助功能等不同分为若干型号；供X射线检查及摄影时支撑患者，提供普通摄影体位用。	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	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线诊断设备附属电动悬吊、支撑装置（吊架/立柱/导轨）	X-ray diagnostic equipment subsidiary electric suspension, support device (hanger/post/rail)	X射线诊断设备附属电动悬吊、支撑装置（吊架/立柱/导轨）是X射线机的附属设备，通常由基座、立柱、支撑臂等部件构成，可进行电动平移，转动等动作，为支撑X射线管、监视器或人体装置。	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	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	胸片架	sternum stand	胸片架是医用X射线诊断附属设备，由基座、立柱、支撑臂等部件构成，可电动平移，转动等，可按设计、技术参数、附加辅助功能等不同分为若干型号；供支撑X射线监视器和胸片摄影点片装置，提供合适的人体摄片体位等用。	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 radiographs	II
247	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线造影剂注射装置	X-ray contrast agent injection device	X射线造影剂注射装置可由主机（含控制/显示等单元）、注射机头等组成，可带遥控控制装置，可按设计、技术参数、附加辅助功能等不同分为若干型号；通过向人体血管内注入造影剂获得清晰的血管影像，配合专用注射器，用于X射线血管造影时造影剂的注入。YY/T 0891-2013 血管造影高压注射装置专用技术条件。	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	II
248	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	X射线诊断设备附属防散射滤线栅	Subsidiary anti-scatter grids of X-ray diagnostic equipment	X射线诊断设备附属防散射滤线栅是放置于影像接收面之前，以减少辐射到影像接收面上的散射辐射，从而改善X射线影像对比度的一种装置，多由铅条和介质等组成；可按设计、技术参数、附加辅助功能等不同分为若干型号；配合X射线机使用，以增加X射线影像的对比度。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0480-2004诊断X射线成像设备通用及乳腺摄影防散射滤线栅的	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—	II
249	6831	医用X射线附属设备及部件	Module and subsidiary equipment for medical X-ray	医用射线防护喷剂	Medical Radiation Protection Spray	医用射线防护喷剂主要成分为超氧化物歧化酶及其稳定剂，以冻干粉形式存在于可加盖喷雾泵的棕色塑料瓶(A瓶)中，其他辅料(姜黄素、山梨醇、山梨酸钾)以水溶液形式存在于加盖的白色塑料瓶(B瓶)中，可按设计、技术参数、装量等不同分为若干型号与规格；供预防和减轻医用射线等理化因素产生的自由基对人体皮肤、粘膜组织造成的损伤。	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	II

250	6833	医用核素设备	Medical radionuclide equipment	液体闪烁计数器	Liquid scintillation counter	液体闪烁计数器由探测单元、测量单元、数据处理/显示单元组成，可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号；采用液体闪烁体（闪烁液）接受射线并转换成荧光光子，供临床用于人体样本中放射性核素H-3、C-14等含量测定用。	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	医用射线防护用品、装置	Medical radiation protection products and instruments	医用射线防护面罩	Medical radiation protective masks	医用射线防护面罩结构内层为多层薄厚均匀、柔软的铅橡胶、铅橡塑、铅玻璃及其他含重金属元素的防护材料片，适用于进行射线诊断或放射治疗时对人体的辐射防护。产品性能指标采用下列参考标准中的适用部分，如：YY 0292-1997医用诊断X射线辐射防护器具。	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	II
252	6834	医用射线防护用品、装置	Medical radiation protection products and instruments	医用射线防护手套	Medical-ray protective gloves	医用射线防护手套结构内层为多层薄厚均匀、柔软的铅橡胶、铅橡塑、铅玻璃及其他含重金属元素的防护材料片。适用于进行放射治疗时对人体手部的辐射防护。产品性能指标采用下列参考标准中的适用部分，如：YY 0292-1997 医用诊断X射线辐射防护器具。	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	医用射线防护用品、装置	Medical radiation protection products and instruments	医用射线防护眼镜	Medical-ray protective glasses	医用射线防护眼镜可用铅玻璃及其他含重金属元素的玻璃制成，供射线诊断或放射治疗时对人体眼部的辐射防护用。产品性能指标采用下列参考标准中的适用部分，如：YY 0292-1997医用诊断X射线辐射防护器具。	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	医用射线防护用品、装置	Medical radiation protection products and instruments	医用射线防护背心	Medical-ray protective vest	医用射线防护背心结构内层可用多层薄厚均匀、柔软的铅橡胶、铅橡塑、铅玻璃及其他含重金属元素的防护材料片制成，可按材料、设计及尺寸不同分为若干型号及规格，适用于进行射线诊断或放射治疗时对人体的辐射防护。产品性能指标采用下列参考标准中的适用部分，如：YY0292-1997医用诊断X射线辐射防护器具。	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	II
255	6834	医用射线防护用品、装置	Medical radiation protection products and instruments	医用射线防护衣	Medical radiation protective clothing	医用射线防护衣结构内层为多层薄厚均匀、柔软的铅橡胶、铅橡塑、铅玻璃及其他含重金属元素的防护材料片制成，多为反穿袍式，也可设计成其他样式，适用于进行射线诊断或放射治疗时对人体的防护。产品性能指标采用下列参考标准中的适用部分，如：YY 0292-1997医用诊断X射线辐射防护器具。	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	II

256	6834	医用射线防护用品、装置	Medical radiation protection products and instruments	医用射线防护帽	Medical-ray protective cap	医用射线防护帽结构内层为多层薄厚均匀、柔软的铅橡胶、铅橡塑、铅玻璃及其他含重金属元素的防护材料片，适用于进行射线诊断或放射治疗时对人体头部非治疗部位的辐射防护。产品性能指标采用下列参考标准中的适用部分，如：YY 0292-1997医用诊断X射线辐射防护器具。	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	II
257	6834	医用射线防护用品、装置	Medical radiation protection products and instruments	医用射线防护裙	Medical-ray protective skirt	医用射线防护裙结构内层为多层薄厚均匀、柔软的铅橡胶、铅橡塑、铅玻璃及其他含重金属元素的防护材料片，适用于进行射线诊断或放射治疗时对人体的辐射防护。产品性能指标采用下列参考标准中的适用部分，如：YY 0292-1997医用诊断X射线辐射防护器具。	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	II
258	6834	医用射线防护用品、装置	Medical radiation protection products and instruments	医用射线防护围领	Medical-ray Protective Collar	医用射线防护围领结构内层为多层薄厚均匀、柔软的铅橡胶、铅橡塑、铅玻璃及其他含重金属元素的防护材料片，适用于进行射线诊断或放射治疗时对人体颈部的辐射防护。产品性能指标采用下列参考标准中的适用部分，如：YY 0292-1997医用诊断X射线辐射防护器具。	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	II
259	6834	医用射线防护用品、装置	Medical radiation protection products and instruments	医用射线多用途防护帘	Medical-ray multipurpose Shields	医用射线多用途防护帘结构内层为多层薄厚均匀、柔软的铅橡胶、铅橡塑、铅玻璃及其他含重金属元素的防护材料片。适用于进行放射治疗时对人体的防护。产品性能指标采用下列参考标准中的适用部分，如：YY0292-1997医用诊断X射线辐射防护器具。	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	II
260	6840	临床检验分析仪器	Clinical examination and analysis instrument	血红蛋白计	Haemoglobin instrument	血红蛋白计为分光光度法检测人体血液中血红蛋白含量的临床检验设备，手动加样，共用比色池，检测结果可以打印输出，可按分光原理、技术参数及附加功能等不同分为若干型号。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0032-2004 血红蛋白计。	It is a clinical inspection equipment for testing blood hemoglobin content.Manual loading, shared cuvette; Test results can be printed out. Can be divided into various specifications according to spectral theory, technical parameters and additional functions. Reference standard: YY / T 0032-2004 Haemoglobin instrument	II
261	6840	临床检验分析仪器	Clinical examination and analysis instrument	血红蛋白检测仪	Hemoglobin detector	血红蛋白检测仪由检测单元（含微量检测容器）、控制单元、数据处理、显示与打印单元等组成，可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号；采用光电比色法测定人体静脉血中血红蛋白含量。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0032-2004血红蛋白计。	Mainly consist of detection unit (containing trace detection container), control units, data processing, display and printing unit, etc.. Can be divided 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 Haemoglobin	II

262	6840	临床检验分析仪器	Clinical examination and analysis instrument	血红蛋白干化学分析仪	Hemoglobin dry chemistry analyzer	血红蛋白干化学分析仪与血红蛋白试纸条配套使用, 由检测单元、控制单元、数据处理、显示与打印单元等组成, 可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号; 采用干化学光电比色法测定人体末梢全血、静脉全血中血红蛋白含量。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 1150-2009 血红蛋白干化学分析仪。	Use with hemoglobin test strip. Mainly consist of detection unit, control unit, data processing, display and printing unit, etc.. Can be divided into various specifications 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	II
263	6840	临床检验分析仪器	Clinical examination and analysis instrument	血球计数板	Hemocytometer	血球计数板由计数池、计数方格、斜坡组成, 不含玻璃吸管。计数板材料应选用符合GB4871的5mm厚, 外观为优等品的平板玻璃。供血细胞计数用。	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	临床检验分析仪器	Clinical examination and analysis instrument	全自动血液分析仪	Automatic blood analyzer	全自动血液分析仪由主机和附件组成, 附件由传感器、探头、自动进样系统、数据计算及处理系统组成; 可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号; 采用阻抗法对血液样本中红细胞、白细胞、血小板进行计数, 采用比色法对血红蛋白含量进行检测, 并可计算出出血细胞相关参数信息, 包括白细胞三分类但不包括白细胞五分类血液分析仪。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0653-2008 血液分析仪。	Mainly consist of host and accessories. The accessories are mainly composed of sensors, probes, autosampler systems, data computing and processing system; Can be divided 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 Hematology analyzer	II
265	6840	临床检验分析仪器	Clinical examination and analysis instrument	半自动血细胞分析仪	Semi-automatic hematology analyzer	半自动血细胞分析仪由主机和附件组成, 机外稀释, 可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号; 采用阻抗法对血液样本中红细胞、白细胞、血小板进行计数, 采用比色法对血红蛋白含量进行检测, 并可计算出出血细胞相关参数信息, 包括白细胞三分类但不包括白细胞五分类血液分析仪。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0653-2008 血液分析仪。	Mainly consist of host and accessories, dilution outside. Can be divided 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 Hematology analyzer	II
266	6840	临床检验分析仪器	Clinical examination and analysis instrument	半自动血凝分析仪	Semi-automatic coagulation analyzer	半自动血凝分析仪由检测单元、控制单元、数据处理、显示与打印单元等组成, 可按工作原理、设计、技术参数、预期用途、附加辅助功能等不同分为若干型号; 分别通过采用凝固法、发色底物法或免疫比浊法, 供临床测定凝血酶原时间(PT)、活化部分凝血活酶时间(APTT)、凝血酶时间(TT)、纤维蛋白原(FIB)、凝血因子等用。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0658-2008 半自动血凝分析仪。	Mainly consist of detection unit, control unit, data processing, displaying and printing unit, etc.. Can be divided 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	II

267	6840	临床检验分析仪器	Clinical examination and analysis instrument	全自动血小板聚集仪	Automatic platelet aggregation instrument	全自动血小板聚集仪主要由自动进样单元、样品处理单元、检测单元、控制及数据处理单元等部分组成；可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号；供临床采用光电比浊法或电阻法检测定量分析血液样本中血小板数量及聚集率等相关指标。	Mainly consist of autosampler unit, sample processing unit, detection unit, control and data processing unit, etc.; Can be divided 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	临床检验分析仪器	Clinical examination and analysis instrument	半自动血小板聚集仪	Semi-automatic platelet aggregation instrument	半自动血小板聚集仪主要由检测单元、控制及数据处理单元等部分组成；可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号；供临床采用光电比浊法或电阻法检测定量分析血液样本中血小板数量和聚集率等相关指标。	Mainly consist of autosampler unit, sample processing unit, detection unit, control and data processing unit, etc.; Can be divided 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	临床检验分析仪器	Clinical examination and analysis instrument	自测用血糖分析仪	Self-test blood glucose analyzer	自测用血糖分析仪应用电化学、光化学等原理检测人体毛细血管全血和/或静脉全血中葡萄糖浓度，通常由主机和附件组成，可按工作原理、设计、技术参数、附加辅助功能等不同分为若干型号；与相应试纸配套，供患者进行血糖监测用，不用于糖尿病诊断。产品性能指标采用下列参考标准中的适用部分，如：GB/T 19634-2005 体外诊断检验系统 自测用血糖监测系统通用技术条件。	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 divided 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	II
270	6840	临床检验分析仪器	Clinical examination and analysis instrument	全自动生化分析仪	Automatic biochemical analyzer	全自动生化分析仪由自动进样单元、样品处理单元、检测单元、控制及数据处理单元等部分组成；可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号（如：光源：滤光片式/光栅式；比色池：共用式/直立分读式）；分别供定量分析血清、血浆、尿液、脑脊液等样本的临床化学成分。不包括整合的电解质等分析部分。产品性能指标采用下列参考标准中的适用部分，如：YY/T	Mainly consist of autosampler unit, sample processing unit, detection unit, control and data processing unit; Can be divided 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	II
271	6840	临床检验分析仪器	Clinical examination and analysis instrument	半自动生化分析仪	Semi-automatic biochemical analyzer	半自动生化分析仪由检测单元、控制单元、数据处理、显示、打印单元等部分组成；可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号（如：光源：滤光片式/光栅式；比色池：共用式/直立分读式）；分别供定量分析血清、血浆、尿液、脑脊液等样本的临床化学成分。产品性能指标采用下列参考标准中的适用部分，如：YY/T	Mainly consist of detection unit, control unit, data processing, displaying and printing unit, etc.; Can be divided 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	II

272	6840	临床检验分析仪器	Clinical examination and analysis instrument	干式化学分析仪	Dry chemistry analyzer	干式化学分析仪与试纸条配套使用, 由检测单元、控制单元、数据处理、显示与打印单元等组成, 可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号; 采用干化学光电比色法测定人体血清、血浆、尿液等样本的临床化学成分。产品性能指标采用下列参考标准中的适用部分, 如: 产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0655-2008 干式化学分析仪。	Use with test strip; Mainly consist of detection unit, control unit, data processing, displaying and printing unit, etc.. Can be divided into various specifications 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 Dry chemistry	II
273	6840	临床检验分析仪器	Clinical examination and analysis instrument	电解质分析仪	Electrolyte Analyzer	电解质分析仪由检测单元、控制单元、数据处理、显示、打印单元等部分组成; 可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号; 采用电极法测定人体血清中钾(K ⁺)、钠(Na ⁺)、氯(Cl ⁻)、钙(iCa ²⁺)、总钙(TCa)、锂(Li ⁺)、pH值(酸碱度)、AG(阴离子间隙: 剩余阴离子总数)、KT(阳离子总数)浓度并计算总钙(TCa)、AG(阴离子间隙: 剩余阴离子总数)、KT(阳离子总数)等。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0589-2005 电解质分析仪。	Mainly consist of detection unit, control unit, data processing, displaying and printing unit; Can be divided into various specifications 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	II
274	6840	临床检验分析仪器	Clinical examination and analysis instrument	半自动酶标分析仪	Semi-automatic ELISA analyzer	半自动酶标分析仪通常由检测单元、控制单元和显示/打印单元组成, 可按检测位、检测通道、检测速度、附加功能等不同分为若干型号; 供临床采用光电比色法进行人体样本的酶免疫测定用。	Mainly consist of detection unit, control unit and display/print units; Can be divided 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	临床检验分析仪器	Clinical examination and analysis instrument	全自动酶标分析仪	Automated ELISA analyzer	全自动酶标分析仪通常由进样单元、检测单元、控制单元和显示/打印单元组成, 可按检测位、检测通道、检测速度、附加功能等不同分为若干型号; 供临床采用光电比色法进行人体样本的酶免疫测定用。	Mainly consist of detection unit, control unit and display/print units; Can be divided 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	临床检验分析仪器	Clinical examination and analysis instrument	荧光免疫分析仪	Fluorescence immunoassay analyzer	荧光免疫分析仪可由微孔板平台、光源、检测器、振荡装置等组成, 可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号; 配合微孔板与相关试剂, 基于分光光度法, 定性或定量检测人体样本微量被测物质。	Mainly consist of microplate platforms, light source, detector, oscillator devices and other components..Can be divided into various specifications 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	临床检验分析仪器	Clinical examination and analysis instrument	干式荧光免疫分析仪	Dry fluorescence immunoassay analyzer	干式荧光免疫分析仪主要由光学单元、机械单元、控制单元、输出/显示单元及系统检测卡组成, 可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号; 与适配的基于荧光免疫层析法的特定干式试剂配套, 供人体样本的免疫荧光检测用。	Mainly consist of optical unit, mechanical unit, control unit, output/display unit and system test card. Can be divided 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	临床检验分析仪器	Clinical examination and analysis instrument	半自动时间分辨荧光免疫分析仪	Semi-automatic time-resolved fluorescence immunoassay analyzer	半自动时间分辨荧光免疫分析仪主要由激发光源、激发光透镜组、样品池及其运动平台、滤光系统、信号光接收透镜组、光电检测系统、计算机及数据处理系统、打印机等组成,可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号;适用于临床时间分辨荧光免疫检测。	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 divided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc. Used for clinical time resolution fluorescence immunoassay.	II
279	6840	临床检验分析仪器	Clinical examination and analysis instrument	半自动化学发光免疫分析仪	Semi-automatic chemiluminescence immunoassay analyzer	半自动化学发光免疫分析仪主要由检测单元、控制单元、数据处理/显示及打印单元组成,可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号;通过对人体样本中直接化学发光免疫反应产生的光子进行计数分析处理,从而对样本中的相关物质作定量或定性测定。产品性能指标采用下列参考标准中的适用部分,如:YY/T 1174-2010 半自动化学发光免疫分析仪。	Mainly consist of detection unit, control unit and display/print units; Can be divided 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 chemiluminescence .Reference standard: YY/T 1174-2010 semi-automatic chemiluminescence	II
280	6840	临床检验分析仪器	Clinical examination and analysis instrument	特定蛋白免疫分析仪	Specific protein immunoassay analyzer	特定蛋白免疫分析仪通常由检测单元、控制单元、数据处理/显示及打印单元组成,可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号;多通过光电比浊法、化学发光、荧光、时间分辨荧光等,对人体液体生物样本中特定的一种或几种蛋白进行定性或定量检测用。	Mainly consist of detection unit, control unit, data processing/ displaying and printing units. Can be divided into various specifications 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,	II
281	6840	临床检验分析仪器	Clinical examination and analysis instrument	全自动细菌培养系统	Automatic bacterial culture system	全自动细菌培养系统通常由孵育单元、荧光检测单元、控制/报警单元、显示单元等组成,还可包括空气过滤、条码扫描等,可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号;通过制造适宜环境,供临床快速培养、检测血液和体液等标本中需氧菌、厌氧菌、酵母菌、真菌和分枝杆菌等。	Mainly consist of incubation unit, fluorescence detection unit, control/alarm unit, display unit, etc., may also include air filters, barcode scanning, etc. Can be divided into various specifications according to design, technical parameters, intended use, additional auxiliary functions,etc. Used for fast clinical cultivation and determination of aerobic and anaerobic bacteria, yeasts, fungi, and mycobacteria in blood and body fluid.	II
282	6840	临床检验分析仪器	Clinical examination and analysis instrument	干化学尿液分析仪	Dry chemical urine analyzer	干化学尿液分析仪主要由试纸传送单元、测试单元、显示单元、打印设备等组成,可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号;与尿试纸条配套,用于对尿液检验分析,可包括尿pH、尿白细胞、尿亚硝酸盐、尿蛋白、尿糖、尿酮体、尿胆原、尿胆红素、尿比重、尿红细胞等。产品性能指标采用下列参考标准中的适用部分,如:YY/T 0475-2011 干化学尿液分析仪。	Mainly consist of paper transfer unit, test unit, display unit, printing equipment and other components.Can be divided into various specifications according to design, technical parameters, intended use, additional auxiliary functions,etc.. Use with urine test strip for urine test, including urine pH, urine leukocytes, nitrite 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	II

