
CFDA UPDATE : LIST OF MEDICAL DEVICES EXEMPTED FROM CLINICAL TRIAL REQUIREMENTS

CLASS III DEVICES EXEMPTED FROM CLINICAL TRIAL REQUIREMENTS

Serial number	Product name	Classification code	Product description
1	Puncture needle	6815	Usually consists of a needle, piercing, protection sleeve. Used to puncture the human body in order to collect human samples, drug injection and gas or as channels to other device enters the body. Product principle, scope, performance and structure identical to the already available products. Exemption does not include: using new materials containing polymers, special coating products such as drugs, biological products, and has a special structure and scope and other products.
2	Biopsy needles	6815	Made up of needles, needle core, handles and other parts. Used to get the bone marrow biopsy, or b Ultra or x- line surveillance, percutaneous substantive organ or biopsy cytology of tumors or other soft tissue biopsy. For one-time use. Product principle, scope, performance and structure identical to the already available products. Exemption does not include: using new materials containing polymers, special coating products such as drugs, biological products, and has a special structure and scope and other products.
3	Coaxial biopsy needles	6815	Stainless steel needle with a needle (outer casing) and needle core with needle and plastic ring (used to mark the puncture depth in stainless steel), gets soft tissue biopsy specimen, not used for bone biopsy. Product rationale, scope, performance and structure identical to the already available products. Exemption does not include: using new materials containing polymers, special coating products such as drugs, biological products, and has a special structure and scope and other products.

4	Sterile hypodermic syringes for single use with needle	6815	Performance, structure, composition, purpose, belonging to GB 15810 Sterile syringes for single use GB 15811 Sterile hypodermic needle for single use products that can be fully covered, for disposable sterile syringes in a published list of exemptions comply with sterile needles for single use in the published list of exemptions. Injector core-jacket, piston, rings, Rod, hand, cone-pin, connection part, needles, retaining sleeve, used for intradermal, subcutaneous, intramuscular, intravenous or extraction solution. Such as products with specific properties or structures (such as self-destruction, acupuncture, etc) cannot be exempted, such as clinical. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
5	Low resistance syringes for single use with needle	6815	Performance, structure, composition, purpose, belonging to YY/T0909 Disposable syringe can be completely covered by the low resistance of the product. Product generally consists of jackets, Pistons caps, Pistons, core pin and needles (optional), sterile supply, for pumping liquids immediately after injecting liquid, or injection. Such as products with specific properties or structures (such as self-destruction, acupuncture, etc) cannot be exempted, such as clinical. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
6	Sterile, disposable insulin syringes	6815	Performance, structure, composition, purpose, belonging to YY 0497 Of the sterile insulin syringes for single use products that can be fully covered, mainly by the core-jacket, Rod, piston, injection needles, rubber sheath / End cap components. Such as products with specific properties or structures (such as self-destruction, acupuncture, etc) cannot be exempted, such as clinical. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
7	Ring handle syringe	6815	Usually consists of jackets, 6% Outer cone connectors, core, core bar handles, rings, Pistons, seals "O" ' Ring composition, intended for minimally invasive Interventional therapeutic or diagnostic manual bolus contrast liquid and liquid during the operation. Such as products with specific properties or structures (such as self-destruction, acupuncture, etc) cannot be exempted, such as clinical. Exemption does not

			include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
8	Lock syringe	6815	Usually consists of coat, tapered core-connectors, rods, rings, Pistons, seals "O" ' Ring composition, intended for intervention, as shadow surgical or radiological check balloon prior to surgery or aspiration. Such as products with specific properties or structures (such as self-destruction, acupuncture, etc) cannot be exempted, such as clinical. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
9	Disposable injection needles	6815	Sealing foil, needles, needle seat, exterior sheathing, trim sleeve. Product is sterile, pyrogen-free. To the human subcutaneous injection of drugs used in conjunction with injection pen. Such as products with specific properties or structures (such as self-destruction, acupuncture, etc) cannot be exempted, such as clinical. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
10	Single use implantable device-specific needles	6815	Performance, structure, composition, purpose, belonging to YY 0881 The special needles for single use implantable device can fully cover the product, implantable drug delivery device-specific needles into the injection needles and transfusion type of needle two, and infusion devices and implantable drug delivery device used. Such as products with specific properties or structures cannot be exempted from clinic. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.