283	6840	临床检验分析仪器	Clinical examination and analysis instrument	全自动干化学尿液分析仪	Automatic dry chemical urine analyzer	全自动干化学尿液分析仪由检测系统、液路系统(包括自动采样、滴样,清洗液路)、试管架进样机构、选条机构、操作控制系统等部分组成,可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号;与尿试纸条配套,用于对尿液检验分析,可包括尿pH、尿白细胞、尿亚硝酸盐、尿蛋白、尿糖、尿酮体、尿胆原、尿胆红素、尿比重、尿红细胞等。产品性能指标采用下列参考标准中的适用部	Mainly consist of detection system,liquid path system,test tube stand. Can be divided into various specifications according to design, technical parameters, intended use, additional auxiliary functions,etc.. Use with urine test strip for urine test, including urine pH, urine leukocytes, nitrite 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	II
284	6840	临床检验分析仪器	Clinical examination and analysis instrument	血气分析仪	Blood gas analyzer	血气分析仪主要由进样/处理单元、测试单元、数据处理/显示单元及附件(含各类电极PO ₂ 电极、pH电极、PCO ₂ 电极、参比电极、毛细管组件等)组成,可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号;通过利用电化学原理。供临床直接测量动脉全血血样中的pH、PCO ₂ 、PO ₂ 、Na ⁺ 、K ⁺ 、Ca ²⁺ 、Cl ⁻ 、Glu、tHb和SO ₂ 或血清和血浆中的pH、Na ⁺ 、K ⁺ 、Ca ²⁺ 、Cl ⁻ 、Glu。pH值(每离子活度)、PCO ₂ (二氧化碳分压)、PO ₂ (氧分压)	Mainly consist of inlet/processing unit, test unit, data processing/display unit and accessories (including various kinds of PO ₂ electrode, pH electrode, PCO ₂ electrode, reference electrode, capillary assembly, etc.). Can be divided into various specifications according to design, technical parameters, intended use, additional auxiliary functions,etc.. Used for direct determination of pH, PCO ₂ , PO ₂ , Na ⁺ , K ⁺ , Ca ²⁺ , Cl ⁻ , Glu, tHb and SO ₂ or serum and plasma pH, Na ⁺ , K ⁺ , Ca ²⁺ , Cl ⁻ , Glu in arterial whole blood	II
285	6840	临床检验分析仪器	Clinical examination and analysis instrument	PCR扩增仪	PCR amplification	PCR扩增仪由变温金属模块组件、开关电源模块、微电脑控制系统、操作键盘、显示屏、热盖组成,可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号;通过精确的温度等条件控制,供临床相关诊断的聚合酶链式反应应用。	Mainly consist of variable temperature metal modular components, switching power module, microcomputer control system, keyboard, display, thermal cover, etc. Can be divided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc. Used for clinical diagnostic polymerase chain reaction by controlling precise temperature.	II
286	6840	临床检验分析仪器	Clinical examination and analysis instrument	生物芯片阅读仪	Biochip reading instrument	生物芯片阅读仪由摄像显微镜、控制器、支持软件(生物芯片图像分析系统)三部分组成,可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号;通过将经化学显色方法处理过的基因芯片扫描成图像,并用专用软件对其进行识别和分析,须与基因芯片配套使用。	Mainly consist of microscope, controller, supporting software. Can be divided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc.. Scan gene chip which was treated by chemical chromogenic method into images and identify and analyze them by a special software. Shall be used with gene chip.	II
287	6840	临床检验分析仪器	Clinical examination and analysis instrument	精子质量分析仪	Sperm Quality Analyzer	精子质量分析仪由摄像显微镜、图像分析处理单元、存储/打印单元组成,可按设计、技术参数、附加辅助功能等不同分为若干型号;供临床对精子的密度、活率、活动轨迹等进行检测分析用。自动诊断需提供可靠性报告。	Mainly consist of camera microscope, image analysis and processing unit, storage/printing units. Can be divided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc.. Used for clinical sperm density, viability, track events, etc. If it is a automatic diagnosis device, reliability report shall be provided.	II

288	6840	临床检验分析仪器	Clinical examination and analysis instrument	尿液沉渣分析仪	Urine sediment analyzer	尿液沉渣分析仪由显微光学单元、摄影传输单元与专用软件组成，可按设计、技术参数、辅助功能等不同分为若干型号；供尿液沉渣等有形成分分析用。不包括自动检测、自动判读设备。	Mainly consist of microscopic optical unit, photography transmission unit and special software. Can be divided into various specifications according to design, technical parameters, intended use, additional auxiliary functions, etc.. Used for analysis of urine sediment and other tangible component. Does not include automatic detection, automatic interpretation equipment.	II
289	6840	临床检验分析仪器	Clinical examination and analysis instrument	细菌内毒素分析仪	Bacterial endotoxin analyzer	细菌内毒素分析仪通常由控制单元、温育单元、光电比色/光电比浊测试单元、数据处理/显示/打印单元及附件等组成；可按工作原理、设计、技术参数、辅助功能等不同分为若干型号；配合试剂，供人体样本细菌内毒素定量检测用。	Mainly consist of control unit, incubation unit, photoelectric colorimeter/photoelectric turbidity test unit, data processing/display/printing unit and accessories, etc.; Can be divided into various specifications 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	临床检验分析仪器	Clinical examination and analysis instrument	光化学血脂分析仪	Photochemical lipid analyzer	光化学血脂分析仪由液晶显示屏、按键、感温探头、测试条座子、电池盒盖、USB端口组成，可按设计、技术参数、辅助功能等不同分为若干型号；应用光化学原理检测人体新鲜毛细血管或静脉血中总胆固醇浓度。应提供系统准确性报告。	Mainly consist of LCD screen, buttons, temperature probes, test strips transposons, battery cover, USB ports. Can be divided into various specifications 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	II
291	6840	临床检验分析仪器	Clinical examination and analysis instrument	电化学法血脂分析仪	Electrochemical lipid analyzer	电化学法血脂分析仪由液晶显示屏、按键、感温探头、测试条座子、电池盒盖、USB端口组成，可按设计、技术参数、辅助功能等不同分为若干型号；应用电化学原理检测人体新鲜毛细血管或静脉血中总胆固醇浓度。应提供系统准确性报告。	Mainly consist of LCD screen, buttons, temperature probes, test strips transposons, battery cover, USB ports. Can be divided into various specifications 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	II
292	6840	临床检验分析仪器	Clinical examination and analysis instrument	胶体金试纸分析仪	Colloidal gold strip analyzer	胶体金试纸分析仪由试纸机械定位单元、图像生成/传输单元、数据处理软件、数据显示/打印单元、校正附件组成；可按设计、技术参数、辅助功能等不同分为若干型号；与特定胶体金试纸配套，用于胶体金试纸的半定量或定量分析。	Mainly consist of test strip mechanical positioning unit, image generation/transmission unit, data processing software, data display/print unit, correction annexes; Can be divided 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	临床检验分析仪器	Clinical examination and analysis instrument	机械计数器	Mechanical Counter	机械计数器通过人工按压联动形成机械计数并用阿拉伯数字显示，供临床人工计数细胞或有形成分等用。	Form arabic numerals by manual press mechanical count. Used for clinical manual counting cells or tangible ingredients.	II
294	6840	临床检验分析仪器	Clinical examination and analysis instrument	细胞计数板	Cell counting board	细胞计数板用玻璃或有机玻璃制成，其上有精确刻度标识，供临床显微计数细胞或人体血液、体液样本中有形成份时作计数背景用。	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	临床检验分析仪器	Clinical examination and analysis instrument	血细胞计数器	Cytometer	血细胞计数器主要由输入、计算、显示等部分组成，可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号；与显微镜配合使用，供临床对骨髓细胞和外周血细胞进行计数及计算用。	Mainly consist of input, calculation, display composition, etc. Can be divided into various specifications 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	临床检验分析仪器	Clinical examination and analysis instrument	自动酶标洗板机	Automatic microplate washer	自动酶标洗板机可由控制电路部分、正压、负压泵系统、电磁阀控制部分、试剂瓶、液晶显示器组成，可按技术参数不同分为若干型号，供自动清洗平底、U型底、V型底多孔酶标板用。	Mainly consist of control circuit, positive, negative pump system, solenoid valve control part, reagent bottles, liquid crystal display components. Can be divided into various specifications according to technical parameters, etc.. Used for automatic cleaning microtiter plates with flat bottom, U-bottom, V-bottom.	II
297	6840	临床检验分析仪器	Clinical examination and analysis instrument	冰点渗透压测定仪	Freezing point osmotic pressure tester	冰点渗透压测定仪由制冷单元、测试单元、控制单元、数据处理、显示和打印单元组成，可按工作原理、设计、技术参数、预期用途、附加辅助功能等不同分为若干型号；供人体体液的渗透压测量用。	Mainly consist of refrigeration unit, test unit, control unit, data processing, display and printing units. Can be divided 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
298	6840	临床检验分析仪器	Clinical examination and analysis instrument	细菌鉴定及药敏分析系统	Bacterial identification and susceptibility analysis system	细菌鉴定及药敏分析系统通常由自动接种器、培养和监测系统、数据管理系统组成。细菌鉴定采用微生物数码鉴定原理，将待测菌液进行基于比色法或荧光法生化试验获得的结果转换成数字编码，通过与编码数据库内容进行比对，得到细菌鉴定结果。药物敏感性试验基于比色法或荧光法的微型化肉汤稀释试验，仪器以一定时间间隔检测自动测定细菌生长的浊度，或测定培养基中荧光指示剂的强度，或荧光原性物质的水解，得出待检菌在各药物浓度的生长斜率，经回归分析得到最低抑菌浓度MIC值。用于对分离自人类体液中的菌种进行鉴定和药物敏感性分析。	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	III
299	6840	临床检验分析仪器	Clinical examination and analysis instrument	全自动血凝分析仪	Automated coagulation analyzer	全自动血凝分析仪由自动进样单元、检测单元、控制单元、数据处理、显示与打印单元等组成，可按工作原理、设计、技术参数、预期用途、附加辅助功能等不同分为若干型号；分别通过采用凝固法、发色底物法或免疫比浊法，供临床测定凝血酶原时间(PT)、活化部分凝血活酶时间(APTT)、凝血酶时间(TT)、纤维蛋白原(FIB)、凝血因子等用。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0659-2008 全自动血凝分析仪。	Mainly consist of autosampler unit, detection unit, control unit, data processing, display and printing unit, etc. Can be divided 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 and other purposes by coagulation method, chromogenic substrate method or immunoturbidimetric method. Reference standard: YY/T 0659-	III

300	6840	临床检验分析仪器	Clinical examination and analysis instrument	结核杆菌分析仪 (全自动分枝杆菌培养监测仪)	Mycobacterium tuberculosis analyzer (automatic mycobacterial culture Monitor)	通常由固定式条码扫描系统、图片对话功能液晶显示器、测试箱、内置式系统定标管、软件和计算机组成。通过监测微生物代谢活动时产生的CO ₂ 或O ₂ 来反映微生物的生长状况, 通过监测气体变化导致的反射光变化或激发感应器中的荧光, 被光电检测器捕获读取, 对结核分枝杆菌的生长情况进行分析。该产品用于结核分枝杆菌的检测及药敏试验。	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 CO ₂ or O ₂ 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	III
301	6840	临床检验分析仪器	Clinical examination and analysis instrument	全自动免疫分析仪	Automated immunoassay analyzer	通常由取样中心、处理中心、废液和供应中心、系统控制中心等组成, 通过以抗原抗体相互结合的免疫学反应为基础, 使用酶标记或化学发光剂标记抗原抗体, 通过一系列级联放大反应, 将光信号或电信号与分析物浓度等相联系, 分析人体样本中的待测的抗原或者抗体。用于对人类体液中的各分析物, 如肿瘤标志物, 病原体抗原抗体等进行定量、半定量或定性检测。	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, pathogen antigens and antibodies.	II
302	6840	临床检验分析仪器	Clinical examination and analysis instrument	全自动医用PCR分析系统	Automatic Medical PCR analysis system	通常由PCR系统、荧光检测系统和软件等组成, 其中PCR系统主要包括温控单元, 荧光检测系统主要包括激发光源和检测器。以聚合酶链反应为基础, 对特定基因进行合成放大, 利用反应管内的荧光信号到达设定阈值时所经历的循环数 (Ct值) 与该模板的起始拷贝数的对数存在线性关系的特点, 通过荧光检测系统对荧光信号进行测定, 分析人体样本中的待测基因。用于对人类体液中的各种分析物, 如病原体核酸、肿瘤基因、人类遗传基因等进行定性或定量检测。	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,	II
303	6841	医用化验和基础设备器具	Medical assay device and basic equipment	二氧化碳培养箱	Carbon dioxide incubator	二氧化碳培养箱通过在培养箱箱体内模拟形成一个类似细胞/组织在生物体内的生长环境如恒定的酸碱度、稳定的温度、较高的相对湿度、稳定的CO ₂ 水平, 来对细胞/组织进行体外培养的一种实验室用设备, 可由加热与温控系统、CO ₂ 浓度控制系统、湿度控制系统箱体、工作室 (内胆) 组成, 可按加热方式 (气套式加热或水套式加热)、CO ₂ 浓度控制方式 (红外传感器(IR)或热传导传感器(TC))、辅助功能 (辅助加热、紫外消毒、CO ₂ 浓度、自动校验、风量管理等) 及内胆容积、重要参数控制能力与精度等不同分为若干型号, 供临床检验用于生物细胞、组织、细菌等培养用。	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 CO ₂ level. Mainly consist of heating and temperature control system, CO ₂ concentration control system, humidity control system box, studio (interior). Can be divided into different specifications according to heating mode, CO ₂ concentration control or thermal conductivity sensor (TC), supporting function(auxiliary heating, ultraviolet disinfection, CO ₂ concentration, automatic calibration, air flow management, etc.), interior volume, important parameters control ability and precision, etc. Used for biological cells, tissues,	II

304	6841	医用化验和基础设备器具	Medical assay device and basic equipment	超净恒温培养箱	Ultra-clean standing-temperature cultivator	超净恒温培养箱通过在培养箱箱体内模拟形成一个类似细胞/组织在生物体内的生长环境如恒定的酸碱度、稳定的温度和相对湿度、洁净环境，来对细胞/组织、微生物等进行体外培养的一种实验室用设备，可由加热与温控系统、工作室（内胆）组成，可按加热方式（气套式加热或水套式加热）、辅助功能（智能温度调节等）及内胆容积、重要参数控制能力与精度等不同分为若干型号；供生物细胞、组织、细菌等培养用。	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	II
305	6841	医用化验和基础设备器具	Medical assay device and basic equipment	厌氧培养箱	Anaerobic incubator	厌氧培养箱通过在培养箱箱体内模拟形成一个类似细胞/组织在生物体内的生长环境如微氧浓度、稳定的温度和相对湿度的环境，来对厌氧微生物行体外培养的一种实验室用设备，可由恒温培养室、厌氧操作室、取样室、气路及电路控制系统、箱架、瓶架、熔蜡消毒器等部分组成，供厌氧微生物体外培养用。	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.. Used for anaerobic	II
306	6841	医用化验和基础设备器具	Medical assay device and basic equipment	台式培养箱	Desktop incubator	台式培养箱由恒温系统、电子显示系统、左/右培养箱、一次性使用加湿瓶、连接软管等组成；可按容量、设计参数、附加功能等不同分为若干型号；温度通常控制在35~40℃，可具备加湿、通风的功能；供临床细胞培养等用。	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 ~ 40 °C, can be with humidification, ventilation function; Used	II
307	6841	医用化验和基础设备器具	Medical assay device and basic equipment	一次性使用末梢采血针	Single-use tip lancet	一次性使用末梢采血针通常由针体和针柄组成，针体可采用不锈钢丝或适用金属材料制成，针柄可采用聚丙烯制成；可按设计、针径、长度、附加功能等不同分为若干型号规格；以无菌形式提供；供人体指尖、耳垂等循环末梢点刺取血样化验用。包括一次性使用自毁式末梢采血针。	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 divided 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 disposable sterile lancets	II
308	6841	医用化验和基础设备器具	Medical assay device and basic	足跟采血器	Heel Lancing Devices	足跟采血器通常由弹簧刀片、弹出机构及外壳组成，刀片通常用不锈钢制成，可按材质、设计、技术参数、辅助功能等不同分为若干型号；以无菌形式提供；主要供新生儿足跟采血用。	Mainly consist of spring blade, eject mechanism and shell, the blade is usually made of stainless steel. Can be divided into various specifications according to texture, design, technical parameters, auxiliary functions, etc.. Can be sterile state. Used for newborns	II
309	6841	医用化验和基础设备器具	Medical assay device and basic equipment	一次性使用宫颈取样毛刷	Single-use cervical sampling brush	一次性使用宫颈取样毛刷可由毛刷、手柄组成；毛刷用多股尼龙丝缠绕在多股不锈钢丝而成，手柄由高分子套管套固定在不锈钢丝上而成；可按材质、手柄长度、毛刷大小等分为若干型号和规格；非灭菌器械；供子宫颈内膜收集细胞用，也可用于阴道分泌物取样。	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 divided 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	医用化验和基础设备器具	Medical assay device and basic equipment	一次性使用无菌拭子	Single-use Sterile swabs	一次性使用无菌拭子通常由柄部和取样头组成, 柄部可用天然竹、木或高分子材料制成, 取样头由脱脂棉在柄部患者端卷绕而成; 拭子可按材质、设计、尺寸等不同分为若干型号、规格, 可带取样容器; 通常以无菌形式提供; 供人体自然腔道, 如鼻腔、口腔、阴道、尿道口等部位沾取生物样本检验用。	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 divided 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	医用化验和基础设备器具	Medical assay device and basic	一次性使用妇科刮板	Single-use Gynecological scraper	一次性使用妇科刮板由竹、木、高分子材料等制成, 由手柄及头端组成, 头端 (病人端) 为月牙形光滑平板; 可按尺寸不同分为若干规格; 产品以无菌形式提供, 供妇科检查宫颈取样用。	Mainly consist of bamboo, wood, polymer materials, composed by handle and head end, head end is a crescent smooth plate; Can be divided into various specifications according to different sizes; Be sterile form. Used for cervical sampling in gynecological	II
312	6841	医用化验和基础设备器具	Medical assay device and basic equipment	一次性使用真空采血容器	Single-use vacuum blood collection container	一次性使用真空采血容器由容器、塞子以及采血管内的添加剂和附加物组成, 容器有玻璃容器和PET塑料容器, 可有涂层; 可按材质、添加剂 (可含培养基)、容量、负压值、灭菌与微生物状态、预期用途、适用地域等不同分为若干型号及规格, 添加剂可以包括K2EDTA、K3EDTA、Na2EDTA、柠檬酸钠、氟化钠、草酸钾、肝素钠、肝素锂、促凝剂、分离胶等; 与采血针等配合, 分别用于临床人体静脉血液标本的采集、抗凝/促凝/分离/培养和保存。需提供血液添加剂预期用途的确认报告。产品性能指标采用下列参考标准中的适用部分, 如: YY 0314-2007 一次性使用静脉血样采集容器。	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 divided 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-use containers for human venous blood specimen	II
313	6841	医用化验和基础设备器具	Medical assay device and basic equipment	一次性肝素化毛细管微量采血管	Single-use heparinization capillary micro blood	一次性肝素化毛细管微量采血管用玻璃制成, 由肝素化毛细管, 混合用铁芯, 毛细导管盖组成; 灭菌状态提供; 通过虹吸作用, 用于人体末梢微量血液标本采集。	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	医用化验和基础设备器具	Medical assay device and basic equipment	新生儿血液收集卡	Neonatal blood collection card	新生儿血液收集卡由信息卡和血样收集滤纸组成, 滤纸上有印制的圆圈 (通常为4个) 用于标记血样采集的位置及血量, 可按滤纸材质、设计、血量采集要求等不同分为若干种; 非灭菌包装; 通过足跟等部位采集新生儿血样, 干燥后便于运输、保存, 以备进一步的临床检验用。	Mainly consist of information card and blood collection filter. Can be divided into various specifications according to texture, design, and blood collection requirements, etc.. Non-sterile packaging; Used for neonatal blood samples from the heel parts to dry for transporting, storing for further clinical testing.	II
315	6841	医用化验和基础设备器具	Medical assay device and basic equipment	粪便分析工作站	Fecal analysis workstation	粪便分析工作站由工作站控制台、染色输送带、全自动双吸样针、光学流动计数池 (OSA)、便携式试管座等组成。与粪便寄生虫离心管配套使用, 供样本离心、浓缩、计数等用。不包括自动诊断及自动计数功能。	Mainly consist of workstation console, dyeing conveyor, full-automatic dual suction needles, optical flow count cell (OSA), portable tubes seat, etc. Used with fecal parasite centrifuge tube for sample centrifugation, concentration, counting. Does not include automatic diagnosis and automatic counting function.	II

316	6841	医用化验和基础设备器具	Medical assay device and basic	一次性使用隐血采样胶囊	Single-use occult blood sampling	一次性使用隐血采样胶囊由医用空心胶囊、医用脱脂棉、棉线组成，供提取胃液作隐血检查用。	Mainly consist of medical hollow capsules, medical degreasing cotton, cotton thread. Used to extract gastric juice for occult blood examination.	II
317	6845	体外循环及血液处理设备	Extracorporeal circulation and blood processing equipment	血液透析反渗透纯水制水机	Hemodialysis reverse osmosis pure water water generator	血液透析反渗透纯水制水机为直接供水模式的反渗透水处理装置,可包括前处理工艺,膜组件和后处理工艺。反渗透膜组(如聚酰胺膜)由内毒素过滤器(如聚醚砜膜)、管道(医用不锈钢AISI316)、反渗透膜罐(医用不锈钢AISI316)、框架(医用不锈钢AISI304)、微处理监控、报警系统以及显示面板组成;设备可按技术参数、制水容量等不同分为若干规格,供制取血液透析和相关治疗用水用。产品性能指标采用下列参考标准中的适用部分,如:GB/T 19249 反渗透水处理设备,YY 0793 血液透析和相关治疗用水处理设备技术要求,YY 0572-2005 血液透析和相关治疗用水。	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 divided 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 haemodialysis, YY 0572-2005 Water for haemodialysis and	II
318	6845	体外循环及血液处理设备	Extracorporeal circulation and blood processing equipment	透析器复用机	Dialyzer reprocessing machine	透析器复用机主要由控制系统、监测系统和水路系统组成,可按设计、技术参数、辅助功能等不同分为若干型号。与含过氧化氢和过氧乙酸的血液透析器专用消毒液配合使用,供可复用中空纤维血液透析器使用后进行冲洗、清洁、检测、消毒等处理,使其达到可再次使用的标准。	Mainly consist of control system, monitoring system and water system. Can be divided 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	体外循环及血液处理设备	Extracorporeal circulation and blood processing equipment	冰冻血浆解冻仪	Frozen plasma thawing instrument	冰冻血浆解冻仪由加热水箱、解冻槽、循环管路、进水管、排水管、控制箱等组成,可有水浴式、隔水式,可按工作原理、设计、技术参数、辅助功能等不同分为若干型号。	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 divided into various specifications according to working principle, design, technical parameters, auxiliary functions,etc..	II
320	6845	体外循环及血液处理设备	Extracorporeal circulation and blood processing equipment	输血输液透析管路加温仪	Transfusion dialysis tubing heating device	输血输液透析管路加温仪通常由主机、加热管、报警装置和固定装置组成,用于输血、输液、血液透析和血液过滤等操作过程中对通液管路进行即时加温,仪器不与被加温液体直接接触。	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	体外循环及血液处理设备	Extracorporeal circulation and blood processing equipment	一次性使用腹膜透析管探针	single-use peritoneal dialysis tube probe	一次性使用腹膜透析管探针通常用不锈钢制成,可按材质、设计、技术参数等不同分为若干型号及规格;以无菌形式提供;供腹膜透析管辅助置入及透析管疏通等用。	Mainly consist of stainless steel. Can be divided 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	植入材料和人工器官	Implant materials and artificial organs	盒式助听器	Cassette Hearing Aid	盒式助听器主要由输入换能器、信号调理单元、输出换能器和电源组成，多为模拟式助听器，可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号；经验配，供气导性听力损失患者补偿听力用。产品性能指标采用下列参考标准中的适用部分，如：GB/T 14199-2010 电声学 助听器通用规范。	Mainly consist of input transducer, signal conditioning unit, output transducer and power supply. Can be divided 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	植入材料和人工器官	Implant materials and artificial organs	膝关节用骨水泥定型模具	Bone cement mould forming for knee	膝关节用骨水泥定型模具由医用级硅胶制成，不包含加固柄，以无菌形式提供；供膝关节用骨水泥定型用。	Mainly made of medical grade silicone, does not include a reinforced handle. Be sterile; Used for knee joint bone cement setting.	II
324	6846	植入材料和人工器官	Implant materials and artificial organs	耳背式助听器	BTE hearing aids	耳背式助听器主要由输入换能器、信号调理单元、输出换能器和耳钩外壳等组成，可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号（模拟/数字/可编程等）；经验配，供气导性听力损失患者补偿听力用。产品性能指标采用下列参考标准中的适用部分，如：GB/T 14199-2010 电声学 助听器通用规范。	Mainly consist of input transducers, signal conditioning unit, output transducer and ear hook shell, etc.. Can be divided 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	III
325	6846	植入材料和人工器官	Implant materials and artificial organs	耳内式助听器	In-ear hearing aids	耳内式助听器包括耳甲腔式和耳道式助听器，主要由输入换能器、信号调理单元、输出换能器和电源等组成，可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号（现多为数字化可编程助听器）；经验配，供气导性听力损失患者补偿听力用。产品性能指标采用下列参考标准中的适用部分，如：GB/T 14199-2010 电声学 助听器	Mainly consist of input transducers, signal conditioning unit, output transducer and ear hook shell, etc.. Can be divided 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	III
326	6846	植入材料和人工器官	Implant materials and artificial organs	U型钉	U-nails	该类产品结构参见ISO 882，由符合GB 4234、GB/T 13810、ISO 5832-1、ISO 5832-3标准规定的不锈钢、钛合金材料，通过常规的机械加工、热处理及表面处理工艺（不包括3D打印等创新工艺）制成。适用于四肢骨折内固定。	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	III
327	6846	植入材料和人工器官	Implant materials and artificial organs	骨栓	Bone plug	该类产品由螺杆和螺母组成，由符合GB 4234、GB/T 13810、ISO 5832-1、ISO 5832-3标准规定的不锈钢、钛合金材料，通过常规的机械加工、热处理及表面处理工艺（不包括3D打印等创新工艺）制成。适用于四肢骨折内固定。	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	III
328	6846	植入材料和人工器官	Implant materials and artificial	硅橡胶组织扩张器	Silicone tissue expander	手术中使用的或植入后6个月内取出的组织扩张器，主要由壳体、导管、注射座（或起相同作用的组件）和连接器（如果有）组成。壳体的主要材料为硅橡胶。作用原理为可填充盐水以增大自身体积对组织进行扩张。用于整形外	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	III

329	6846	植入材料和人工器官	Implant materials and artificial organs	角度型金属接骨板（非锁定）	Angle metal bone fracture plate (non-locking)	该类产品结构参见YY 0017，由符合GB 4234、GB/T 13810、ISO 5832-1、ISO 5832-2、ISO 5832-3标准规定的不锈钢、纯钛、钛合金材料，通过常规的机械加工、热处理及表面处理工艺（不包括3D打印等创新工艺）制成。适用于股骨近端、股骨远端、胫骨近端合并/不合并骨干骨折内固定。	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	III
330	6846	植入材料和人工器官	Implant materials and artificial organs	解剖型金属接骨板（非锁定）	Anatomical metal bone fracture plate (non-locking)	该类产品结构参见YY 0017，由符合GB 4234、GB/T 13810、ISO 5832-1、ISO 5832-2、ISO 5832-3标准规定的不锈钢、纯钛、钛合金材料，通过常规的机械加工、热处理及表面处理工艺（不包括3D打印等创新工艺）制成。适用于四肢干骺端骨折内固定。	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	III
331	6846	植入材料和人工器官	Implant materials and artificial organs	金属股骨颈固定钉	Metal femoral neck fixation nail	该类产品结构参见YY 0346，由符合GB 4234、GB/T 13810、ISO 5832-1、ISO 5832-3标准规定的不锈钢、钛合金材料，通过常规的机械加工、热处理及表面处理工艺（不包括3D打印等创新工艺）制成。适用于股骨颈骨折内固定。	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	III
332	6846	植入材料和人工器官	Implant materials and artificial organs	金属骨针	Metal spicules	该类产品包括克氏针和斯氏针，结构参见YY 0345。由符合GB 4234、GB/T 13810、ISO 5832-1、ISO 5832-3标准规定的不锈钢、钛合金材料，通过常规的机械加工、热处理及表面处理工艺（不包括3D打印等创新工艺）制成。适用于四肢骨折复位时部分植入人体做牵引或四肢骨折内固定。	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 partial implantment in limb fracture reduction.	III
333	6846	植入材料和人工器官	Implant materials and artificial organs	金属接骨螺钉（非锁定）	Metal bone screws (non-locking)	该类产品结构参见YY 0018，由符合GB 4234、GB/T 13810、ISO 5832-1、ISO 5832-3标准规定的不锈钢、钛合金材料，通过常规的机械加工、热处理及表面处理工艺（不包括3D打印等创新工艺）制成。适用于四肢骨折内固定。	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	III
334	6846	植入材料和人工器官	Implant materials and artificial organs	金属缆线和缆索	Metal cables and ropes	该类产品结构参见YY/T 0812，由符合GB/T 13810、ISO 5832-1、ISO 5832-2、ISO 5832-3、ISO 5832-11标准规定的的不锈钢、纯钛、钛合金材料，通过常规的机械加工、热处理工艺（不包括3D打印等创新工艺）制成。适用于四肢骨折捆扎内固定。	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	III

335	6846	植入材料和人工器官	Implant materials and artificial organs	金属髓内针	Metal intramedullary needle	该类产品结构参见YY 0019, 不包含带锁髓内钉。由符合GB 4234、GB/T 13810、ISO 5832-1、ISO 5832-3标准规定的不锈钢、钛合金材料, 通过常规的机械加工工艺、热处理及表面处理工艺(不包括3D打印等新技术和新工艺)制成; 适用于四肢骨折内固定。	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	植入材料和人工器官	Implant materials and artificial organs	空心接骨螺钉(非锁定)	Hollow bone screws (non-locking)	该类产品由符合GB 4234、GB/T 13810、ISO 5832-1、ISO 5832-3标准规定的不锈钢、钛合金材料, 通过常规的机械加工、热处理及表面处理工艺(不包括3D打印等创新工艺)制成。可单独使用, 适用于四肢骨折内固定。	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 be used	III
337	6846	植入材料和人工器官	Implant materials and artificial	尿失禁悬吊带	Urinary incontinence suspensory	植入体内的带状物, 一般主要由聚丙烯材料制成, 可带有部分可吸收材料。作用原理为植入尿道附近形成对尿道的支撑。用于因女性的尿道过度移动和/或括约肌功能障碍而造成的压力性尿失禁。	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	III
338	6846	植入材料和人工器官	Implant materials and artificial organs	柔性金属丝	Flexible wire	该类产品结构参见YY/T 0816, 由符合YY 0605.9、ISO 5832-1、ISO 5832-2标准规定的不锈钢、纯钛、高氮不锈钢材料, 通过常规的机械加工工艺、热处理工艺(不包括3D打印等新技术和新工艺)制成。适用于四肢骨折捆扎内固定。	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	植入材料和人工器官	Implant materials and artificial organs	外固定架配合用固定钉	External fixator fixation nails	该类产品由符合GB 4234、GB/T 13810、ISO 5832-1、ISO 5832-3标准规定的不锈钢、钛合金材料, 通过常规的机械加工、热处理及表面处理工艺(不包括3D打印等创新工艺)制成。与外固定支架配合, 适用于四肢骨折复位时部分植入人体做固定。	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	植入材料和人工器官	Implant materials and artificial organs	外科疝修补补片	Surgical hernia repair patch	不包括最终全部吸收的产品。植入体内的平片或由平片折叠组合形成的网塞, 一般由聚丙烯、聚对苯二甲酸乙二醇酯材料制成, 可带有部分可吸收材料。作用原理为填补缺损组织或起到桥接作用。用于腹腔外对疝进行修补。	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 repair.	II
341	6846	植入材料和人工器官	Implant materials and artificial organs	直型金属接骨板(非锁定)	Straight metal bone fracture plate (non-locking)	该类产品结构参见YY 0017, 由符合GB 4234、GB/T 13810、ISO 5832-1、ISO 5832-2、ISO 5832-3标准规定的不锈钢、纯钛、钛合金材料, 通过常规的机械加工、热处理及表面处理工艺(不包括3D打印等创新工艺)制成。适用于四肢长骨骨干骨折内固定。	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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	子宫加压膨宫器	Uterine pressurized Hysteroscopy pump	子宫加压膨宫器由加压器主机、管路及充气针组成，需有超压报警并自动泄气功能；可按设计、技术参数、辅助功能、预期用途等不同分为若干型号；供妇科内窥镜检查 and 手术过程中，对子宫进行加压膨胀以形成可视空间用。	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 divided 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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	经皮黄疸测试仪	Percutaneous jaundice tester	经皮黄疸测试仪为手持式，由光学测试单元、显示单元、电源/电池及充电附件等组成，可按工作原理、设计、技术参数、适用部位、适用对象、辅助功能等不同分为若干型号；通过特定波长光反射，主要用于新生儿经皮黄疸测量用。	Handheld percutaneous jaundice tester, mainly consist of testing unit, display unit, power supply/battery and charging accessories, etc.. Can be divided 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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	医用浸浴治疗机	Medical immersion bath therapeutic machine	医用浸浴治疗机由主机、病人浴床、供/排水系统、温控单元等组成，也可包括病人转运吊架及冲其他辅助浸浴功能，可按设计、技术参数、辅助功能等不同分为若干型号；供烧烫伤病人浸浴、创面处理等用。	Mainly consist of host, patient sunbeds, supply/drainage systems, temperature control unit, etc., may also include patient hanging bracket for transportation and other auxiliary bath functions. Can be divided into various specifications according to design, technical parameters, auxiliary functions, etc.; Used for burns patients bathing and wound treatment.	II

345	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	输液泵	Infusion Pump	输液泵主要由容量式输液泵单元、检测单元、控制与报警单元组成，可按工作原理、设计、技术参数、附加辅助功能等不同分为若干型号；与输液器具配套，不接触输注液体，供医院以可调节的方式为患者静脉输注药液等用。产品性能指标采用下列参考标准中的适用部分，如：GB 9706.27-2005 医用电气设备 第2-24部分：输液泵和输液控制器安全专用要求。	Mainly consist of capacity type infusion pumps unit, detection unit, control units and alarming unit. Can be divided 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 2-24: Medical electrical equipment - Part 2 :Particular requirements for the safety of infusion pumps and controllers	II
346	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	注射泵	Syringe Pump	注射泵产品是通过一个或多个单一动作的注射器或类似容器来控制注入患者体内液体流量的设备（例如通过推动推杆清空筒内溶液），输液速度由操作者设定，并由设备指示单位时间内的流量；一般由泵外壳、电机驱动系统、输入系统、存储系统、控制系统、显示系统、传感监测系统和报警系统组成，产品结构组成中一般不包含注射器和输注管路，可按设计、技术参数、预期用途、附加辅助功能等不同分为若干型号；与特定注射器具配套，用于动、静脉长时间恒定给药速度和精确给药量输液。产品性能指标采用下列参考标准中的适用部分，如：GB 9706.27-2005 医用电气设备 第2-24部分：输液泵和输液控制器安全专用要求。	It is an equipment for controlling fluid flow of patient injection via one or more syringes 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 divided 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	II
347	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	脚踏吸引器	Pedal absorber	脚踏吸引器由活塞缸、储液瓶、真空表、支撑架等部件组成，由机械运动产生负压，供对早期妊娠孕妇施行人工流产手术时及其他临床负压吸引用。产品性能指标采用下列参考标准中的适用部分，如：YY 0636.2 医用吸引设备 第2部分：人工驱动吸引设备。	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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	医用负压吸引器	Medical vacuum extractor	医用负压吸引器主要由负压系统、压力显示、主控电路、储液容器组成，通常不包括吸引管，可负压产生原理、设计、技术参数、预期用途、附加辅助功能等不同分为若干型号；供医院和家庭为病人作吸痰等普通负压吸引用，不适用于流产吸引用，不包括以负压或压力源为动力的吸引设备。产品性能指标采用下列参考标准中的适用部分，如：YY 0636.1-2008 医用吸引设备 第1部分：电动吸引设备 安全要求。	Mainly consist of negative pressure system, pressure display, main control circuit, liquid storage container. Usually does not include a suction tube. Can be divided 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 suction equipment-Safety requirements	II
349	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	简易呼吸器	Simple respirator	简易呼吸器可由呼吸阀阀体、直角接头、头带、面罩接头、面罩、空气导管、弹性呼吸球等组成，按结构型式（活瓣结构和三通结构）、技术参数等不同分为若干型号与规格，供混合空气与氧气气体作单向间歇正压人工呼吸急救和辅助呼吸用。	Mainly consist of breathing valve, right-angle connector, headband, mask connector, masks, air conduit, flexible breathing balls, etc.. Can be divided into various specifications according to structure, technical parameters, etc.. Used for artificial respiration and assisted breathing with mixed gas and oxygen.	II
350	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	小型分子筛制氧机	Small molecular sieve oxygenator	小型分子筛制氧机采用变压吸附原理、通过分子筛吸附氮气和其他气体，从空气中分离出90%以上的氧气，可由制氧机主机和附件（湿化器、吸氧管/面罩等），具备氧浓度报警功能，可按单位时间制氧量、附加组件、功能等不同分为若干型号，供氧疗或缓解各种因缺氧导致的不适用。产品性能指标采用下列参考标准中的适用部分，如：YY 0732-2009医用氧气浓缩器 安全要求，GB 8982-2009医用及航空呼吸用氧。	It is an equipment for separating 90% oxygen by using molecular sieve to absorb nitrogen and other gases with the principle of changable pressure. Mainly consist of host and accessories. It has a oxygen concentration alarming function. Can be divided 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 aircraft breathing	II

351	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	电动手术台	Electric operating table	电动手术台主要由台面、台座、电气控制系统、配套件等部分组成，按驱动方式、技术参数、辅助功能、配套件等不同分为若干型号及规格，可分别适用于头、颈、胸、腹腔、会阴、四肢等外科、妇科、泌尿科、五官科、骨科等手术承载患者，提供合适的手术体位用。产品性能指标采用下列参考标准中的适用部分，如：YY/T 1106—2008电动手术台，YY 0570-2005 医用电气设备 第2部分：手术台安全专用要求。	Mainly consist of operating table, pedestal, electrical control systems, parts and auxiliary equipment, etc.. Can be divided 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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	液压手术台	Hydraulic operating table	液压手术台主要由台面、台座、液压控制系统、配套件等部分组成，按驱动部位、技术参数、辅助功能、配套件等不同分为若干型号及规格，可分别适用于头、颈、胸、腹腔、会阴、四肢等外科、妇科、泌尿科、五官科、骨科等手术承载患者，提供合适的手术体位用。	Mainly consist of table, pedestal, hydraulic control systems, parts and auxiliary equipment, etc.. Can be divided 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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	电动液压手术台	Electro-hydraulic operating table	电动液压手术台主要由台面、台座、电动液压控制系统（通常台面升降由液压控制）、配套件等部分组成，按驱动方式/部位、技术参数、辅助功能、配套件等不同分为若干型号及规格，可分别适用于头、颈、胸、腹腔、会阴、四肢等外科、妇科、泌尿科、五官科、骨科等手术承载患者，提供合适的手术体位用。产品性能指标采用下列参考标准中的适用部分，如：YY/T 1106—2008电动手术台，YY 0570-2005 医用电气设备 第2部分：手术台安全专用要求。	Mainly consist of table, pedestal, hydraulic control systems, parts and auxiliary equipment, etc.. Can be divided 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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	手术病人静态搬运车	Static surgical patients carrier	手术病人静态搬运车由车体升降机构、平衡板机构、吊架、吊架升降机构、操作系统组成，可按工作原理、设计、技术参数、辅助功能等不同分为若干型号；用于在手术台和病床间辅助搬运病人。	Mainly consist of lifting mechanism, balance board mechanism, hanger, hanger lifting mechanism, operating system. Can be divided 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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	电动洗胃机	Electric lavage machine	电动洗胃机主要由压力泵、控制单元、冲吸转换装置、过滤瓶、软管、冲洗液和污水容器等组成，可按压力泵、控制方式、技术参数、附加辅助功能等不同分为若干型号。供医疗单位作抢救服毒、食物中毒及手术前洗胃用。产品性能指标采用下列参考标准中的适用部分，如：YY 1105-2008 电动洗胃机。	Mainly consist of pressure pump, control unit, flushing and sucking conversion device, filtration bottles, hoses, flushing fluid and waste containers, etc.. Can be divided 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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	输卵管通液诊断仪	Hydrotubation diagnostic apparatus	输卵管通液诊断仪主要由控制系统、电源系统、助推系统、打印机等组成，可按设计、技术参数、附加辅助功能等不同分为若干型号；供输卵管造影注液诊断和输卵管疏通用。	Mainly consist of control systems, power systems, boosting systems, printers, etc.. Can be divided into various specifications according to design, technical parameters, additional auxiliary functions, etc.. Used for liquid injection diagnosis or dredging for salpingography	II

357	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	耳鼻喉科检查治疗台	ENT examination and treatment units	耳鼻喉科检查治疗台通常由操作检查治疗台、主机和附件（喷枪、吸枪、吹枪、除雾、射灯及支架、托盘、棉球缸、监视器、冷光源、CCD摄像机、紫外线消毒灯、观片灯等），可按结构组成、功能与技术参数等不同分为若干型号及规格；可与耳鼻喉内窥镜配套，供耳鼻喉科作检查、诊断、治疗等用。	Mainly consist of operation inspection treatment tables, host and accessories. Can be divided 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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	手术无影灯	Surgical shadowless lamp	手术无影灯由固定座、横梁、平衡体、平衡弯管、灯头弯管、灯头、调光手柄、拉手组成，可按光源、结构型式、技术参数、配置、附加功能等不同分为若干型号，供手术照明用。产品性能指标采用下列参考标准中的适用部分，如：YY 0627-2008 医用电气设备 第2部分：手术无影灯和诊断用照明灯安全专用要求。	Mainly consist of permanent seat, beams, balance body, balance pipe, lamp elbow pipe, lamp, dimming handle, handle. Can be divided 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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	医用冷光纤维导光手术灯	Medical cold light fiber light guide surgical light	医用冷光纤维导光手术灯通常由支撑部分、冷光源、导光纤维及灯头组成，可按结构、组成及技术参数等不同分为若干型号，供临床诊查、治疗（包括小手术）照明用。	Mainly consist of supporting section, cold light source, light guide fibers and lamp. Can be divided into various specifications according to different structures, compositions and technical parameters, etc.. Used for clinical diagnosis, treatment.	II

360	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	医用真空负压机	Medical vacuum machine	医用真空负压机用于医用气体管路系统，可由真空泵、真空罐、管路、接头和电控箱组成；通过真空泵抽吸，使系统各管路产生医用负压。	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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	医用空气压缩机	Medical Air Compressor	医用空气压缩机用于医用气体导管系统，可由气罐、连接装置和电控箱组成；产生压缩气体供诊疗用。	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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	医用空氧混合仪	Medical air oxygen mixture machine	医用空氧混合仪由氧浓度测定仪、空气调节阀、流量指示仪、湿化器组成；与吸氧管配套，供患者给氧时空氧混合气体的氧浓度监测、调节和湿化用。	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