11	Disposable endoscopic ultrasonic aspiration biopsy needles	6815	This product can be used by the biopsy needle and probe wire, needle sheaths, the probe CAP, handle, needle and needle sheaths adjustment lock and needle sheath adjustment and depth adjusting gauge, plug valve needle and syringe components. This product has been sterilized and disposable. This product is used with ultrasonic endoscope used for diseased tissue by ultrasound-guided fine needle aspiration (FNA) biopsy and the tissue samples. Exemption does not include: use of new materials using non- DEHP plasticizer containing special coating such as functional polymer, pharmaceutical, bio-products, containing active ingredients, new technology, new design or new mechanisms, as well as with special structures, the scope of products.
12	Resectoscope	6822	By the rigid optical endoscopes, sheath, Operations Manager, surgical electrodes, coupled with cold light source, camera system and high-frequency surgical equipment used to organize the excision. Including intrauterine resectoscope and prostatic resectoscope two intrauterine resectoscope for transcervical intrauterine tissues were removed, prostatic resectoscope for Transurethral resection of the prostate.
13	Rigid optical joint endoscope	6822	Rigid endoscope optical joint, generally by the optical imaging system and lighting system. Optical imaging systems, transfer system, the objective lens eyepiece consists of three parts. Lighting system for optical fiber. Are observed by the objective lens into the image, through the relay system would like to like, and transmitted to the eyepiece by the magnification of the eyepiece or camera system for observation. Joint observation of Imaging.
14	Rigid optical thoracic endoscopy	6822	Rigid optical endoscopes of the chest, usually composed of optical imaging systems and lighting systems. Optical imaging systems, transfer system, the objective lens eyepiece consists of three parts. Lighting system for optical fiber. Are observed by the objective lens into the image, through the relay system would like to like, and transmitted to the eyepiece by the magnification of the eyepiece or camera system for observation. Observation on the part of the chest imaging.

15	Electronic laryngoscope	6822	Electronic laryngoscope for soft electronic Endoscope, generally by the head end, bend, insert, operational and connected to the electrical and lighting components. Head end of the CCD will receive optical signals to electrical signals through observation camera system on the display. Through video monitors provide images for the nose and throat of observation, diagnosis, photography.
16	E-lower gastrointestinal endoscope	6822	Soft electronic Endoscope, generally by the head end, bend, insert, Operations Division and the Department of electrical and lighting connection, generally contain working channel. Head end of the CCD will receive optical signals to electrical signals, on display through image processing system to observe. Video monitor provides images for lower digestive tract (Except for the small intestine) Observation, diagnosis, and photography.
17	Spectrum Doppler ultrasonic diagnostic equipment	6823	Spectrum Doppler ultrasonic diagnostic equipment using principles of Ultrasonic Doppler blood flow direction, speed and other information, after treatment with spectrum-time or flow-time to be displayed, is divided into continuous pulse boduopule and boduopule. Usually by probe (unit type, and convex array, and line array, and phase control array, and mechanical fan sweep), and ultrasonic launches / received, and signal processing and spectrum displayed, part composition; can by models, and signal collection / processing nature (simulation and digital), and probe configuration, and technology parameter, and additional auxiliary function, and expected uses, different is divided into several model; by surface, and by vaginal, and by rectal or operation in the on abdominal organ , Heart, superficial tissue blood flow to organs and other parts of the test, excluding the application of non-conventional and contact circulating blood. Product performance using applicable parts of the following reference standards, such as:YY 0767-2009 ultrasound color flow imaging systems.

18	Ultrasound color flow Imaging Equipment	6823	<p>Ultrasound color flow imaging equipment based on ultrasonic pulse-echo imaging using Doppler blood flow imaging and correlation technology to, and superimposed on the color coded information B Models on a gray-scale image be displayed in real time. Usually by probe (convex array, and line array, and phase control array, and mechanical fan sweep), and ultrasonic launches/ received circuit, and signal processing and image displayed, part composition; can by models, and imaging nature (simulation and digital), and probe configuration, and technology parameter, and additional auxiliary function, and expected uses, different is divided into several model; by surface, and by vaginal, and by rectal or operation in the on abdominal organ, and heart, and shallow table organization organ, parts of blood flow for imaging, Do not include non-routine contact circulating blood and applied in such a manner. Product performance using applicable parts of the following reference standards, such as: GB 10152-2009 b -type ultrasonic diagnosis equipment,YY 0767-2009 ultrasound color flow Imaging System.</p>
19	Ultrasonic pulsed echo imaging device	6823	<p>Using the principle of ultrasonic pulse-echo ultrasonic pulse-echo imaging equipment, complete human organ tissue imaging ultrasound system. Usually by probe (line array, and convex array, and phase control array, and mechanical fan sweep), and ultrasonic launches / received, and signal processing and image displayed, part composition; can by models, and imaging nature (simulation and digital), and probe configuration, and technology parameter, and additional auxiliary function, and expected uses, different is divided into several model; by surface, and by vaginal, and by rectal or operation in the on abdominal organ, and heart, and shallow table organization organ, parts of ultrasound imaging, Do not include non-routine contact circulating blood and applied in such a manner. Product performance using applicable parts of the following reference standards, such as:GB 10152-2009 b -type ultrasonic diagnosis equipment.</p>
20	Single-use eye laser fiber	6824	<p>Connectors, fiber optic, and a handle by laser, and laser connection, for transmission to the eye laser. Fiber optic reflectance end surfaces, does not contain other features such as pumping or lighting.</p>

21	Beam scanning system -Blue tank	6832	<p>Products from the perspex box, control units, software and components, such as the optional probe.</p> <p>By injected the equivalent of human density in the water tanks of water to simulate a human body, and the use of computers to control three-dimensional movement of the probe installed in the water tank to simulate various locations inside the human body to the received dose. Using the results of tank measurement system, on the one hand is to simulate the human body measurements in the curves and dose relationship (which represents the radiation dose distribution) as a radiation treatment planning system (TPS) an important basis for data import system, so that the system can use these data to calculate the final each patient's treatment plan. The other hand, you can adjust the parameters of the accelerator, and ultimately enable Accelerator performance indicators should conform to factory requirement.</p>
22	Beam scanning system- Two-dimensional dose measurement matrix	6832	<p>Products by two-dimensional ion Chamber array, software and components, such as solid-water.</p> <p>Two-dimensional ion Chamber array are in tumor patients in radiotherapy treatment prior to treatment, through multiple ionization chamber for a particular flat-dose measurement by software processing, analysis of the actual radiation dose received and pre-designed TPS (Treatment planning) dose of plan compliance, and predict whether the practical implementation of the treatment plan to be able to achieve the desired effect, so as to determine whether the plan can be implemented and how to modify the plan, Before your treatment plan for patients with normal to verify before treatment the treatment plan, ensure the quality of radiotherapy. Treatment plan will be used to modify the beam scanning system comparison.</p>
23	Arterial, venous intubation	6845	<p>Support cardiopulmonary bypass systems, drainage during cardiopulmonary bypass open heart surgery or reperfusion blood use. Products comply with forthcoming 2017 years mandatory industry standard YY 0948-2015cardiopulmonary bypass system provisions of the disposable venous catheter, and basic principles, scope, performance and structure identical to the already available products.</p> <p>Exemption does not include: use of new materials; non- DEHPPlasticizer containing special coating products such as polymers, pharmaceuticals, biological products, and has a special structure and the scope of products.</p>

24	Single use cardioplegia perfusion of the heart	6845	<p>Products comply with the mandatory industry standards YY 0485-2004The provisions of the single use cardioplegia perfusion of the heart, and the basic principles, scope of application, performance and structure identical to the already available products. Exemption does not include: use of new materials; non- DEHPPlasticizer containing special coating products such as polymers, pharmaceuticals, biological products, and has a special structure and the scope of products.</p>
25	Left heart catheter, right heart suction tube	6845	<p>Suction tip, tube, fittings comprising a three-part structure. For cardiovascular surgery for left heart vent, attract relief or reducing heart burden to attract wild blood and other fluids used in cardiac surgery. Product line with the introduction of mandatory industry standards and basic principles, scope, performance and structure identical to the already available products. Exemption does not include: use of new materials; non- DEHP Plasticizer containing special coating products such as polymers, pharmaceuticals, biological products, and has a special structure and the scope of products.</p>
26	Centrifugal pump head	6845	<p>Product principle, scope, performance and structure identical to the already available products. Exemption does not include: using new materials containing polymers, special coating products such as drugs, biological products, and has a special structure and scope and other products.</p>
27	Dialysis fluid filtration	6845	<p>Effect of hollow fiber membrane, supporting haemodialysis equipment used for filtering dialysate. Product line with the introduction of mandatory industry standards and basic principles, scope, performance and structure identical to the already available products. Exemption does not include: using new materials containing polymers, special coating products such as drugs, biological products, and has a special structure and the scope of products.</p>