363	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	医用气体报警系统	Medical Gas Alarm System	医用气体报警系统可由多种多点气体传感器械及显示传输系统构成的监测点通过有线连接方式集中传输至中央气体管理系统，由中央管理系统对医用气体监测点进行集中监测，超出预警值可自动报警；可用于对医院供气系统的各种气体如氧气、麻醉气体等进行监测。	Medical gas alarm system monitoring point multi-point gas sensors by a variety of mechanical transmission and display system consisting of centralized transmission via a wired connection to a central gas management system consisting of a central management system for medical gas monitoring point for 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.	II
364	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	麻醉视频喉镜	Anesthesia video laryngoscope	麻醉视频喉镜由手柄、摄像头和窥视片组成，手柄另一端可接显示器。窥片可用金属制成，重复使用，也可用高分子材料制成，一次性使用；手柄与窥片通常为可分离式，可按适用人群、材质、设计、技术参数、窥片尺寸等不同分为若干型号和规格；供临床挑起患者会厌部暴露声门，指引医护人员准确进行气道插管供麻醉或急救用，也可用于口腔内诊察、治疗。	Mainly consist of handle, camera and spy slices. The handle can be connected by a display. The spy slices can be reusable if made of metal or single-use if made of polymer material; The handle and spy slices are generally detachable. Can be divided into various specifications according to suitable crowd, texture, design, technical parameters, spy slices size; Used for clinical provoking patients epiglottis exposed glottis. Used for anesthesia or emergency use in airway intubation or can also be used in the oral examination and treatment.	II
365	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	呼吸机用加热/湿化器	Heater/humidifier for ventilator	呼吸机用加热/湿化器由加热模块、控制模块和水浴容器组成，水浴温度可控、可调；设备可按设计型式、技术参数、附加功能等不同分为若干型号；设备通过麻醉呼吸管路串接在呼吸机和气管插管之间，使用吸入的气流通过热水表面时受热和湿化，减少机械通气对心肺系统的刺激，保持肺泡湿润，利于吸痰和防止气道阻塞。不包括被动保温湿化的热湿交换器（人工鼻）。	Mainly consist of heating module, control module and water incubator. The water incubator temperature can be controlled, adjustable; Can be divided into various specifications according to design type, technical parameters, additional functions, etc.. The equipment can be connected in series between the ventilator and endotracheal intubation. Used for reducing mechanical stimulation and keeping pulmonary alveoli moist via heating and humidifying the inhaled gas flow to facilitate phlegm suction and prevent airway obstruction. Do not include passive heating and humidifying heat and moisture exchanger(artificial nose).	II

366	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	桡动脉压迫止血带	Radial artery tourniquet	桡动脉压迫止血由支撑板和带皮带的压迫垫组成，可按材质、设计、技术参数等不同分为若干种；供桡动脉导管插管术后压迫止血用。	Mainly consist of supporting plate and oppression mat with belt. Can be divided into various specifications according to texture, design and technical parameters, etc.. Used for hemostasis compression in radial artery catheterization.	II
367	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	股动脉气动压迫装置	Femoral artery pneumatic compression device	股动脉气动压迫装置由无菌气动压力圆顶拱架，装有压力表的充气管路，充气源，绑带等附件组成，可按设计、技术参数、辅助功能等不同分为若干种；供血管插管术后压迫股动脉或静脉止血或股动脉假性动脉瘤超声导引的压迫修复用。	It is with a sterile pneumatic dome arch and equipped with inflatable gauge pipe, inflatable source, bandage, etc.. Can be divided into various specifications according to design, technical parameters, and other auxiliary functions, etc.. Used for femoral artery or vein compression hemostasis after vascular nasal intubation or ultrasound-guided compression repair in femoral artery pseudoaneurysm.	II
368	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	无源压脉止血带	Passive sphygmopressing tourniquet	无源压脉止血带可采用硅橡胶管、弹性织物带或非弹性织物带和粘扣带等固定件制成，可有捆扎型、卡扣型、松紧带粘贴型等多种设计；通常通过加压直接/间接实时或间歇压迫四肢静脉或动脉，以达到阻滞血流，充盈静脉或止血目的；供临床静脉穿刺或四肢出血时止血处理用。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0031-2008 输液、输血用硅橡胶管路及弹性件。	Mainly consist of silicone rubber tube, elastic or non-elastic fabric belt and velcro fasteners. Can be tied up type, snap joint type, elastic paste type, etc. Used for stopping blood or hemostasis via direct/indirect oppression. Can be used for limb bleeding or vein puncture hemostasis. Reference standard: YY/T 0031-2008 Silicone tubes and elastomeric parts for infusion and transfusion	II

369	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	头架和头托系统	Headstock and head rest system	头架和头托系统可分别由底座、连接器、头架或多功能头架、头托、坐姿龙门架等通过机械组合而成，可用不锈钢或钛合金等金属材料制成，部分部件也可用透X射线或核磁兼容材料制成；部分部件有精确长度或角度刻度，可用于三维定位；可按设计、预期用途、技术参数、适用人群等不同分为若干型号及规格；可分别供头/颈部影像定位、头颈外科手术中的固定、支撑和引导用。	Mainly consist of base, connector, headgear or multifunctional headstock, head rest, sitting portal frame, etc.. Can be made of stainless steel or titanium alloy, etc.. Partial assembly unit has exact length or angle scale. Can be used in three-dimensional positioning; Can be divided into various specifications according to design, intended use, technical parameters, applicable crowd, etc.. Used for fixing, supporting and guiding in neck/head image positioning and head and neck surgery.	II
370	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	麻醉和呼吸用呼吸系统过滤器	Anesthesia and respiratory breathing system filters	麻醉和呼吸用呼吸系统过滤器可由上盖、过滤介质、下盖、护帽等四个部分组成，过滤器壳体可ABS等材料制成，过滤介质可用聚丙烯复合材料等制成，可按过滤介质、外形、尺寸等不同分为若干型号和规格，以无菌形式提供，与麻醉呼吸设备和肺功能仪相配套，供降低患者吸入或呼出颗粒性物质（包括微生物）的数量用。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0753 麻醉和呼吸用呼吸系统过滤器。	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 divided 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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	输液信息采集系统	Infusion Information Collection System	输液信息采集系统由带有红外通讯接口和电源的移动支架、集成软件组成；为输液泵/推注泵供电，并通过红外接口与指定型号的输液泵/推注泵进行数据通讯；采集输液泵/推注泵数据，通过有线/无线网络传输到中央工作站，并提示报警信息。	Mainly consist of infrared communication interface and traversing carriage for power supply, integrated software, etc. Used to provide power supply and data communication to infusion pump/injection pump via infrared interface. Used for infusion pump/injection pump data collection and data transmitting to a central station via a wired/wireless network, it can also prompt alarm information.	III

372	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	麻醉蒸发器	Anesthesia evaporator	麻醉蒸发器一般由蒸发室、浓度控制装置、注入系统（包括罐充瓶 适配器）和药剂液面指示器等组成。在盛有挥发性吸入麻醉药容器内的上方空间通过一定量的气体，一部分气体经过调节阀流入蒸发室，携走饱和的麻醉蒸汽，在输出口形成含有一定百分比浓度的麻醉蒸汽气流。可配用不同的麻醉剂类型。该产品为麻醉系统的组成部件，用于提供浓度可控的麻醉剂蒸汽。	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	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	生物安全柜	Biological safety cabinets	产品一般由柜体、前窗操作口、支撑脚及脚轮、风机、集液槽、过滤器、控制面板及紫外灯和照明光源组成。要求前窗操作口流入最低平均流速的气流，下降气流经过高效过滤器过滤后送至工作区，污染气流经过高效过滤器过滤后可以排到下一环节，安全柜内所有生物污染部位均处于负压状态或者被负压通道和负压通风系统环绕。生物安全柜是具有前窗操作口的安全柜，操作者可以通过前窗操作口在安全柜内进行操作，对操作过程中的人员、产品及环境进行保护。	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,	II
374	6854	手术室、急救室、诊疗室设备及器具	Equipment and appliance used in operating rooms, emergency rooms, clinics room utensils	血路连接器	Blood Trail Connector	血路连接器（简称接头），属于心肺转流系统，供体外循环手术心肺转流系统中血路通道输送血液、观察和连接使用。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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 fuction can not be exempt clinical trails.	II
375	6855	口腔科设备及器具	Equipment and appliance for department of	气动洁牙机	Pneumatic Dental Descaler	气动洁牙机由气动主机/手机、连接器、洁牙头、附件等组成，可有辅助照明、喷水等功能，可按设计、技术参数、辅助功能、预期用途等不同分为若干型号；可用于去除牙齿表面所粘着的牙垢、牙结石和着色斑用。	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	口腔科设备及器具	Equipment and appliance for department of	气动牙科喷砂装置	Pneumatic Dental sand-blasting appaatus	气动牙科喷砂装置由手柄、连接装置等组成，可按材质、设计、技术参数等不同分为若干种；借助人工控制的高压气流及其内含的微小氧化铝细粒，去除牙体表面所粘着的牙垢、着色斑或抛光牙表面用。	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	口腔科设备及器具	Equipment and appliance for department of stomatology	电动牙科综合治疗设备	Electric Dental Comprehensive Therapy Apparatus	电动牙科综合治疗设备为电驱动设备，用于支撑患者保持坐姿，以便进行牙科检查、治疗和/或监测外科手术过程。高度通常可调，以方便医护人员操作。通常包括头枕和扶手，可躺式椅背可从垂直位置倾斜到水平位置，并具有旋转功能；有些类型的牙科手术椅还可以程控几种标准体位，牙科检查和/或治疗（如灯、冲洗装置）器械可作为手术椅的组件固定，也可以独立式壁式或悬吊式安装装置单独安放。典型结构可由牙科综合治疗机、电动牙科椅及医师座椅组成，牙科综合治疗机可由三用喷枪、口腔灯、灯臂、观片灯、器械盘、吸唾组件、强吸组件、医用脚踏开关、地箱、净水系统等组成，可按结构组成、配置、技术参数、功能等不同分为若干型号；供口腔诊断、治疗、手术用。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0058 牙科病人椅、YY 0055牙科-光固化机、YY/T 1147 电动牙钻通用技术条件、YY 1045.1 牙科手机 第2部分：直手机和弯手机、YY1045.1 牙科手机 第1部	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	II
378	6855	口腔科设备及器具	Equipment and appliance for department of stomatology	液压牙科病人椅	Hydraulic dental patient chair	一种液压驱动器械，用于支撑患者保持坐姿，以便进行牙科检查、治疗和/或监测外科手术过程。高度通常可调，以使医护人员可站立操作。通常包括头枕和扶手，可躺式椅背可从垂直位置倾斜到水平位置，可具有旋转功能；牙科检查和/或治疗（如灯、冲洗装置）器械可作为手术椅的组件固定，也可以独立式壁式或悬吊式安装装置单独安放，上述装置可为电驱动设备。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0058 牙科病人椅。	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	II

379	6855	口腔科设备及器具	Equipment and appliance for department of stomatology	牙科光固化机	Dental photocuring machine	根据发光源的不同, 分为石英钨卤素灯和发光二极管(LED)灯两种。石英钨卤素灯电源部分主要包括变压器、电源整流器、电子开关电路;光源部分通常包括卤素灯泡、滤光片、光导纤维管、散热风扇、定时装置、触发开关等, 另应有挡光装置。LED灯网电源和可充电电池供电类由主机、电池、导光棒、护目镜、充电开关电源、充电座组成;交流电类由LED灯、控制电路板、主机手柄(包括散热座)、电源适配器、导光棒、护目镜组成。产品性能指标采用下列参考标准中的适用部分, 如: YY 0055-2002 牙科光固化机。	Can be divided 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, etc.. Shall 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	II
380	6855	口腔科设备及器具	Equipment and appliance for department of	牙科中/高容量吸引器及附件	Dental medium/high capacity aspirator and Accessorie	牙科有源设备, 至少包括一台负压吸引机、吸引手机, 可作为牙科综合治疗机附件, 可按吸引类型(干系统、半干系统和湿系统三种)、流量(中高流量与高流量)等不同分若干型号;供口腔检查、治疗过程中产生负压气流, 清除患者飞沫、口水、唾液、食物残渣、血液等用。YY/T 0629牙科设备 高容量和中容量吸引系统。	Active device. Mainly consist of vacuum aspirator, aspiration drill. Can be accessories of dental unit. Can be divided 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	口腔科设备及器具	Equipment and appliance for department of stomatology	牙科车针	Dental burs	牙科旋转器械中的一种, 由柄(钢或适合的材料)和头部工作端(钢或硬质合金、金钢石等制成)组成, 可按柄及头部的材质、型式、尺寸等不同分为若干型号及规格;供口腔治疗中钻削牙用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0761.1牙科旋转器械 金刚砂车针 第1部分: 尺寸、要求、标记, YY 0302.1牙科旋转器械 车针 第1部分: 钢质和硬质合金车针, YY 0302.2牙科旋转器械 车针 第2部分: 钢质和硬质合金抛光用车针。	Mainly consist of handle and working end. Can be divided 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	病房护理设备及器具	Equipment and appliance for ward nursing	医用气体管道系统—供氧系统	Medical gas pipeline systems-oxygen system	医用气体管道系统—供氧系统通常包含一个中心供氧站(可以是氧气浓缩器、医用氧站或两者的结合)、一套监测和报警系统和具有若干终端的管道分配系统组成, 可按中心供氧站类型等不同分为若干型号, 系统具欠压等声、光报警等功能;供医疗机构集中供氧用。主要产品性能指标采用下列参考标准中的适用部分, 如: YY 0801-2010医用气体管道系统终端, YY/T 0799-2010 医用气体低压软管组件, ISO 10083:2006 医用气体管道系统用氧气浓缩器供气系统, YY/T 0187 医用中心供氧系统通用技术条件。	Mainly consist of central oxygen supply station, monitoring and alarming systems and piping distribution system with several terminals. Can be divided 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	II

383	6856	病房护理设备及器具	Equipment and appliance for ward	医用供氧器	Medical oxygen supply	医用供氧器由氧气瓶、流量计、压力表、减压器、推车等，供医疗急救或医疗现场供氧用。	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	病房护理设备及器具	Equipment and appliance for ward nursing	一次性使用鼻氧管	Single-use nasal oxygen tube	一次性使用鼻氧管按照型式不同，分为鼻架式、单鼻塞型、头箍式、挂耳式四种型式，鼻架式由锥形接头、分流管、延长管、双孔鼻架、三通和调节圈组成，单鼻塞型由锥形接头、分流管、延长管、单孔鼻塞、三通和调节圈组成，头箍式由耳环挂钩、套圈、接头组成，挂耳式由接头、细导管、鼻塞、挂钩组成；调节圈、耳环采用聚乙烯塑料制成，其他部件采用聚氯乙烯塑料制成；产品应无菌。与输氧系统连接供人体吸入氧气用。	Can be divided 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. Connected with the oxygen	II
385	6856	病房护理设备及器具	Equipment and appliance for ward nursing	一次性使用湿化鼻氧管	Single-use humidifying nasal oxygen tube	一次性使用湿化鼻氧管由湿化瓶、湿化液和鼻氧管(型号规格可选)组成，湿化瓶的瓶身用聚丙烯树脂制成，上盖采用ABS树脂制成，鼻氧管的管路、鼻塞接头均采用软聚氯乙烯材料制成；湿化液采用符合《中华人民共和国药典》（2010版）要求的注射用水制成；可按设计、技术参数、鼻氧管型式等不同分为若干种；连接供氧装置，供病人湿润、输送氧气用。	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 divided into various specifications according to design, technical parameters, nasal oxygen tube, etc.. Used with oxygen supply device for patient moist and oxygen	II
386	6856	病房护理设备及器具	Equipment and appliance for ward nursing	睡眠呼吸暂停治疗用面罩	Sleep apnea treatment mask	睡眠呼吸暂停治疗用面罩用高分子材料制成，可由罩体（鼻罩、口罩或口鼻罩）和固定带组成，可带管路、气路接口和防窒息阀等附件，不包括口腔矫治器或其他特殊用途功能附件；产品可以无菌形式提供，单一患者可重复使用；供睡眠呼吸暂停治疗用。产品性能指标采用下列参考标准中的适用部分，如：YY 0671.2-2011睡眠呼吸暂停治	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, which 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	II
387	6856	病房护理设备及器具	Equipment and appliance for ward	婴幼儿输氧头罩	Infant oxygen hoods	婴幼儿输氧头罩由输氧管、锁紧套、调节板、盖板、罩体组成；该产品与氧气源、氧气流量计配合，供婴幼儿安全输氧用。	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	病房护理设备及器具	Equipment and appliance for ward	婴儿吸氧面罩	Infant oxygen-inspiration mask	婴儿吸氧面罩可采用可用聚氯乙烯等适用材料制成，由罩体及固定两部分组成，可按材质、设计、尺寸等不同分为若干型号和规格；可以无菌形式提供；供婴儿吸氧用。	Mainly made of PVC and other suitable material. Can be divided into various specifications according to texture, design, size, etc.. Can be sterile state; Used for infant oxygen inhaling.	II

389	6856	病房护理设备及器具	Equipment and appliance for ward nursing	医用气体管道系统—真空系统	Medical gas pipeline systems-vacuum system	医用气体管道系统—真空系统通常包含一个中心真空负压站、一套监测和报警系统和具有若干终端的管道分配系统组成, 系统具有负压越限声、光报警等功能; 供医疗机构集中真空负压吸引用。主要产品性能指标采用下列参考标准中的适用部分, 如: YY 0801-2010 医用气体管道系统终端, YY/T 0799-2010 医用气体低压软管组件, YY/T 0186 医用中心吸引系统通用技术条件。	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	II
390	6856	病房护理设备及器具	Equipment and appliance for ward nursing	电动病床	Electric sickbed	电动病床为网电源或内部电源或组合式电驱动式设备, 可由床面部分(如背板、坐板、腿板、脚板)、床架部分(前后床头板、左右护栏等)、下床架部分(升降机构、中控机构、脚轮等)、电控部分(升降电机、背板电机、腿板电机、控制器、手控板)、输液架等附件组成, 按功能配置等不同分为若干型号, 供临床各类病房承载和护理患者用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0571-2005 医用电气设备 第2部分·医院电动床安全	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 divided 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 electrically operated hospital beds	II
391	6856	病房护理设备及器具	Equipment and appliance for ward nursing	手动轮椅车	Manual wheelchairs	手动轮椅车由人力驱动, 可由车架、前轮、后轮、坐、背垫、扶手、挂脚、刹车、脚踏板等组成, 可按驱动方式、轮椅材质、配置、功能、尺寸、适用范围等不同分为若干型号, 供行动困难的残疾人、病人及年老体弱者作代步工具用。产品性能指标采用下列参考标准中的适用部分, 如: GB/T 13800-2009 手动轮椅车。	Driven by manpower. Mainly consist of frame, front wheel, rear wheel, seat, back pad, handrails, hitching leg, foot brake, pedals, etc.. Can be divided 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	II
392	6856	病房护理设备及器具	Equipment and appliance for ward nursing	电动轮椅车	Electric wheelchairs	电动轮椅车为有配套椅式支持系统的两轮个人移动设备, 有一个或数个电机提供驱动力。行进速度由电机控制, 行进方向由陪同人员或乘用者手动或电动控制; 可按材质、功能、附件、技术参数等不同分为若干型号; 供残疾或无完全行走能力者(不含肥胖症)代步用。产品性能指标采用下列参考标准中的适用部分, 如: GB 12996-1991 电动轮椅车和GB/T 18029 轮椅车 电动轮椅系列。	Driven by one or more motors. The moving speed is controlled by motor. The direction is controled by user or accompanied staff or electrically controlled; Can be divided 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 powered wheelchair series	II
393	6856	病房护理设备及器具	Equipment and appliance for ward	乳头内陷吸牵器	Nipple inversion retraction device	乳头内陷吸牵器由筒形管、内芯等组成, 利用负压原理, 将乳头吸牵到位; 供治疗乳头内陷用。	Mainly consist of cylindrical tube, core, etc.. Used for nipple suction reduction via the negative principle; Used for nipple retraction therapy.	II
394	6856	病房护理设备及器具	Equipment and appliance for ward	医用防褥疮气垫	Medical anti-bedsore cushion	医用防褥疮气垫主要由气囊、电动充气泵、控制器、按摩电机、床罩组成; 可按材质、设计、技术参数、充气模式等不同分为若干型号; 供卧床患者褥疮防治用。	Mainly consist of airbags, electric air pump, controller, massager motors, bedspreads; Can be divided into various specifications according to texture, design, technical parameters, inflatable model, etc. Used for bedsores prevention.	II