28	Citric acid Disinfection solution	6845	Raw materials by water, citric acid, lactic acid, Malic acid, raw materials conform to Pharmacopoeial requirements, for internal waterways of haemodialysis devices thermal disinfection. Originally managed by the health planning Commission, in the form of disinfection supplies entering the hospital sales, basic principles, scope and composition, share content and has listed the same. Exemption does not include: containing other ingredients, as well as with special functions, scope of citric acid disinfectant products.
29	Urinary incontinence Sling	6846	Including band implanted and implantation tools, strap usually made from polypropylene, with partial absorption material, implant tool consists of a handle and a metal rod. Formed around the urethra for urethral support principles for implantation. Due to excessive movement of the urethra of women and / or sphincter dysfunction caused by stress urinary incontinence.
30	Metal cables and cable	6846	The product structure see YY/T 0812 Can be used in conjunction with annex (such as locking pin, such as binding). Meet the ASTM F1314 standard of 22Cr-13Ni-5Mn stainless steel materials, in line with ISO 5832-5 standard wrought cobalt chromium tungsten nickel alloy material, via conventional machining, heat treatment (does not include 3D Innovative technology such as print). Apply to internal fixation of limb fractures and banding.
31	Metal needles	6846	Such products include Kirschner wires and pins, the structure see YY 0345 。 Meet the ISO 5832-5 standard wrought cobalt chromium tungsten nickel material, via conventional machining, heat treatment and surface treatment process (not including 3D printing innovation process). Apply to a limb fracture reduction part of the implant body traction or limbs fracture with internal fixation.

32	Not absorption line anchors	6846	The product formed by the anchors and suture. Anchor line with GB 4234, andGB/T 13810, andISO 5832-1, andISO 5832-3, andISO 5832-11Standard stainless steel, titanium alloy, via conventional machining, heat treatment and surface treatment process (not including 3D printing innovation process). Stitches can be made from polypropylene, polyester, polyamide and non absorbable materials, performance indicators in line with the YY0167standard of the appropriate sections. The product can be preloaded inserter inserter in contact with body parts are usually made in accordance with YY/T 0294and theASTM F899 or YY/T 0726 set stainless steel material. Suitable for connection of bone and soft tissue fixation.
33	Acetabular screw	6846	The products made by GB 4234 、 GB/T 13810 、 ISO 5832-1 、 ISO 5832-2、 ISO 5832-3 、 ISO 5832-11 、 ISO 5832-12 Standard stainless steel, titanium, forged titanium alloy, Cobalt chrome molybdenum material, via conventional machining, heat treatment and surface treatment process (does not include 3D Innovative technology such as print). Applied bio-acetabular prostheses in place.
34	Bone defect filling block captive screw	6846	The products made by GB/T 13810 、 ISO 5832-3 、 ISO 5832-11 Standard titanium alloy materials, via conventional machining, heat treatment and surface treatment process (does not include 3D Innovative technology such as print). Applies to the hip joint, knee joint of metal fixation of the bone defects filling block.
35	Vertebral fixation system	6846	The products formed by the fixed plate and screws, fixing plate made by GB/T 13810 、 ISO 5832-2 、 ISO 5832-3 Standard of pure titanium, titanium alloy, screws up by GB/T 13810 、 ISO 5832-3Standard titanium alloy materials, via conventional machining, heat treatment and surface treatment process (does not include 3D Innovative technology such as print). Applied spine after laminoplasty by vertebral enlarging decompression.

36	Foot and ankle locking plate system	6846	The products formed by the lock plate and locking screws and locking plate to meet the GB 4234 、 GB/T 13810 、 ISO 5832-1 、 ISO 5832-2 、 ISO 5832-3 、 ISO 5832-11 Standard stainless steel, titanium, titanium alloys, locking screws in accordance with GB 4234 、 GB/T 13810 、 ISO 5832-1 、 ISO 5832-3 、 ISO 5832-11 Standard stainless steel, titanium alloy, via conventional machining, heat treatment and surface treatment process (does not include 3DInnovative technology such as print). Apply to internal fixation for ankle fracture ...
37	Wrists locking bone plate system	6846	The products formed by the lock plate and locking screws. Locking plate made by GB 4234, andGB/T 13810, andISO 5832-1, andISO 5832-2, andISO 5832-3, and ISO 5832-11 standard stainless steel, titanium and titanium alloy material, locking screws in line with GB 4234, andGB/T 13810, andISO 5832-1 、 ISO 5832-3 、 ISO 5832-11 Standard stainless steel, titanium alloy, via conventional machining, heat treatment and surface treatment process (does not include 3DInnovative technology such as print). Suitable for wrist fracture with internal fixation
38	Reset device	6846	This product is available from PMMA , In line with GB/T19701.2Standard ultra high molecular weight polyethylene materials.Apply bone cement type placed in the keep the distal femoral stem in total hip replacement surgery, bone cement in cement barrier and to ensure that uniform distribution around the prosthesis.
39	Remote plug	6846	This product is available from PMMA , In line with GB/T19701.2Standard ultra high molecular weight polyethylene materials.Apply bone cement in total hip arthroplasty, bone cement barrier.
40	Stereotypes of hip bone cement molds	6846	Made from stainless steel reinforced handle and bone cement made of medical grade silicone rubber molding die, single use, sterile products. Used to create temporary hemiarthroplasty prosthesis, applies to require two-stage revision due to infection of skeletal maturation patients.