395	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and sterilization	大型蒸汽灭菌器（手动控制型）	Large-scale steam sterilizers (manual type)	大型蒸汽灭菌器（手动控制型）采用蒸汽为灭菌因子杀灭负载微生物，压力、温度、时间等灭菌的主要技术参数由手工设定并控制，通常不具有预真空或脉动抽真空功能。主要由容器、大门、管道系统和控制系统等组成，内室材质为SUS304或SUS316L 不锈钢板压制而成，内容积大于60升；蒸汽灭菌器可按预期用途或负载、结构型式、灭菌内室大小等不同分为不同型号和规格（如自带蒸汽发生器 and 外接蒸汽式；按门的多少分为单开门灭菌器、双开门灭菌器；按缸体形状分为矩形灭菌器、圆形灭菌器）；供医疗器械、卫生材料等湿热灭菌用。产品性能指标采用下列参考标准中的适用部分，如：YY 0731-2009 大型蒸汽灭菌器 Manual control 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 divided 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—Manual control type	II
396	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and sterilization	大型蒸汽灭菌器（自动控制型）	Large steam sterilizer (automatic type)	大型蒸汽灭菌器（自动控制型）采用蒸汽为灭菌因子杀灭负载微生物，压力、温度、时间等灭菌的主要技术参数由程序设定并控制，可具有预真空或脉动抽真空功能。灭菌器主要由容器、大门、管道系统和控制系统等组成，内室材质为SUS304或SUS316L 不锈钢板压制而成，内容积大于60升；蒸汽灭菌器可按预期用途或负载、结构型式、灭菌内室大小等不同分为不同型号和规格（如按门的结构形式分为自动门灭菌器、手动门灭菌器；按门的多少分为单开门灭菌器、双开门灭菌器；按缸体形状分为方形灭菌器、圆形灭菌器）；供医疗器械、卫生材料等湿热灭菌用。产品性能指标采用下列参考标准中的适用部分，如：GB 8599-2008 大型蒸汽灭菌器技术要求 自动控制型。同类产品名称有：台式灭菌器、盒式灭菌器、台式压力蒸汽灭菌器等。	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 divided 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, electric steam sterilizer, high	II
397	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and sterilization	小型蒸汽灭菌器	Small steam sterilizers	小型蒸汽灭菌器采用蒸汽为灭菌因子杀灭负载微生物，多为自动控制型，压力、温度、时间等灭菌的主要技术参数由程序设定并控制，可具备预真空或脉动真空；灭菌器主要由容器、大门、管道系统和控制系统等组成，内室材质为SUS304或SUS316L 不锈钢板压制而成，内容积小于60升；蒸汽灭菌器可按预期用途、结构型式、灭菌内室大小等不同分为不同型号和规格；供医疗器械、卫生材料等湿热灭菌用。产品性能指标采用下列参考标准中的适用部分，如：YY 0646-2008 小型蒸汽灭菌器 自动控制型。同类产品名称有：台式灭菌器、盒式灭菌器、台式压力蒸汽灭菌器等。	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 divided 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,	II

398	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and sterilization	立式蒸汽灭菌器	Vertical steam sterilizer	立式蒸汽灭菌器采用蒸汽为灭菌因子杀灭负载微生物, 压力、温度、时间等灭菌的主要技术参数可手动控制, 也可由程序设定并控制, 也可具有脉动抽真空功能。灭菌器主要由容器、大门、管道系统和控制系统等组成, 开门方向向上, 内室材质为SUS304或SUS316L不锈钢板压制而成, 内容积小于60升; 蒸汽灭菌器可按预期用途或负载、结构型式、灭菌内室大小等不同分为不同型号和规格; 供医疗器械、卫生材料等湿热灭菌用。产品性能指标采用下列参考标准中的适用部分, 如: YY 1007-2010 立式蒸汽灭菌器	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 divided 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.	II
399	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and sterilization	自动控制型小型蒸汽灭菌器	Automatically controlled small steam sterilizers	自动控制型小型蒸汽灭菌器采用蒸汽为灭菌因子杀灭负载微生物, 压力、温度、时间等灭菌的主要技术参数由程序设定并控制, 可具有脉动抽真空功能。灭菌器主要由容器、大门、管道系统和控制系统等组成, 内室材质为SUS304或SUS316L 不锈钢板压制而成, 内容积小于60升; 蒸汽灭菌器可按预期用途或负载、结构型式、灭菌内室大小等不同分为不同型号和规格; 供医疗器械、卫生材料等湿热灭菌用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0646-2008 小型蒸汽灭菌器 自动控制型。同类产品名称有: 台式灭菌器、盒式灭菌器、台式压力蒸汽灭菌器、小型脉动真空蒸汽灭菌器等。	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 divided 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,	II
400	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and	手提式压力蒸汽灭菌器	Portable Pressure Steam Sterilizer	手提式压力蒸汽灭菌器可由提手、灭菌室腔体、蒸汽发生器和控制系统组成, 按加热方式、结构型式、灭菌室容积、控制方式与精度、附加功能等不同分为若干型号和规格, 供临床机构对医疗器械等物品用蒸汽法消毒灭菌用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0504—2005 手提式压力蒸汽灭菌器。	Mainly consist of handle, sterilization chamber body, steam generator and control system. Can be divided into various specifications according to heating mode, structure type, sterilization chamber volume, control means, precision, additional functions, etc.. Used for medical device sterilization in clinical institution. Reference standard : YY 0504-2005 Portable Mode	II
401	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and sterilization	环氧乙烷灭菌器	Ethylene oxide sterilizers	环氧乙烷灭菌器可由灭菌箱体、加热及热循环装置、真空装置、加药及气化装置、加湿装置、密封装置、残气处理装置、监测与控制装置组成, 可按灭菌室容积、监测与控制能力、附加功能等不同分为若干型号, 供医疗器械等适宜环氧乙烷灭菌的物品环氧乙烷灭菌用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0503—2005 环氧乙烷灭菌器。	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 divided into various specifications according to sterilization chamber volume, monitoring and control capabilities, additional functions, etc.. Used for medical device ethylene oxide sterilization. Reference standard:	II

402	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and sterilization	医用低温蒸汽甲醛灭菌器	Medical low temperature steam formaldehyde sterilizers	医用低温蒸汽甲醛灭菌器以蒸汽或气态甲醛为灭菌介质，灭菌器可由灭菌室腔体、门、灭菌器管线系统、电气系统、控制系统和蒸汽发生器（为可选配件）组成，按腔体结构、门的型式、腔体体积、真空能力、附加程序/功能等不同分为若干型号和规格。供医疗机构用于医疗物品的低温甲醛蒸汽灭菌。产品性能指标采用下列参考标准中的适用部分，如：YY 0679—2008 医用低温蒸汽甲醛灭菌器。	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 divided 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	II
403	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and sterilization	低温等离子过氧化氢灭菌器	Low-temperature plasma hydrogen peroxide sterilizers	低温等离子过氧化氢灭菌器通常由灭菌仓、灭菌物品架、过氧化氢蒸汽发生器、等离子电极、高频发生器和控制单元组成；灭菌器可按型式、结构、灭菌容量、技术参数、附加辅助功能等不同分为若干型号；通过等离子态的蒸汽或气体灭活医疗物品上的微生物，多供对高温高湿敏感物品灭菌用。	Mainly consist of sterilization bin, sterilization items frame, hydrogen peroxide vapor generator, plasma electrode, high-frequency generator and control unit; Can be divided 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 inactivation.	II
404	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and sterilization	医用臭氧水生成器	Medical ozone water generator	医用臭氧水生成器通常由进水/进气（空气或氧气）、臭氧发生器、臭氧水气混合系统、控制系统组成，也可包括臭氧监测/分解系统；设备可按臭氧产生原理、单位臭氧产生量、附加辅助功能等不同分为若干型号；供手术器械等医疗用品臭氧水消毒用。不用于人体臭氧治疗。	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 divided 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 human therapy.	II
405	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and sterilization	酸性氧化电位水生成器	EOW generator	酸性氧化电位水生成器通常由电源、封闭式隔膜电解槽、氯化钠溶液贮存/软化水混合供给系统、酸/碱电位水贮存系统、监测系统组成；利用电解槽将0.1%氯化钠溶液电解，生成酸性氧化电位水，直接用于患者伤口、皮肤粘膜以及手术器械等的消毒灭菌。产品性能指标采用下列参考标准中的适用部分，如：GB 28234-2011 酸性氧化电位水生成器安全与卫生标准。	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	II
406	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and	医用内窥镜清洗消毒设备	Medical endoscope cleaning and disinfecting	医用内窥镜清洗消毒设备为整体工作系统，可由初洗槽、酶洗槽、次清洗槽、浸泡消毒槽、末洗槽、干燥台、控制台组成，不含消毒液，可具备加热清洗功能；可按设计、技术参数、附加辅助功能等不同分为若干型号；配合消毒液，供医用内窥镜可清洗部件的清洗、消毒用。	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 divided into various specifications according to design, technical parameters, additional auxiliary functions, etc. Used with disinfectant for medical endoscope	II

407	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and	呼吸管路消毒机	Breathing circuit sterilizer	呼吸管路消毒机可由臭氧发生器、过氧化氢雾化装置、气泵、滤芯、臭氧检测装置、冷却风机、控制系统等组成；可按设计、型式、技术参数、附加辅助功能等不同分为若干型号；串接于呼吸管路中，用臭氧和过氧化氢混合气体对呼吸机、麻醉机管路内部回路进行消毒。	Mainly consist of ozone generators, hydrogen peroxide atomizing device, pump, filter, ozone detection devices, cooling fans, control systems, etc.. Can be divided 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	II
408	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and sterilization	干热灭菌器	Dry Heat Sterilizers	干热灭菌器在接近大气压压力下运行，利用热空气或热惰性气体对适宜物品进行灭菌的设备，通常为电驱动设备，可由灭菌腔体、门、控制系统、显示系统等部分组成，可按灭菌器腔体结构、容积、门的型式、控制类型与控制参数、附加功能等不同分为若干型号和规格，供医疗器械或物品干热灭菌用。产品性能指标采用下列参考标准中的适用部分，如：YY 0602-2007 测量、控制和试验室用电气设备的安全使用热空气或惰性气体处理医用材料及供试验室用的干热灭菌器的特殊要求。	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 divided 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	II
409	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and sterilization	超声消毒设备	Ultrasonic disinfection equipment	超声消毒设备为电驱动设备，经超声清洗、超声漂洗、电热风干燥等多槽流水线组合而成，可由程序控制清洗相关参数（如清洗时间、水温等），可按结构组成、技术参数、附加功能（如加热清洗、程序控制等）等不同分为若干型号，配合清洗剂与消毒剂，供医疗机构用于复用医疗器械的清洗、烘干、消毒用。	It is an electric drive equipment. Mainly consist of multi-slot assembly line for ultrasonic cleaning, ultrasonic rinsing, electric drying wind, etc.. Can be divided 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, drying, disinfection in medical	II
410	6857	消毒和灭菌设备及器具	Equipment and appliance for disinfection and	口腔科卡式蒸汽灭菌器	Dental Cassette Steam Sterilizer	口腔科卡式蒸汽灭菌器为电驱动设备，由电加热模块、卡式灭菌盒、控制/显示模块及附件组成，可按结构组成、灭菌盒容积、技术参数及附加程序/功能等不同分为若干型号与规格，供口腔科复用器械快速灭菌用。	Electric drive equipment. Mainly consist of electric heating module, cassette sterilization boxes, control/display module and annexes. Can be divided 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	医用冷疗、低温、冷藏设备及器具	Medical cold therapy, low temperature, cold storage equipment	医用低温冰箱	Medical cryogenic refrigerator	医用低温冰箱可为内部电源驱动设备，可由内胆、保温箱体、制冷系统、控制（含报警）/显示系统组成，可按制冷工作机理、保温层及内胆材料、有效冷藏容积、冷藏参数及精度、附加功能等不同分为若干型号及规格，最低温可达-86℃，供医疗机构冷藏样本、血液、药物、试剂等用。	Electric drive equipment. Mainly consist of liner, incubator body, refrigerating system, control(with alarm function) /display system. Can be divided 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℃. Used for samples, blood, drugs, reagents, etc. refrigeration	II

412	6858	医用冷疗、低温、冷藏设备及器具	Medical cold therapy, low temperature, cold storage equipment	血液冷藏箱	Refrigerators for conserved blood	血液冷藏箱为电驱动设备，可由制冷系统、温控/显示系统及箱体外壳组成，可控制制冷工作机理、保温层及内胆材料、有效冷藏容积、冷藏参数及精度、附加功能等不同分若干型号及规格，供贮藏血液及其制品用。产品性能指标采用下列参考标准中的适用部分，如：YY/T 0168血液冷藏箱。	Electric drive equipment. Mainly consist of refrigerating system, temperature control/display system and tank shell. Can be divided 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 refrigerator.	II
413	6858	医用冷疗、低温、冷藏设备及器具	Medical cold therapy, low temperature, cold storage equipment	脏器冷藏装置	Organ refrigeration unit	脏器冷藏装置为电驱动设备，也可为无源器具，可由制冷系统或冰块等冷媒、温控/显示系统及箱体外壳组成，可控制制冷工作机理、保温层及内胆材料、有效冷藏容积、冷藏参数及精度、附加功能等不同分若干型号及规格，温控范围约在4℃±1℃，供贮藏人体脏器及其组织用。	Electric drive equipment, can also be passive device. Mainly consist of refrigerating system or ice media, temperature control/display system and tank shell. Can be divided 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 range is about of 4 °C±1 °C. Used for storage of human organs and tissues.	II
414	6858	医用冷疗、低温、冷藏设备及器具	Medical cold therapy, low temperature, cold storage equipment	冷冻干燥血浆机	Freeze-dried plasma machine	冷冻干燥血浆机通过将血浆冻结成固态，而后使其中的水分从固态升华成气态，以除去水分而保存血浆的方法，电驱动设备，可由制冷系统、真空系统、加热系统、电器仪表控制系统所组成，可按结构组成、技术参数、附加功能等不同分为若干型号，供冷冻干燥血浆用。	Remove water by sublimation from plasma which is frozen into solid to store plasma. Electric drive equipment. Mainly consist of refrigerating system, vacuum system, heating system, gauge control system, etc.. Can be divided into various specifications according to structure and composition, technical parameters, additional functions, etc.. Used for freeze-dried plasma.	II
415	6858	医用冷疗、低温、冷藏设备及器具	Medical cold therapy, low temperature, cold storage equipment	真空冷冻干燥机	vacuum freeze drier	真空冷冻干燥机通过将被干燥物质冻结成固态，而后使其中的水分从固态升华成气态，以除去水分而保存物质的方法，电驱动设备，可由制冷系统、真空系统、加热系统、电器仪表控制系统组成，可按结构组成、技术参数、附加功能等不同分为若干型号，供冷冻干燥血液、生物样品或活性物质等用。	Remove water by sublimation to store substances. Electric drive equipment. Mainly consist of refrigerating system, vacuum system, heating system, gauge control system, etc.. Can be divided into various specifications according to structure and composition, technical parameters, additional functions, etc.. Used for freeze-dried blood, biological samples or active substances, etc.	II
416	6858	医用冷疗、低温、冷藏设备及器具	Medical cold therapy, low temperature, cold storage equipment	冰冻血浆解冻箱	Thaw box for frozen plasma	冰冻血浆解冻箱由加热水箱、解冻槽、循环管路、进水管、排水管、电器控制箱等组成，可具有报警等功能，可按结构组成、最大化浆量、解冻时间等技术参数、附加功能等不同分为若干型号，从解冻冰冻血浆用。	Mainly consist of heating tanks, thawing tank, circulation pipes, inlet pipe, drains, electrical control box, etc.. Can be with alarming function. Can be divided into various specifications according to structure and composition, the maximize thawing amount, thawing time, additional function, etc.. Used for thawing frozen plasma.	II

417	6858	医用冷疗、低温、冷藏设备及器具	Medical cold therapy, low temperature, cold storage equipment	封闭式血液冷藏周转箱	Closed blood refrigerated Recycle Case	封闭式血液冷藏周转箱可由箱体（含隔热层）、铝制冷却匣、手推车、塑料锁扣等组成；可有温度监测显示功能；箱内可放置蓄能袋，供血液短时运输、贮存时隔热冷藏用。	Mainly consist of box body, aluminum cooling box, trolleys, plastic lock, etc; Can be with the function of temperature monitoring; The energy storage bag can be put into the box. Used for insulation refrigeration blood in transportation, storage for short time.	II
418	6858	医用冷疗、低温、冷藏设备及器具	Medical cold therapy, low temperature, cold storage equipment	开放式血液冷藏周转箱	Closed blood refrigerated Recycle Case	开放式血液冷藏周转箱可由箱体（含隔热层）、冷藏板、平板手推车等组成；可有温度监测显示功能；箱内可放置蓄能袋，供血液短时贮存、转移时隔热冷藏用。	Mainly consist of case (including insulation layer), refrigerated plate, flat plate carts etc; May have temperature monitoring display; The energy storage bag can be put into the box. Used for insulation refrigeration blood in transportation, storage for short time.	II
419	6858	医用冷疗、低温、冷藏设备及器具	Medical cold therapy, low temperature, cold storage equipment	医用冷藏冰箱	Medical refrigeration refrigerator	医用冷藏冰箱由箱体、内胆、箱门、机组、控制系统、搁架、拉手、脚轮等组成，可按设计、技术参数、辅助功能等不同分为若干型号；供贮存人体检测样本、药品、疫苗、生物制品、试剂等用。	Mainly consist of box body, liner, door, crew, control systems, shelves, handles, casters, etc.. Can be divided into various specifications according to design, technical parameters, and other auxiliary functions, etc.. Used for human samples, medicines, vaccines, biologicals, reagents, etc. storage.	II
420	6858	医用冷疗、低温、冷藏设备及器具	Medical cold therapy, low temperature, cold storage equipment	升温毯	Warming Blankets	升温毯一般由主机、毯子和体温传感器组成。在医疗机构临床使用环境下，通过控制毯子温度，具有对人体进行体外物理升温功能，达到辅助调节人体温度目的的设备。可按设计、技术参数、辅助功能等不同分为若干型号。	Mainly consist of host, blankets and temperature sensors. Used for controlling blanket temperature to regulate human body temperature by in vitro physical temperature rising. Can be divided into various specifications according to design, technical parameters, and other auxiliary functions, etc..	II
421	6858	医用冷疗、低温、冷藏设备及器具	Medical cold therapy, low temperature, cold storage equipment	降温毯	Cooling blankets	降温毯一般由主机、毯子和体温传感器组成。在医疗机构临床使用环境下，通过控制毯子温度，具有对人体进行体外物理降温功能，达到辅助调节人体温度目的的设备。可按设计、技术参数、辅助功能等不同分为若干型号。	Mainly consist of host, blankets and temperature sensors. Used for controlling blanket temperature to regulate human body temperature by in vitro physical cooling. Can be divided into various specifications according to design, technical parameters, and other auxiliary functions, etc..	II

422	6863	口腔科材料	dental material	定制式固定义齿	Customized fixed denture	定制式固定义齿由固位体、桥体和连接体组成, 包括金属烤瓷冠、金属烤瓷桥、金属冠、金属桥、全瓷冠、全瓷桥; 金属烤瓷冠、金属烤瓷桥采用牙用镍铬烤瓷铸造合金和高温瓷粉或低温烤瓷粉等适用材料制成, 金属冠、金属桥采用牙科用镍基铸造合金等适用材料制成。用于牙体、牙列缺失、缺损的固定修复。	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	II
423	6863	口腔科材料	dental material	定制式活动义齿	Customized removable denture	定制式活动义齿可分为局部义齿和全口义齿两类, 局部义齿由人工牙、基托和卡环构成, 全口义齿由人工牙和基托构成; 活动义齿采用牙科用钴铬合金、义齿基托聚合物、多层色合成树脂牙制成。用于缺失牙、牙列的活动修复。	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	口腔科材料	dental material	定制式义齿用烤瓷粉	Ceramic powder for customized denture	定制式义齿制作用材料, I型粉状陶瓷, 可按组分、预期用途等不同分为若干类, 可分别供定制式义齿的牙核、牙本质瓷/牙体、牙釉质、牙颈部、染色、透明、添加、上釉用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0716-2009 牙科陶瓷。	It is I-type ceramics powder to be the raw material for customized denture.Can be divided 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	II
425	6863	口腔科材料	dental material	齿科铸造合金	Dental casting alloys	定制式义齿制作用材料, 应符合YY 0621-2008 牙科金属烤瓷修复体系标准相关要求。贵金属应符合YY 0620-2008 牙科学 铸造金合金和GB/T 17168-2008牙科铸造贵金属合金标准相关要求; 包括金属烤瓷修复用和部分牙列全口支架、局部义齿支架以及卡环制作用铸造合金, 包括镍铬基合金、钴铬合金、纯钛与钛合金。	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 alloys.	II
426	6863	口腔科材料	dental material	全瓷义齿用氧化锆瓷块	All-ceramic dental zirconia ceramic	全瓷义齿用氧化锆瓷块主要成分为: 氧化锆、氧化钇、氧化铝及其他氧化物, 可按成分、成型工艺、形状等不同分为若干型号、规格; 供采用CAD/CAM(计算机辅助设计/计算机辅助制造)方法制作全瓷义齿内冠用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0716-2009 牙科陶	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	口腔科材料	dental material	牙科陶瓷修复用全瓷材料	All-ceramic material for dental ceramic restoration	定制式义齿制作用材料, I型粉状陶瓷, 可按组分、预期用途等不同分为若干类, 可分别供定制式义齿的牙核、牙本质瓷/牙体、牙釉质、牙颈部、染色、透明、添加、上釉用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0716-2009 牙科陶瓷。用于全瓷单冠、长桥和嵌体的制作及全瓷修复。	It is I-type ceramics powder to be the raw material for customized denture.Can be divided 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	II

428	6863	口腔科材料	dental material	正畸托槽	Orthodontic bracket	正畸托槽可采用不锈钢、陶瓷等适用材料制成，可按材质、牙位、技术参数、使用部位等不同分为若干型号与规格；与正畸丝等配套，供牙齿正畸治疗用。	Mainly made of stainless steel, ceramic, etc.. Can be divided into various specifications according to texture, teeth position, technical parameters, applicable sites, etc.. Used with orthodontic wire for teeth orthodontic treatment.	II
429	6863	口腔科材料	dental material	正畸丝	Orthodontic wire	正畸丝采用不锈钢或镍钛合金等制成，表面可涂PFA树脂涂层（隐形），可按材质、弹性、截面形状（圆形和矩形）和尺寸等不同分为若干型号及规格，与正畸托槽等配套，供口腔正畸用。产品性能指标采用下列参考标准中的适用部分，如：YY 0625-2008 牙科学 正畸产品：正畸丝。	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:	II
430	6863	口腔科材料	dental material	正畸弹性体附件	Orthodontic elastomeric attachments	正畸弹性体附件包括正畸弹性牵引圈、正畸弹力线/弹力管、正畸橡皮链、正畸结扎圈、正畸分牙圈，用天然或合成橡胶制成，可按材质、形状、尺寸等不同分为若干型号及规格；在口内与口外与固定或活动矫治器起协同矫治作用。产品性能指标采用下列参考标准中的适用部分，如：YY 0624-2008 牙科学 正畸产品：正畸弹性体附件。	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	II
431	6863	口腔科材料	dental material	牙科用磷酸酸蚀剂	Dental phosphoric acid etching agent	牙科用磷酸酸蚀剂为液状，可按组方、磷酸含量、装量等不同分为若干型号及规格；供牙齿充填修复、正畸托槽粘固、防龋材料使用前对牙齿表面作酸蚀处理用。产品性能指标采用下列参考标准中的适用部分，如：YY 9769-2009 牙科用磷酸酸蚀剂。	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	口腔科材料	dental material	印模石膏	Plaster impression	印模石膏主要由半水硫酸钙及改性剂组成，按材料、配方、技术参数等不同分为若干种，供牙齿和口腔组织印模用。产品性能指标采用下列参考标准中的适用部分，如：YY 0462—2003 牙科石膏产品。	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	II
433	6863	口腔科材料	dental material	牙科琼脂基水胶体印模材料	Agar-based hydrocolloid dental impression material	琼脂基水胶体印模材料为可逆性凝胶材料，可按稠度等技术参灵长不同分为若干型号和规格，供牙齿和口腔组织印模用。若用于技工室复制模型，可重复使用。产品性能指标采用下列参考标准中的适用部分，如：YY 0494—2004 牙科琼脂基水胶体印模材料。	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	口腔科材料	dental material	弹性体印模材料	Elastomeric impression material	弹性体印模材料是经塑性后，印模具有弹性的材料，如硅橡胶、聚醚橡胶，通常由基质、交联剂、催化剂和填料组成，可按材料、配方、印模技术参数（如弹性、化学稳定性、凝固时间等）等不同分为若干型号和规格，经聚合反应后，对牙齿和口腔组织取模用。产品性能指标采用下列参考标准中的适用部分，如：YY 0493—2011 牙科学 弹性	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	II

435	6863	口腔科材料	dental material	齿科藻酸盐印模材料	Dental alginate impression material	齿科藻酸盐印模材料为粉末状, 外观均匀无杂质, 调和后的材料应是均匀, 不结团, 不成粒, 且表面光滑, 能形成光滑的可塑体, 一次性使用产品, 无口腔粘膜刺激性, 无致敏毒性, 主要组成成分为海藻酸盐、硫酸钙、硅藻土、滑石粉等, 可按组方、调和时间、总工作时间、固化时间等不同分为若干规格, 供制取牙齿和口腔组织印模用。产品性能指标采用下列参考标准中的适用部分, 如: YY 1027-2001 齿科藻酸盐印模材料。	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 standard: YY 1027-	II
436	6863	口腔科材料	dental material	硅橡胶咬合记录材料	Silicone bite registration	硅橡胶咬合记录材料主要成分为二氧化硅、聚二甲基硅氧烷, 用于咬合关系的记录用。	The main component are silicon dioxide, polydimethylsiloxane. Used for recording occlusion.	II
437	6863	口腔科材料	dental material	牙齿干燥剂	Teeth desiccant	牙齿干燥剂由乙醇、丙酮、蒸馏水等组成; 敷于待诊疗牙齿表面, 使其快速清洁、干燥, 以利进一步的诊疗操作。	The main component are ethanol, acetone, distilled water, etc.. Covered on the teeth surface for rapid cleaning, drying for further diagnosis and treatment.	II
438	6863	口腔科材料	dental material	排龈线	Gingival retraction cord	排龈线为辫子结构的白色棉线等适用材料制成, 不含止血等药物成分, 可按材质、线径、长度等不同分为若干种, 供牙体制备、取印模或粘冠等操作前排开牙龈, 减少损伤、干燥局部等用。	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	口腔科材料	dental material	排龈膏	Gingival retraction cream	排龈膏可由氯化铝、高岭土和辅料组成, 膏状, 不含止血等药物成分, 可按配方、装量、附件等不同分为若干种; 通过物理吸附、填充, 供牙体制备、取印模或粘冠等操作前排开牙龈, 减少损伤、干燥局部等用。	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,	II
440	6863	口腔科材料	dental material	口内研磨抛光材料	Intraoral polishing material	口内研磨抛光材料主要由二氧化硅或碳酸氢钠及辅料制成, 可为粉状或膏状, 可按组方、磨料颗粒大小、装量、附件等不同分为若干种; 供在口内研磨抛光牙体组织或修复体, 使其表面平滑均匀。	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	口腔科材料	dental material	固位纤维	Fiber Reinforcement	固位纤维主要成分为高分子材料如聚对苯二甲酸乙二醇酯或玻璃纤维, 可按材质、设计、物理性能、尺寸等不同分为若干种; 供松牙固定、缺失牙齿的临时修复、牙列间隙保持、固定桥的临时或永久加固和修复等用。	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	口腔科材料	dental material	牙科光学喷粉	Dental Optical dusting	牙科光学喷粉由乙醇、氟化烃、薄荷香料组成, 用于牙科修复体计算机辅助设计的制作过程, 喷涂在病人牙齿上, 以辅助口腔摄像机获取清晰的牙齿3D图像。	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	II
443	6863	口腔科材料	dental material	种植基台用保护帽	Protective cap for planting base	种植基台用保护帽由聚甲基丙烯酸甲酯和塑料聚甲醛制成, 帽状, 覆盖在种植体的上部结构(基台)上, 防止细菌进入种植体及上部结构(基台)内部引起感染并防止划伤种植体表面。	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	II
444	6863	口腔科材料	dental material	义齿密合剂	Denture sealing agent	义齿密合剂可由山羧甲基纤维素钠和聚甲基乙烯醚钠盐、钙盐和缩苹果酸混合物及其他辅料等制成的膏状物, 可按组方、技术参数等不同分为若干种; 供义齿修复中, 涂覆在义齿与牙龈间间隙, 防止食物残渣等进入引起感染。	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 caused by food	II
445	6863	口腔科材料	dental material	氢氧化钙根管消毒剂	Calcium hydroxide root canal disinfectant	氢氧化钙根管消毒剂为单组分糊剂或双组分粉剂, 单组分主要含氢氧化钙与赋型剂, 双组分主要成分是氢氧化钙和丙二醇水溶液, 可附工具; 可按组方、技术参数及附件等不同分为若干种; 口腔内根管的消毒用。	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	II
446	6863	口腔科材料	dental material	正畸颊面管	Orthodontic buccal tubes	正畸颊面管可由主体和拉钩组成, 通常由不锈钢等适用材料制成, 可按材质、设计、技术参数等不同分为若干型号及规格; 与正畸托槽、正畸丝等配套, 供口腔正畸用。	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	口腔科材料	dental material	正畸结扎丝	Orthodontic ligature wire	正畸结扎丝可由不锈钢丝等适用材料制成, 可按材质、物理性能、丝径/长度等不同分为若干种, 主要用于口腔科牙列正畸时将正畸丝与托槽或其他附件相结扎, 以达到固定及牵引牙齿移动的目的。	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	口腔科材料	dental material	游离牵引钩	Free towing hook	游离牵引钩可由不锈钢丝等适用材料制成, 可按材质、物理性能、尺寸等不同分为若干种, 与其他正畸产品配套, 供口腔正畸用。	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	口腔科材料	dental material	螺旋扩弓器	Spiral arch expansion device	螺旋扩弓器用不锈钢等适用材料制成, 可由丝杆、螺母、导向杆、调节杆组成, 可按材质、设计、技术参数、适用部位等不同分为若干种, 供牙弓狭窄者扩大牙弓间隙等用。	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	口腔科材料	dental material	正畸弹簧	Orthodontic spring	正畸弹簧采用不锈钢丝等适用金属材料制成，可按材质、设计、技术参数、预期用途等不同分为若干种，如拉伸、压缩、旋转弹簧；与其他正畸产品配套，供口腔正畸用。	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	口腔科材料	dental material	颌前方牵引口外装置	Front jaw Extraoral traction appliances	颌前方牵引口外装置由前额托架、可调式支架、调节器和下颌兜等组成，前额托架和下颌兜采用聚丙烯树脂制成，可调式支架采用不锈钢制成；可按材质、设计、技术参数等不同分为若干种；配合口内正畸装置，供人体上颌矫正时辅助牵引用。不包括口内正畸装置。	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 apparatus.	II
452	6863	口腔科材料	dental material	磨牙推进器	Molar propeller	磨牙推进器用不锈钢等适用金属材料制成，由各类支杆和弹簧组成，可按材质、设计、技术参数等不同分为若干种；与托槽、带环、种植钉等配套，用于推动磨牙，获得错牙排齐所需间隙。不包括种植钉、托槽、带环。	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	口腔科材料	dental material	牙科膜片	Dental diaphragm	牙科膜片可采用聚乙烯、醋酸乙烯酯、可食用色素等适用材料制成，物理性能稳定，具有一定的弹性、抗压、易塑性,单层片状结构，可按材质、形状、尺寸等不同分为若干种，供制作运动护齿、托槽定位、正位等护垫用。	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 positioning, anteroposterior,	III
454	6863	口腔科材料	dental material	玻璃离子水门汀	Glass ionomer cement	经硅铝酸盐玻璃粉与链烯酸水溶液反应，或经硅铝酸盐玻璃粉/聚酸粉与水货酒石酸水溶液反应而固化的水门汀。豁免临床的产品须至少符合YY 0271.1 牙科水基水门汀 第1部分：粉/液酸碱水门汀的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	III
455	6863	口腔科材料	dental material	不含丁香酚的氧化锌水门汀	zinc oxide cement without eugenol	主要由氧化锌、矿物油等组成。适用于牙科暂时修复和垫底。豁免临床的产品须至少符合YY 0272 牙科学 氧化锌/丁香酚水门汀和不含丁香酚的氧化锌水门汀的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	Mainly composed of zinc oxide, mineral oil. Used for temporary dental restoration and rebase. 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	口腔科材料	dental material	固位钉	Retention nails	用于牙体大面积缺失，为修复牙齿提供固位力。多由金属组成。	Used in large area of missing teeth repair and to provide retention in teeth repair. Mainly made of metal.	III

457	6863	口腔科材料	dental material	合成树脂牙	Synthetic resin teeth	主要由丙烯酸酯类聚合物制作而成, 适用于局部义齿和全口义齿的制作。豁免临床的产品须至少符合YY 0300 牙科学 修复用人工牙的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	口腔科材料	dental material	金属桩	Metal post	用于根管治疗后牙体大面积缺损时对重建的冠核进行可靠固位。豁免临床的产品须至少符合YY/T 0517 牙科预成根管桩的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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 mechanism or	III
459	6863	口腔科材料	dental material	聚合物基冠桥材料	Polymer-based crown and bridge material	主要由高分子材料组成, 用于牙列缺损、牙列缺失的修复。豁免临床的产品须至少符合YY 1042 《牙科学 聚合物基修复材料》的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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 new action mechanism or function.	III
460	6863	口腔科材料	dental material	聚羧酸锌水门汀	Zinc polycarboxylate cement	经氧化锌与聚丙烯酸水溶液或聚链烯酸反应或经氧化锌/聚链烯酸粉与水反应而固化的水门汀。适用于牙科窝洞的垫底及衬层。豁免临床的产品须至少符合YY 0272 牙科学 氧化锌/丁香酚水门汀和不含丁香酚的氧化锌水门汀的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	口腔科材料	dental material	磷酸锌水门汀	Zinc phosphate cement	经氧化物粉末(主要组成为氧化锌)与磷酸水溶液反应而固化的水门汀。豁免临床的产品须至少符合YY 0271.1 牙科水基水门汀 第1部分: 粉/液酸碱水门汀的相关要求。	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	III
462	6863	口腔科材料	dental material	氢氧化钙水门汀	Calcium hydroxide cement	主要成分为氢氧化钙和螯合剂。常作为低强度垫底材料、衬层、间接衬层或盖髓剂。豁免临床的产品须至少符合YY 0271.1 牙科水基水门汀 第1部分: 粉/液酸碱水门汀 的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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 mechanism or function.	III

463	6863	口腔科材料	dental material	纤维桩	Fiber post	用于根管治疗后牙体大面积缺损时对重建的冠核进行可靠固位。豁免临床的产品须至少符合YY/T 0517 牙科预成根管桩的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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 mechanism or	III
464	6863	口腔科材料	dental material	牙胶尖	Gutta percha	主要由古塔胶、氧化锌、硫酸钡组成。属于牙科固体根管充填材料。适用于牙髓炎及根尖周围组织疾病,于患牙处打孔清洗后填充根管,配合药物使用达到治疗的目的。豁免临床的产品须至少符合YY 0495 牙根管充填尖的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	III
465	6863	口腔科材料	dental material	氧化锌丁香酚水门汀	Zinc oxide eugenol cement	由粉剂和液剂组成。粉剂由氧化锌、树脂、硬脂酸锌和粗酸锌等组成。液剂由丁香油、橄榄油等组成。适用于牙科暂时修复和垫底。豁免临床的产品须至少符合YY 0272 牙科学 氧化锌/丁香酚水门汀和不含丁香酚的氧化锌水门汀的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	III
466	6863	口腔科材料	dental material	义齿基托聚合物	Denture base polymer	主要由甲基丙烯酸甲酯（MMA）的均聚物或丙烯酸酯类的共聚物以及甲基丙烯酸甲酯单体制成，适用于义齿基托的制作。豁免临床的产品须至少符合YY 0270.1牙科学 基托聚合物 第1部分：义齿基托聚合物的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	III
467	6863	口腔科材料	dental material	银汞合金	silver amalgam	主要由银、锡、铜和少量的钢、钯、铂、锌及汞等元素组成。适用于龋齿治疗时的窝洞充填。豁免临床的产品须至少符合YY 1026 牙科学 汞及银合金粉的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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 new action mechanism or function.	III
468	6863	口腔科材料	dental material	预处理剂	Pretreating agent	主要由硅烷偶联剂、粘接性单体和挥发性单体组成。也有的是酸如氢氟酸。用于提高修复体之间粘结力。	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	口腔科材料	dental material	暂时冠桥树脂	Temporary Crown and Bridge Resin	主要由高分子材料组成，用于制作临时冠桥。豁免临床的产品须至少符合YY 1042牙科学 聚合物基修复材料的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	口腔科材料	dental material	造牙粉及造牙水	powder for synthetic polymer teeth and liquid for synthetic polymer teeth	主要由甲基丙烯酸甲酯（MMA）的均聚物或丙烯酸酯类的共聚物以及甲基丙烯酸甲酯单体制成，适用于义齿的制作。豁免临床的产品须至少符合YY 0270.1 牙科学 基托聚合物 第1部分：义齿基托聚合物的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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 function.	II
471	6863	口腔科材料	dental material	正畸基托聚合物	Orthodontic base polymers	主要由甲基丙烯酸甲酯（MMA）的均聚物或丙烯酸酯类的共聚物以及甲基丙烯酸甲酯单体制成，适用于正畸基托的制作。豁免临床的产品须至少符合YY 0270.2-2011 牙科学 基托聚合物 第2部分：正畸基托聚合物的相关要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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 new action mechanism or function.	II
472	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	医用脱脂棉及其制品	Medical degreasing cotton and related products	医用脱脂棉系用纯棉花（绒）经开松、除杂、脱脂、漂白等工序加工而成，按分装重量不同分为若干规格，为非灭菌产品。医用脱脂棉还可加工成其他大小、形状、形式各异的医用敷料，如医用脱脂棉块、垫等，可以灭菌或非灭菌形式提供（用前灭菌），供临床护创伤、吸湿用。产品性能指标采用下列参考标准中的适用部分，如：YY 0331—2006 脱脂棉纱布、脱脂棉粘胶混纺纱布的性能要求，YY 0594—2006 外科纱布敷料通用要求（含1号修改单）。	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 be 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, moisture absorption. Reference standard: YY 0331-2006 Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze, YY	II
473	6864	医用卫生材料及敷料	Medical hygienic materials and	医用无菌液体石蜡无纺布	Medical sterile liquid paraffin	医用无菌液体石蜡无纺布由非织造布和液状石蜡制成，可按配方、材质、尺寸等不同分为若干型号及规格，可以无菌形式提供；供患者检查部位表面及器械表面润滑用。	Mainly made of non-woven and liquid paraffin. Can be divided into different specifications according to recipe, texture, size, etc..Sterile form; Used for lubrication on the surface of patient examination parts and devices.	II

474	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	医用一次性防护服	Medical single-use protective clothing	医用一次性防护服用具有特定液体阻隔功能、特定强度、过滤效率、阻燃性能、抗静电和静电衰减功能的适宜材料制成, 由连帽上衣、裤子组成, 袖口、脚踝口为弹性收口, 帽子面部收口及腰部收口可采用弹性收口、拉绳收口或搭扣; 可分为连身式或分体式两类, 每类按尺寸不同分为若干规格, 供临床医务人员在工作时接触到的具有潜在感染性的患者血液、体液、分泌物等提供阻隔、防护用。产品性能指标采用下列参考标准中的适用部分, 如: GB 19082-2009 医用一次性防护服技术要求。	Made of texture 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	II
475	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	医用防护口罩	Respirator	医用防护口罩用具有较小的气流阻力、合成血液阻隔、特定强度、过滤效率、表面抗湿性及阻燃性能的适宜材料制成, 为自吸式, 由口罩体(含鼻夹)和口罩带组成, 可按过滤效率不同分为3级, 每级按尺寸不同分为若干规格, 供医疗工作环境下, 过滤空气中的颗粒物、阻隔飞沫、血液、体液、分泌物等用。产品性能指标采用下列参考标准中的适用部分, 如: GB 19083-2010 医用防护口罩技术要求。	Made of texture 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	II
476	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	医用一次性防护帽	Medical single-use protective cap	医用一次性防护帽用具有特定液体阻隔功能、特定强度、过滤效率、阻燃性能、抗静电和静电衰减功能的适宜材料制成, 防护帽收口可为弹性收口, 可按形状等不同分为若干种, 每种按尺寸不同分为若干规格, 供临床医务人员在工作时接触到的具有潜在感染性的患者血液、体液、分泌	Made of texture which is with the function of specific liquid 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 which are with	II
477	6864	医用卫生材料及敷料	Medical hygienic materials and	医用防护鞋	Medical Protective Footwear	医用防护鞋可用带透气孔的高分子材料制成, 全包型, 可按材质、型式、使用对象、尺寸等不同分为若干型号和规格; 供医务人员在特殊场所(如手术室、重症监护室等)使用, 防止血液、污液或锋利器械损伤。	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	II
478	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	医用防护鞋套	Medical protective shoe covers	医用防护鞋套用具有特定液体阻隔功能、特定强度、过滤效率、阻燃性能、抗静电和静电衰减功能的适宜材料制成, 防护鞋套封口可为弹性收口, 可按型式、材料等不同分为若干种, 每种按尺寸不同分为若干规格, 供临床医务人员在工作时接触到的具有潜在感染性的患者血液、体液、分泌物等提供阻隔、防护用。	Made of texture 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	II

479	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	一次性使用手术衣	single-use surgical gowns	一次性使用手术衣可用具有一定防护特性的无纺布或覆膜无纺布复合材料制成, 可由衣领、衣身、衣袖组成, 也可由上衣、裤子组成, 袖口、脚踝口为弹性收口, 腰部收口可采用弹性收口、拉绳收口或搭扣; 可分为褂式、连体式、分体式等, 每类按尺寸不同分为若干规格, 前襟、肘部等可设计成加强防护, 通常以无菌形式提供, 供手术人员穿着, 降低感染源向病人手术创面传播以防止术后创面感染; 具有阻止液体透过的手术衣, 也可减小血液或体液中携带的感染源向手术人员传播的风险。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0506 病人、医护人员和器械用手术单、手术衣和洁净服。	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	II
480	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	一次性使用无菌洁净服	single-use sterile clean clothes	一次性使用无菌洁净服可用具有一定防护特性的无纺布或覆膜无纺布复合材料制成, 可由衣领、衣身、衣袖组成, 也可由上衣、裤子组成, 袖口、脚踝口为弹性收口, 腰部收口可采用弹性收口、拉绳收口或搭扣; 可分为褂式、连体式、分体式等, 每类按尺寸不同分为若干规格; 可以无菌或消毒形式提供, 供进入手术洁净区人员穿着以降低因人员携带感染源造成的洁净区空气微生物污染, 防止病人术后创面感染。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0506 病人、医护人员和器械用手术单、	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 resource carried by personnel. Reference standard: YY/T 0506 Surgical drapes gowns	II
481	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	一次性使用隔离衣	single-use isolation gowns	一次性使用隔离衣可用具有一定防护特性的无纺布或覆膜无纺布复合材料制成, 可由衣领、衣身、衣袖组成, 也可由上衣、裤子组成, 也可含鞋; 袖口、脚踝口为弹性收口, 腰部收口可采用弹性收口、拉绳收口或搭扣; 可分为褂式、连体式、分体式等, 每类按尺寸不同分为若干规格, 通常以非灭菌形式提供, 供进入潜在致病源污染区的人员穿着以保护进入人员免于因感染致病。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0506 病人、医护人员和器械用手术单、手术衣和洁净服。	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	II
482	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	一次性使用医用外科口罩	single-use medical surgical masks	一次性使用医用外科口罩通常用无纺布或无纺布复合材料制成, 可为三层结构, 有可塑性鼻夹, 口罩带可为弹性或非弹性, 具有较小的气流阻力、具有合成血液阻隔、过滤颗粒物和细菌、阻燃等特性, 可按型式、尺寸不同分为若干型号、规格; 通常以无菌形式提供, 供临床医务人员在有创操作过程中佩戴, 覆盖住使用者的口、鼻及下颌, 为防止病原体微生物、体液、颗粒物等的直接透过提供物理屏障。产品性能指标采用下列参考标准中的适用部分,	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 filtration. 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	医用卫生材料及敷料	Medical hygienic materials and dressings	一次性使用无菌手术单	single-use sterile surgical drapes	一次性使用无菌手术单可用具有一定防护特性的无纺布或覆膜无纺布复合材料制成, 可按设计型式和尺寸不同分为若干型号和规格, 通常以无菌形式提供, 供覆盖在患者身体表面, 手术洞巾或手术覆膜之上, 降低患者皮肤等非手术部位感染源向手术部位移行, 防止病人术后创面感染, 同时也可因特别设计而具有收集手术污物等功能。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0506 病人、医护人员和器械用手术单、手术衣和洁净服。	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	医用卫生材料及敷料	Medical hygienic materials and dressings	手术洞巾	Surgical drapes	手术洞巾可用具有一定防护特性的无纺布或覆膜无纺布复合材料制成, 可按设计型式和尺寸不同分为若干型号和规格, 通常以无菌形式提供, 供覆盖在患者手术皮肤创面周围, 降低患者手术创口面皮肤的感染源向手术创面部位移行, 防止病人术后创面感染。	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	医用卫生材料及敷料	Medical hygienic materials and dressings	一次性使用无菌手术膜	single-use sterile surgical membrane	一次性使用无菌手术膜可采用天然胶乳(可不涂医用压敏胶)或聚氨酯、聚乙烯基材上涂敷低致敏性压敏胶, 上置离型纸制成, 可按材质、形状、尺寸等不同分为若干规格, 以无菌形式提供; 供简化术前护皮操作, 预防接触性和移行性手术创面感染。产品性能指标采用下列参考标准中的适用部分, 如: YY 0852-2011 一次性使用无菌手术膜。	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, etc.. Sterile 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	II
486	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	医用口罩(非外科用)	Medical masks (non-surgical)	医用口罩(非外科用)通常用无纺布或无纺布复合材料制成, 可为二层或三层结构, 可有可塑性鼻夹, 口罩带可为弹性或非弹性, 具有过滤颗粒物和细菌等特性, 可按型式、尺寸不同分为若干型号、规格; 通常以无菌形式提供, 供临床各类人员在非有创操作过程中佩戴, 覆盖住使用者的口、鼻及下颌, 为防止病原体微生物、颗粒物等的直接透过提供一定的物理屏障。	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 function of particulate matter and bacteria filtration. 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	II
487	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	一次性使用无菌敷贴	Single-use sterile dressing	一次性使用无菌敷贴由涂有医用压敏胶的聚氨酯/聚乙烯复合膜或无纺布制成, 可有纱布、木质棉、活性炭纤维、水胶体的敷芯, 不含药; 可按材质、层次、形状、尺寸等不同分为若干型号、规格; 产品以无菌形式提供; 供手术、外伤创面或留置动、静脉导管贴敷用; 也可用于婴儿脐带创面保护。	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	II

488	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	一次性医用水凝胶眼贴	single-use medical hydrogel eye patch	一次性医用水凝胶眼贴可由无纺布基层、医用聚乙烯醇水凝胶和离型纸组成；可按形状、尺寸等不同分为若干型号和规格；贴敷于全麻或深度昏迷病人的眼外部，通过提供相对密闭的潮湿环境，预防暴露性角膜炎。	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	医用卫生材料及敷料	Medical hygienic materials and dressings	创可贴	Woundplaster	创可贴由涂有医用压敏胶等粘胶剂的聚氨酯复合膜或无纺布等制成，不含药；可按材质、层次、形状、尺寸等不同分为若干型号和规格，以无菌形式提供；供手术创面、动脉、静脉导管留置时贴敷用，也可用于婴儿脐带创面保护用。	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	医用卫生材料及敷料	Medical hygienic materials and dressings	婴儿光疗防护眼罩	Infant phototherapy protective goggles	婴儿光疗防护眼罩可由眼罩和眼罩固定两部分组成；眼罩可由优质无纺布/蓝黑物理复合布等制成，固定部分可用弹力带或柔软魔术贴等材料制成；可按材质、设计、技术参数与尺寸等不同分为若干型号及规格；供婴儿蓝光照射治疗时的眼部防护用。	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	医用卫生材料及敷料	Medical hygienic materials and	医用无纺布敷料	Medical Non-woven dressing	医用无纺布敷料采用无纺布制成，可按材质、是否折叠、层数、大小、预期用途等不同分为若干种；供临床在诊疗过程中护创、吸湿、保护脏器 etc.	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	医用卫生材料及敷料	Medical hygienic materials and dressings	凡士林/石蜡纱布（油纱）	Vaseline/paraffin gauze (gauze)	由医用脱脂纱布、凡士林、石蜡油制成，预期用途仅限于创面引流、覆盖、填塞的凡士林/石蜡纱布。豁免情况不包括以下情况：（1）适应症宣称可以促进伤口愈合、减轻疼痛、止血、减少疤痕、防粘连等作用的产品；（2）用于体内伤口等情况的产品；（3）含有活性成分的产品：如药品/药用活性成分、生物制品/生物活性成分、银、消毒剂等；（4）其他新型产品。	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, anti-adhesion 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	II

493	6864	医用卫生材料及敷料	Medical hygienic materials and dressings	聚氨酯泡沫敷料	Polyurethane foam dressing	主要由聚氨酯泡沫组成, 预期用途仅限于覆盖创面, 吸收创面渗液的聚氨酯泡沫敷料。豁免情况不包括以下情况: (1) 适应症宣称可以促进上皮化、引导组织再生、促进伤口愈合、减轻疼痛、止血、减少疤痕、防粘连等作用的产品; (2) 宣称可以用于体内伤口、三度烧伤、感染创面、坏死组织较多的创面、发生创面脓毒症的患者等情况的产品; (3) 含有活性成分的产品: 如药品/药用活性成分、生物制品/生物活性成分、银、消毒剂等; (4) 其他新型产品。	Mainly made of polyurethane foam. The intended use is limited into wound covering, wound exudate absorption. 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, silver, disinfectants; (4)	II
494	6865	医用缝合材料及粘合剂	Medical suture materials and adhesives	非吸收性外科缝线	Non-absorbable surgical sutures	非吸收性外科缝线可分别由蚕丝、聚酰胺6/66、聚对苯二甲酸乙二酯、聚丙烯、不锈钢丝、钛镍记忆合金丝等制成, 可带或不带缝合针, 可按材质、股数/编织、涂层、带针、束/团、线径、使用部位等不同分为若干型号及规格; 可以灭菌或非灭菌状态提供; 供人体组织的缝合、结扎用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0167-2005 非吸收性外科缝线, YY 0166-2002 带线缝合针	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	II
495	6865	医用缝合材料及粘合剂	Medical suture materials and adhesives	一次性使用皮肤缝合器	Single-use skin stapler	一次性使用皮肤缝合器由推片(12Cr18Ni9/06Cr10Ni10)、壳体(ABS)、手柄(PA/ABS)、缝合钉(022Cr17Ni12Mo2)组成, 可选配拆钉器; 可按照设计、缝合钉数量、缝合钉成形后的外形尺寸等不同分为若干型号及规格; 产品以无菌形式提供; 供创伤及手术切口的表层皮肤缝合用。	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	II
496	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用无菌阴道扩张器	Single-use sterile vaginal dilator	一次性使用无菌阴道扩张器可采用聚丙烯等适用高分子材料制成, 主要由上叶、下叶和手柄组成, 可按材质、型式、尺寸不同分为若干型号和规格; 产品以无菌形式提供; 供妇产科作阴道诊察用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0336-2002 一次性使用无菌阴道扩	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	医用高分子材料及制品	Medical polymer materials and products	天然胶乳橡胶避孕套	Natural rubber latex condoms	天然胶乳橡胶避孕套采用天然胶乳制造, 可按模型差异分为平面型、浮点型、螺纹型、异型; 按添加成分不同分为若干种; 可按标称宽度不同分为若干规格; 彩色型添加食品级颜料, 香味型添加食用香精, 润滑型增加适量湿型润滑剂硅油用量; 标称宽度、模型差异与添加成分可进行一定的组合。供男性用于避孕和预防性传播疾病。产品性能指标采用下列参考标准中的适用部分, 如: GB 7544-2009 天然胶乳橡胶避孕套 技术要求与试验方法。	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 test	II

498	6866	医用高分子材料及制品	Medical polymer materials and products	聚异戊二烯合成橡胶避孕套	Polyisoprene synthetic rubber condoms	用聚异戊二烯橡胶制造，可按模型差异分为平面型、浮点型、螺纹型、异型；按添加成分不同分为若干种；可按标称宽度不同分为若干规格；彩色型添加食品级颜料，香味型添加食用香精，润滑型增加适量湿型润滑剂硅油用量；标称宽度、模型差异与添加成分可进行一定的组合。供男性用于避孕和预防性传播疾病。产品性能指标采用下列参考标准中的适用部分，如：GB 7544-2009天然胶乳橡胶避孕套 技术要求与试验方法。	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 condoms—	II
499	6866	医用高分子材料及制品	Medical polymer materials and products	女用聚氨酯避孕套	Polyurethane female condom	女用聚氨酯避孕套用由带内、外环和聚氨酯薄膜囊组成，内环封闭，内外表面涂有二甲基硅油，可按设计、技术参数等不同分为若干种；供女性用于避孕和预防性传播疾病。	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	医用高分子材料及制品	Medical polymer materials and	子宫托	Pessary	子宫托采用硅橡胶或适用的材料制成，为环形，可按材质、形状、大小等不同分为若干种；用于缓解中老年女性子宫后倾、脱垂带来的疼痛及并发症。	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, prolapse.	II
501	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用导尿管	Single-use catheter	一次性使用导尿管可采用聚氯乙烯、天然胶乳、硅橡胶、橡胶材料制成，通常由管身与接头组成，可按使用对象（如男用、女用、儿童用）、使用材料、管腔数、是否有球囊、管径与长度等不同分为若干型号与规格，一次性使用，除橡胶导尿管外，通常以无菌形式提供，供临床常规导尿用。不含微波、射频理疗/治疗用多腔导尿管。产品性能指标采用下列参考标准中的适用部分，如：YY 0325-2002一次性使用无菌导尿管。	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, etc..Single 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	II
502	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用胆道引流管	Single-use biliary drainage tube	一次性使用胆道引流管可采用硅胶等适用材料制成，可由螺旋形引流端、管身和接头等组成；可按材质、设计及技术参数等不同分为若干型号及规格；产品以无菌形式提供；供内窥镜胆道结石手术或胆囊摘除术后胆汁引流用。	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	医用高分子材料及制品	Medical polymer materials and products	一次性使用体表引流球/管	single-use surface drainage ball/tube	一次性使用体表引流球/管可采用硅橡胶、乳胶等适用材料制成，可设计成多种形状，管身有侧孔，可接负压球，可按材质、设计、管径、适用部位等不同分为若干型号及规格；以无菌形式提供；供体表创伤或切口引流用。	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 drainage.	II

504	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用肠内给养器	Single-use Enteral giving device	一次性使用肠内给养器通常采用高分子材料制成, 可由营养瓶/袋、输注管路(含流量、流速控制装置)、胃/肠营养导管连接装置、胃/肠营养导管组成, 可按材质、设计、技术参数、适用范围、预期用途等不同分为若干型号; 以无菌形式提供; 与肠内营养输液器/泵配套, 供人体肠内营养液输送用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0483-2004 一次性使用肠营养导管、肠给养器及其连接件 设计与试验方法, YY/T 0817-2010 带定位球囊的肠营养导管物理性能要求及试验方法。	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 single use and	II
505	6866	医用高分子材料及制品	Medical polymer materials and	一次性使用泪道引流管	single-use lacrimal drainage tube	一次性使用泪道引流管由硅橡胶等适用材料制成, 可按材质、设计、尺寸等不同分为若干种; 可以无菌形式提供; 适用于泪小管狭窄、阻塞、断裂治疗后冲洗、引流用。	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	医用高分子材料及制品	Medical polymer materials and products	一次性使用J型导尿管	single-use J-type catheters	一次性使用J型导尿管多采用聚氨酯制成, J型端有端孔和多个光滑的侧孔, 可按管径、长度等不同分为若干规格, 以无菌形式提供; 通过微创介入或开放手术置入肾盂与膀胱间, 起支架、引流作用, 滞留时间不超过30天。	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	II
507	6866	医用高分子材料及制品	Medical polymer materials and	一次性使用输尿管引流管	single-use ureteral drainage tube	一次性使用输尿管引流管可采用聚氨酯等适用材料制成, 通常为直型, 管身有侧孔; 可按管径、长度等不同分为若干规格, 以无菌形式提供; 供输尿管支撑、引流用。	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	医用高分子材料及制品	Medical polymer materials and products	一次性使用膀胱造瘘管	single-use bladder fistula	一次性使用膀胱造瘘管由造瘘管(软聚氯乙烯塑料、聚氨酯、硅橡胶等适用材料制成)、导引针(不锈钢制成)和连接管(医用软聚氯乙烯塑料制成)组成; 可按管径、长度、是否有球囊等不同分为若干规格, 以无菌形式提供; 供临床暂时性尿流改道, 耻骨上膀胱穿刺造瘘, 引流尿液用。	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	医用高分子材料及制品	Medical polymer materials and	一次性使用尿道扩张器	single-use urethral dilator	一次性使用尿道扩张器由管体, 接头和导丝组成, 可按材质、设计、管径/长度等不同分若干型号、规格, 可以单个或多个组合成一套; 以无菌形式提供; 适用于泌尿外科尿道狭窄的扩张, 解除尿道梗阻用。	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	II
510	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用膀胱冲洗器	single-use bladder irrigator	一次性使用膀胱冲洗器主要用PVC等塑料制成, 可由穿刺器、保护套、管道夹、管路、滴斗、流量调节器、导管连接器组成, 可按材质、设计、技术参数等不同分为若干型号及规格; 供泌尿外科手术中, 膀胱、尿路、手术器械等冲洗用。	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	医用高分子材料及制品	Medical polymer materials and products	呼吸道用吸引导管	Suction catheter for respiratory tract	呼吸道用吸引导管通常由有端孔的导管和带塞接头组成；导管可采用聚氯乙烯、天然胶乳、硅橡胶、橡胶材料制成，带塞接头可相应采用聚氯乙烯、硅橡胶或MD型聚氯乙烯制成；导管按材质、管径等不同分为若干型号与规格，产品应无菌形式提供。可与真空负压系统或设备连接，供呼吸道吸引痰液等用。不包括没有端孔的多腔呼吸道吸引导管。产品性能指标采用下列参考标准中的适用部分，如：YY 0339-2009 呼吸道用吸引导管。又名一次性使用吸痰管。	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, etc..Sterile 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	II
512	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用气管插管	single-use trachea cannula	一次性使用气管插管通常由气管插管管体、充气管、套囊、接头和充气阀组成；其中气管插管的管体、充气管、套囊可采用聚乙烯等塑料、硅橡胶等适宜材料制成，接头、充气阀可采用聚乙烯等材料制成；气管插管可分为普通有/无套囊插管和加强型有/无套囊插管等不同型号，每型可按公称内径、套囊等不同分成若干规格；产品应以无菌形式提供；供临床麻醉或急救时建立人工气道用。产品性能指标采用下列参考标准中的适用部分，如：YY 0337-2002 气管插管。不包括支气管插管。	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-aid. Reference standard: YY 0337-2002 endotracheal intubation.Does not include bronchial intubation.	II
513	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用气管切开插管	single-use tracheostomy tube	一次性使用气管切开插管由气管切开插管管体（病人端有圆滑尖部、斜面和固定球囊）、标准外圆锥接头（机器端）、一体式指示球囊/阀组合和固定翼组成；其中，气管切开插管的管体、充气管、套囊可采用聚乙烯塑料、橡胶等适宜材料制成，接头、充气阀可采用聚乙烯等材料制成；气管切开插管可分为普通有/无套囊切开插管和加强型有/无套囊切开插管等不同型号，每型可按适用人群、公称内径、套囊容量等不同分成若干规格；产品应以无菌形式提供；供临床急救气管节切开，建立人工气道用。产品性能指标采用下列参考标准中的适用部分，如：YY 0338-2002 气管切开插管。	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	II
514	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用医用喉罩	single-use Medical Laryngeal Mask	一次性使用医用喉罩可用硅橡胶等制成，由套囊、充气管、喉罩插管、机器端、接头、指示球囊等组成，喉罩插管可为金属加强型，可按材质、设计、技术参数、辅助功能等不同分为若干型号及规格；供全麻或心肺人工复苏建立短期人工气道用。	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 cardiopulmonary resuscitation.	II

515	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用口/鼻咽通气道	single-use mouth/nasopharyngeal airway	一次性使用口/鼻咽通气道用高分子材料制成，为带有凸缘末端的呼吸管，可按材质、设计、插入部位管径/长度等不同分为若干型号及规格；可以无菌形式提供，供建立口/鼻咽通气道，防止舌后坠引起气道阻塞等用。	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	医用高分子材料及制品	Medical polymer materials and products	一次性使用麻醉面罩	single-use anesthesia mask	一次性使用麻醉面罩可采用硅橡胶等高分子材料制成，可由面杯、气囊、气门芯组件（气门芯阀体、阀芯、密封圈、弹簧和底盖）和固定圈组成，可按材质、设计、技术参数、预期用途、辅助功能等不同分为若干型号及规格；供临床麻醉呼吸用。	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 breathing.	II
517	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用光纤喉镜	single-use fiber optic laryngoscope	一次性使用光纤喉镜由塑料制手柄和内含防雾CCD摄像头及光纤导线的窥片（塑料制）组成，手柄另一端可接显示器。手柄与窥片通常为可分离式，可按适用人群、材质、设计、技术参数、窥片尺寸等不同分为若干型号和规格；产品以无菌形式提供；供临床挑起患者会厌部暴露声门，指引医护人员准确进行气道插管供麻醉或急救用，也可用于口腔内诊察、治疗用。用于观察和检查患者的上呼吸道以及协助呼吸插管的插入。	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	II
518	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用麻醉咽喉镜	single-use anesthesia laryngoscope	一次性使用麻醉咽喉镜可由窥视片和镜筒组成，窥视片可分为直接照明和光纤照明两种；窥视片采用聚氯乙烯材料制成，镜筒应采用高密度聚乙烯树脂制成；可按使用对象、型式、尺寸等不同分为若干型号与规格；窥视片以无菌形式提供，配合麻醉咽喉手柄，供临床喉部检查、急救及麻醉手术时协助插管用。产品性能指标采用下列参考标准中的适用部分，如：YY 0499-2004 麻醉喉镜通用技术条件。	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	医用高分子材料及制品	Medical polymer materials and products	麻醉机和呼吸机用呼吸管路	Breathing circuit for anesthesia machine and ventilator	麻醉机和呼吸机用呼吸管路采用聚氯乙烯等适用材料制成，分为麻醉机管路和呼吸机管路两类，麻醉机管路由Y型接头、波纹管组成，呼吸机管路由Y型接头、波纹管、旋转弯管组成，两类管路可组合，可选配储气囊、面罩，可按材质、设计、组合、使用对象（成人/儿童）、技术参数、选配件等不同分为若干型号和规格；以无菌形式提供；用于麻醉机、呼吸机接口与供氧面罩的管路连接。产品性能指标采用下列参考标准中的适用部分，如：YY 0461-2003麻醉机和呼吸机用呼吸管路。	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, assemblies, 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 aneathetic apparatus and ventilators	II

520	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用胃管	single-use stomach tube	一次性使用胃管可用聚氯乙烯、天然胶乳、硅橡胶、橡胶材料制成，通常由管身与接头组成，可按使用材料、管径与长度等不同分为若干型号与规格；通常以无菌形式提供，供插入胃部，排空、清洗、灌注用。不包括鼻饲用管。	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 include nasal feeding	II
521	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用鼻饲管	single-use nasogastric tube	一次性使用鼻饲管可采用聚氯乙烯、硅橡胶、天然胶乳、橡胶等材料制成，由导管和锥形接头组成，可按材质、管径等不同分为若干型号和规格；产品可以无菌形式提供；通常由鼻腔插至胃内，供临床鼻饲用。	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 cavity.	II
522	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用直肠导管	single-use rectal catheter	一次性使用直肠导管（一次性使用肛门管）通常由接头、导管组成，其中导管采用聚氯乙烯、硅橡胶、天然胶乳、橡胶制成，接头可采用聚乙烯、硅橡胶等制成；导管可按材质、设计、型式、管径、是否带球囊等不同分为若干型式和规格（如单腔、带塞单腔、双腔和三腔）；产品通常以无菌形式提供，供肠道清洗、灌注、排空等用。产品性能指标采用下列参考标准中的适用部分，如：YY 0488-	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 single use	II
523	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用胃肠营养输注管路	single-use parenteral nutrition infusion pipe	一次性使用胃肠营养输注管路可由袋体或袋接头及输注管路部分组成，由聚氯乙烯等适用材料制用，可按设计、袋体容量等不同分为若干型号及规格；以无菌形式提供；与鼻饲管或胃管配合使用，供向患者肠胃输送营养物质用。产品性能指标采用下列参考标准中的适用部分，如：YY 0483-2004 一次性使用肠营养导管、肠给养器及其连接件设计与试验方法。	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 testing	II
524	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用灭菌橡胶外科手套	Single-use sterile rubber surgical gloves	一次性使用灭菌橡胶外科手套采用天然橡胶胶乳或热塑性胶体制成，可按表面型式不同分为麻面、光面、有粉表面和无粉表面四种，可按设计不同分为直型手套和手指向手掌面弯曲的手套两种，每种可按尺寸不同分为若干规格；产品应无菌形式提供，供临床外科操作时防护使用。产品性能指标采用下列参考标准中的适用部分，如：GB 7543-2006 一次性使用灭菌橡胶外科手套。	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 sterile rubber surgical gloves—Specification	II
525	6866	医用高分子材料及制品	Medical polymer materials and	一次性使用宫颈扩张棒	single-use Cervical dilatation rod	一次性使用宫颈扩张棒采用聚乙烯塑料制成，可根据外径不同分为若干规格，产品以无菌形式提供。供临床妇产科宫腔诊查前的子宫颈扩张用。	Mainly made of polyethylene plastic and can be divided into different specifications according to outside diameters. Sterile form. Used for dilating uterine cervix during clinical obstetrics and gynecology uterine cavity examination.	II

526	6866	医用高分子材料及制品	Medical polymer materials and	一次性使用宫腔组织吸引管	single-use uterine tissue suction	一次性使用宫腔组织吸引管采用聚乙烯塑料制成，可由手柄、管体组成，可按管径不同分为若干规格，以无菌形式提供，供临床与吸引器配合，吸取宫腔内组织用。	Mainly made of polyethylene plastic and consist of handle and tube body. Can be divided into different specifications according to pipe diameter. Sterile form, used with aspirator for intrauterine tissue absorbtion.	II
527	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用流产吸引管	single-use abortion suction tube	一次性使用流产吸引管用聚氯乙烯制成，由管身和接头组成，吸引管上可有刻度，可为套管，可按材质、设计、技术参数等不同分为若干型号和规格；产品以无菌形式提供；与吸引器配套，供临床吸引法终止妊娠用。	Made of PVC and consist of pipes body and connector. The suction tube is with a scale and can be cannula. Can be divided into various specifications according to texture, design and technical parameters, etc.. Sterile form; Used with aspirator for termination of pregnancy by clinical attraction.	II
528	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用宫腔通液造影管	single-use uterine cavity fluid imaging tubes	一次性使用宫腔通液造影管可采用硅橡胶等高分子材料制成，主要由气囊、导管、充气接头、通液接头组成；可按材质、管腔外径等不同分为若干型号及规格；产品以无菌形式提供，供临床人体宫腔通液造影用。	Mainly made of silicone rubber and other polymer materials and consist of balloons, catheters, inflatable connector, and liquid instillations connector. Can be divided into various specifications according to texture, outer diameter of the lumen, etc.. Sterile state. Used for clinical human uterine liquid instillations radiography.	II
529	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用输卵管造影导管	single-use salpingography catheter	一次性使用输卵管造影导管可采用塑料、不锈钢丝等组成，由弯头引导管、牵引杆、内导管、导丝组成；也可用硅胶和塑料等制成，由导管（单腔或双腔）、导管座（可含阀门和三通）、球囊组成；导管可带不透X射线标记；可按材质、设计、技术参数（如管径、球囊压力）等不同分为若干型号和规格；产品以无菌形式提供；通过宫腔镜操作通道或其他子宫介入器械通道插入输卵管，注入色素液或造影剂来评估输卵管的通畅性，并进行注液疏通操作。	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-chamber), catheter seat(may contain valves and tees), balloon; The catheter can be with a X-ray non-penetration mark. Can be divided into various specifications according to texture, design, technical 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 interventional device	II
530	6866	医用高分子材料及制品	Medical polymer materials and	一次性使用无菌脐带夹	single-use Sterile umbilical cord clamp	一次性使用无菌脐带夹采用高分子材料制成，可按材质、设计、技术参数等不同分为若干型号，以无菌形式提供；供新生儿闭合脐带残端用。不包括脐带剪。	Made of polymer materials. Can be divided into various specifications according to texture, design, and other technical parameters, etc.. Sterile form; Used for umbilical cord stump closure. Does not include umbilical cord scissors.	II
531	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用子宫探针	single-use uterine probe	一次性使用子宫探针采用聚丙烯或适用材料制成，由柄部和细棒状有刻度的探针针身组成，可按材质、有无不透X射线标记、针径、长度等不同分为若干型号和规格；以无菌形式提供；供宫腔诊疗时，探测子宫宫腔的方向和深度用。	Made of polypropylene or suitable materials. Mainly consist of handle and fine rod like probe with scale. Can be divided into various specifications according to texture, with or without a X-ray non-penetration mark, needle diameter, length, etc.. Sterile state; Used for detect uterus uterine direction and depth.	II

532	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用妇科冲洗治疗头	single-use gynecological rinse and treatment head	一次性使用妇科冲洗治疗头采用塑料经注塑而成，由管身和接头组成；可按材质、技术参数（如长度、管径等）等不同分为若干型号和规格；产品以无菌形式提供；连接于医用臭氧冲洗治疗仪的治疗或冲洗手柄上，供建立阴道内输送臭氧气体或液体的通道用。	Made of injection molded plastic. Mainly consist of body pipe and connectors. Can be divided into various specifications according to texture, technical parameters (such as length, diameter, etc.). Sterile state; Used to connect to washing or flushing handle of medical ozone treatment instrument. Used to establish intravaginal passage for ozone gas or liquid delivery.	II
533	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用颅内吸引管	single-use intracranial suction tube	一次性使用颅内吸引管可采用聚氯乙烯等适用材料制成，可设计为单管或套管，管的头端及侧管有光滑圆孔，可按型式、管径等不同分为若干型号和规格，以无菌形式提供；供脑外科手术吸取颅内体液、血液、冲洗液等，清理	Made of PVC and other suitable materials. Can be single tube or cannula tube. There are smooth hole on tube tip and side tube. Can be divided into various specifications according to types ,tube diameters, etc. Sterile state; Used for body fluids, blood, flushing	II
534	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用无菌头皮夹	single-use sterile scalp clip	一次性使用无菌头皮夹可采用聚苯乙烯树脂或聚甲醛等适用高分子材料制成，U形结构，连接的两夹持臂刀片互相咬合，使用时可经由手动或头皮夹钳放置，非植入器械；产品以无菌形式提供，供临床手术时固定头皮及止血用。	Mainly made of polystyrene resin or polyacetal, U-shaped structure, two blades connected with each other can be biting together. Can be placed manually or via scalp clamp, non-implanted devices; Products are sterile. Used for scalp fixation and hemostasis in	II
535	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用气流雾化器	single-use air-flow nebulizer	在呼吸装置系统中，一端接入氧气，用氧气的压力将放置于雾化器中的药剂雾化，产生的雾化气体通过雾化器的另一端吸入病人口中。	Used in breathing apparatus and connect with oxygen at one end. Used to atomize medicament by oxygen pressure for patients inhalation.	II
536	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用无菌药液转移器	single-use sterile liquid transfer device	一次性使用无菌药液转移器可以有多种设计，可由两个穿刺器，也可由一个穿刺器和一个鲁尔接头组成，两者均可彼此以不同的通道连接；转移器可以有一个外罩，也可以另接一个空气过滤器或药液过滤器；穿刺器可以是不锈钢，也可以是塑料制，其他组件可由聚氯乙烯等塑料制成；产品以无菌形式提供；供药液从一个容器转移到另一个容器用。产品性能指标采用下列参考标准中的适用部分，如：YY 0804-2010 标准一次性使用无菌药液转移器。	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 and test	II
537	6866	医用高分子材料及制品	Medical polymer materials and products	合成树脂义眼片	Synthetic resin prosthetic eye	合成树脂义眼片主要成分为甲基丙烯酸甲酯、聚甲基丙烯酸甲酯、自凝聚甲基丙烯酸甲酯，模拟人眼，可按材质、设计、尺寸等不同分为若干型号和规格；人体眼球摘除后置于眼结膜内，起填充、支撑等作用。	Mainly made of methyl methacrylate, polymethyl methacrylate, self-condensation of methyl methacrylate, human eye simulation. Can be divided into various specifications according to texture, design, size, etc.. Used for filling and supporting by placing into conjunctiva after enucleation.	II
538	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用内窥镜套管	single-use endoscopic cannula	一次性使用无菌内窥镜套管（有球囊或无球囊；有外涂层或无外涂层）是由聚氯乙烯等适用材料制成的柔性密封式或半密封式透明薄壁套，以无菌形式提供；在内窥镜使用过程中，套在内窥镜外，保护内窥镜，防止镜头损伤或污	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	II

539	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用腹腔吸引管	single-use enterocoeli a suction tube	一次性使用腹腔吸引管采用聚氯乙烯等适用材料制成, 可由管身(直型、弯型、折弯型)和手柄组成, 管身可为套管, 病人端有端孔和规则侧孔, 可带连接负压源的连接管, 可按材质、设计和技术参数等不同分为若干型号和规格; 产品以无菌形式提供; 与医用负压设备配套, 供腹腔手术吸引体液、手术残液等用。产品性能指标采用下列参考标准中的适用部分, 如: YY/T 0191-2011 腹腔吸引管。	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 divided 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	II
540	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用胸腔引流装置	single-use chest drainage unit	一次性使用胸腔引流装置采用高分子材料注塑件组合而成, 为水封式, 可由积液腔、调压腔和水封腔(三腔也可合并成单腔或两腔)及进、出口及管路组成, 积液腔、水封管应有刻度; 可按材质、设计、技术参数、附加辅助功能(如取样、固定等)等不同分为若干规格; 产品以无菌形式提供; 供胸腔闭式引流用。产品性能指标采用下列参考标准中的适用部分, 如: YY 0583-2005 一次性使用胸腔	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 divided 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 single use- Type of water-seal bottle	II
541	6866	医用高分子材料及制品	Medical polymer materials and	鼻贴(不含药)	Nasal paste(without drugs)	鼻贴(不含药)将具有弹性的塑料片通过强力胶和基布固定在鼻梁部位, 供扩张鼻孔, 缓解鼻塞用。	Fix a flexible plastic via glue and fabric onto nose bridge part. Used for nostril expansion to release nasal congestion.	II
542	6866	医用高分子材料及制品	Medical polymer materials and	一次性使用阴道给药器	single-use vaginal drug dispenser	一次性使用阴道给药器采用聚丙烯等适用材料制成, 可由药筒(可有刻度)和推杆组成; 产品通常以无菌形式提供; 可按材质、设计、容量等不同分为若干型号及规格; 供女性阴道给药用。	Mainly made of polypropylene. Mainly consist of cartridge and push rod. Sterile form; Can be divided into various specifications according to texture, design, capacity, etc. Used for female vagina drug administration.	II
543	6866	医用高分子材料及制品	Medical polymer materials and products	微波热疗仪硅胶治疗导管	Silicone catheter for microwave hyperthermia therapy instrument	微波热疗仪硅胶治疗导管采用硅胶制成, 通常由阀门、腔头、多腔管和球囊等组成, 不带电极; 可按材质、设计、技术参数、预期用途等不同分为若干型号及规格; 以无菌形式提供; 配合药物和微波治疗仪分别用于药物灌注和微波治疗。	Mainly made of silicone. Mainly consist of valve, chamber head, multi-lumen tube and balloon, etc., without electrode; Can be divided into various specifications according to texture, design, technical parameters, intended use, etc.. Sterile state; Use with drugs and microwave therapy apparatus for drug infusion and microwave therapy.	II
544	6866	医用高分子材料及制品	Medical polymer materials and	鼻腔冲洗器	Nasal cavity irrigator	鼻腔冲洗器采用塑料制成, 由瓶体、瓶盖和出水管(可带流量控制阀)组成, 不包括冲洗液; 可按材质、设计、技术参数(如容量)等不同分为若干型号及规格; 可以无菌形式提供; 供鼻腔冲洗用。	Mainly made of plastic. Mainly consist of bottle body, cap and outlet pipe. Without flushing fluid; Can be divided into various specifications according to texture, design, technical parameters, etc.. Sterile state; Used for nasal irrigation.	II

545	6866	医用高分子材料及制品	Medical polymer materials and products	一次性隆胸手术用漏斗	single-use funnel for breast augmentation on surgery	一次性隆胸手术用漏斗由弹性尼龙材料制成，内表面涂有由聚氨酯和聚乙烯吡咯烷酮共混物构成的亲水涂层；以无菌形式提供；在外科隆胸手术时，将植入物置于本器械含有亲水性润滑涂层的内表面，通过挤压，使植入物轻易通过漏斗的小开口进入预定部位，以此缩小患者的切口。	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	医用高分子材料及制品	Medical polymer materials and	一次性使用龟头保护套	Single-use glans protective sleeve	一次性使用龟头保护套由ABS塑料制成，以无菌形式提供；包皮环切术中套在龟头上，防止电刀切割包皮时避免损伤龟头。	Mainly made of ABS plastic. Sterile state. Used to avoid glans injury in electric knife circumcision by cover it on glans.	III
547	6866	医用高分子材料及制品	Medical polymer materials and	失禁肛门塞	Incontinence Anal Plug	失禁肛门塞以聚氨酯泡沫为原料，由膨胀栓塞、水溶性薄膜和纱布绳组成，适用于排泄失禁患者或肠胃气失禁者栓塞肛门，延长大便滞留时间。	Mainly made of polyurethane foam. Mainly consist of expansion embolism, water-soluble film and gauze thread. Used for embolism anal for acathetic patients or flatus incontinence to prolong feces residence time.	III
548	6866	医用高分子材料及制品	Medical polymer materials and products	传统型一次性使用输液器	Conventional Infusion sets for single use	性能、结构、组成、用途等属于GB 8368 一次性使用输液器 重力输液式可完全涵盖且原材料符合GB 15593等相关标准要求的传统型一次性使用输液器，由瓶塞穿刺器及保护套、带空气过滤器和塞子的进气口、液体通道、滴管、滴斗、药液过滤器、管路、流量调节器、注射件、外圆锥接头及保护套组成，与输液容器、输液针配套，用于静脉输液。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品，如（1）非PVC材料的产品；（2）材料中含非DEHP增塑剂、避光剂等物质的产品；（3）具有自动止液、自动排气等功能的新型结构设计或属于YY 0286的产品。（4）含有活性成分的产品：如药品/药用活性成分、生物制品/生物活性成分、银、消毒剂等；（5）其他新型产品。	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	III
549	6866	医用高分子材料及制品	Medical polymer materials and products	连通板	Manifolds	产品一般由接头、连接主板、开关（阀门）组成，血管介入手术操作中作为连接通路，建立多通道，提供药液或造影剂注射使用。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	医用高分子材料及制品	Medical polymer materials and products	一次性使用腹腔引流管	single-use peritoneal drainage tube	产品以医用硅橡胶为原材料,用于腹腔积液的引流。原材料符合YY0334 硅橡胶外科植入物通用要求的要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	医用高分子材料及制品	Medical polymer materials and products	一次性使用麻醉导管及接头	single-use anesthesia catheter and connector	性能、结构、组成、用途等属于YY 0321.1一次性使用麻醉穿刺包可完全涵盖的产品。产品一般由导管和导管接头组成,与一次性使用麻醉用针配合,供临床输送麻醉剂用。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	III
552	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用麻醉用过滤器	single-use anesthesia filter	性能、结构、组成、用途等属于YY 0321.3一次性使用麻醉用过滤器可完全涵盖的产品。一次性使用麻醉用过滤器一般由上盖、滤膜、底座、内圆锥接头保护套(可无)、外圆锥接头保护套(可无)组成,分为药液过滤器和空气过滤器。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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 conicalconnecting 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 new action mechanism or function.	III
553	6866	医用高分子材料及制品	Medical polymer materials and products	一次性使用三通(阀)	single-use tee (valve)	一般由外壳、保护套、阀门、旋转手柄、标志塞、螺帽组成(不包含延长管、软管等)。本产品与输液器具连接使用,用于连接、控制静脉输液、测压等液体管路。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	医用高分子材料及制品	Medical polymer materials and products	一次性使用输液用肝素帽	single-use heparin cap for infusion	性能、结构、组成、用途属于YY 0581 输液用肝素帽完全涵盖的以穿刺为主要使用形式的产品,一般由外壳、胶帽组成,与外周套针导管(如静脉留置针)配合使用,通过它可以向血管内输注药液,当留置导管处于非输液状态时,可通过它向里注射适量肝素以防止留置导管内形成凝血。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	医用高分子材料及制品	Medical polymer materials and products	一次性使用无菌注射器用活塞	single-use sterile syringe pistons	性能、结构、组成、用途等属于YY/T 0243 一次性使用无菌注射器用活塞可完全涵盖的产品，呈圆柱形，一般采用富有弹性的材料制成，供一次性使用无菌注射器配套用。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	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	医用高分子材料及制品	Medical polymer materials and products	一次性使用胸腔引流管	single-use intrathoracic drain	产品以医用硅橡胶为原材料，用于胸腔积液的引流。原材料符合YY0334 硅橡胶外科植入物通用要求的要求。豁免情况不包括使用了新材料、活性成分、新技术、新设计或具有新作用机理、新功能的产品。	Mainly made of medical silicone rubber. Used for drainage of pleural effusion. The raw material 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	软件	Software	诊断图像处理软件	Diagnostic image processing software	诊断图像处理软件通常用于人体诊查图像的处理，包括数字化X射线、病理、显微、红外、超声等图像及其融合图像和由原始图像重建的三维图像和动态影像，不包括自动诊断部分。	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	II
558	6870	软件	Software	诊断数据处理软件	Diagnostic data processing software	诊断数据处理软件通常用于人体诊查数据的处理，包括心电图数据、脑电数据、肌电数据、血流变数据、母婴监护检测数据等，不包括自动诊断部分。	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	软件	Software	医学影像、数据传输处理软件	Medical imaging, data processing software	医学影像、数据传输处理软件通常用于人体诊查图像、数据的管理、查看、传输和贮存，不包括自动诊断部分。	Used for human checkups image, data management, view, transport and storage. Does not include automatic diagnosis section.	II
560	6870	软件	Software	过敏原半定量分析软件	Allergen semi-quantitative analysis software	过敏原半定量分析软件内含标准曲线，配合普通扫描仪使用。用于对免疫印迹法和免疫层析法的过敏原特异性抗体和自身免疫抗体的反应试条进行半定量检测。不包括自动诊断功能。	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	软件	Software	迹法分析软件	Blotting analysis software	印迹法分析软件用于将经平板扫描仪扫描获得的膜条信息保存为电子图片，识别膜条位置，鉴别条带特异性。不包括自动诊断功能。	Used for scanning bar code to achieve electron images by a plate scanner. Used for bar code location identification to identify band specificity. Does not include automatic diagnosis function.	III

562	6877	介入器材	Interventional appliances	导管鞘	Catheter sheath	由鞘管、管座（可选）和侧支组成。采用Seldinger术，建立有助于血管内器械的经皮进入通路，不具有血管内定位或建立血管内通路作用。Seldinger术多指数字减影血管造影术中的血管穿刺术。	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	III
563	6877	介入器材	Interventional appliances	导丝	Guide wire	导丝由芯丝、绕丝（如有）、安全丝（如有）、护套（如有）组成，可涂有涂层。采用Seldinger术，建立有助于血管内器械的经皮进入通路，不具有血管内定位或建立血管内通路作用。Seldinger术多指数字减影血管造影术中的血管穿刺术。	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	介入器材	Interventional appliances	扩张器	Dilator	由扩张器管和管座组成。采用Seldinger术，建立有助于血管内器械的经皮进入通路，不具有血管内定位或建立血管内通路作用。Seldinger术多指数字减影血管造影术中的血管穿刺术。	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	介入器材	Interventional appliances	外周血管用导丝	Guide wire for Peripheral Vessel	由芯丝、绕丝（如有）、安全丝（如有）、护套（如有）组成，带有或不带有扭控装置，可涂有涂层。扭控装置由帽盖和轴组成，通常与导丝远端连接，用于导丝的扭转控制。用于引导导管插入外周血管并定位的柔性器械，神经血管内应用除外。	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	介入器材	Interventional appliances	外周血管用导引导管	Guide catheter for Peripheral Vessel	由管体和座组成，可涂有涂层。用于PTA术中血管通路的建立，神经血管内应用除外。	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
567	6877	介入器材	Interventional appliances	外周血管用造影导管	Angiographic Catheter for Peripheral	由管体和座组成，可涂有涂层。用于注射或输入对照介质和/或液体，神经血管内应用除外。	Mainly consist of tubular body and seat, can be coated with a coating. Used for control media and/or liquids injection or transfusion. Exemption does not include neurovascular inner applications.	III

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6.3

62.48

137.32

50.43 250.23

250.23 213.24 250.23

1350

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