41	Rib plate series	6846	The products formed by rib plate and screws. Made by GB/T 13810, andISO 5832-2, andISO 5832-3, andISO 5832-11 standard of pure titanium and titanium alloy material, via conventional machining,Heat treatment and surface treatment process (not including 3Dprinting innovation process). Apply to rib fracture fixation.
42	Non absorbable ligament fixation screw	6846	The products made by GB 4234 、 GB/T 13810 、 ISO 5832-1 、 ISO 5832-3Standard stainless steel, titanium alloy, via conventional machining, heat treatment and surface treatment process (does not include 3D Innovative technology such as print). Applies to the repair and reconstruction of ligament.
43	Biliary tract /Pancreatic duct /Ureteral stent	6846	For implantation under endoscopy sinus tract, expansion into parts of narrow drainage. Support by not biodegradable / absorption of polymer materials (such as polyethylene, polyurethane, etc) made from tubular structure, with radiopaque markers and other components, can be coated with a coating, you can include conveyor components. Products material mature mechanism of clear, and have been registered in the products have the same nature.New structural design and mechanism of exception except for medical device combination products.
44	Self expanding metal non-stent	6846	Used to dilate esophageal, biliary tract, airway, and less vascular parts of intestinal stenosis. Supports with shape memory properties of metal (such as nickel-titanium alloy), with radiopaque markers, can have / no film can include conveyor components. Products material mature mechanism of clear, and have been registered in the products have the same nature. New structural design and mechanism of exception except for medical device combination products.
45	Infusion pump	6854	Generally by the host, and power lines. You can adjust the flow.Cardiac Ablation procedure, and priming line, cardiac ablation therapy equipment (YY0860-2011) together. To set the flow rate to RF ablation catheter infusion solution (YY0778-2010), play a role in cooling.

46	Denture Base polymers	6863	Poly-acrylic resin, polyolefin / Class of alkyne, aromatic polymer, poly-carbonate esters, polysulfone and poly-acetal-type, polyamide, and these polymers are polymers, copolymers, substituted or modified Denture Base polymers. For denture making. Product specifications shall at least comply with YY 0270.1dentistry Denture Base polymers 1 part: requirements of denture base polymers, and basic principles, scope, performance and composition identical to the already available products.Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
47	Implant sealants	6863	Usually made of polysiloxane, anhydrous silicic acid and other components. Used for the closing implant internal voids. Basic principles, scope of application, performance and composition identical to the already available products. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
48	Dental bonding agents	6863	Performance, structure, composition, purpose, belonging to YY/T 0518 The polymer based adhesives used in Dental restorations can be completely covered by the dental adhesive and basic principles, scope, performance and composition and has listed the same. For viscous liquids behavior, mainly composed of methacrylate. For restoration or repair materials and tooth bonding, bonding between material use. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
49	Gingival retraction cord (with aluminum sulfate / Aluminum chloride gingival retraction cord)	6863	Usually braided structure made of suitable material such as cotton, containing aluminum sulfate or aluminum chloride and other ingredients. Tooth preparation, production of impression or sticky Crown before the operation to reduce injury to the gums line the gums. Basic principles, scope of application, performance and structure identical to the already available products. Exemption does not include products already on the market compared to using new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.

50	Core resin ionomer	6863	Performance, structure, composition, and belongs to the YY 1042Dentistry resin polymer based materials could be fully covered by cement, and basic principles, scope, performance and composition identical to the already available products. Ingredients for Bisphenol a- glycidyl dimethacrylate (Bis-GMA) and so on. Used in conjunction with root piles, and when used with post and core Crown tooth filling and repair of body tissues. Exemption does not include products already on the market compared to using new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
51	Adhesive resin cement	6863	Performance, structure, composition, and belongs to the YY 1042Dentistry polymer based materials can be completely covered by polymer bonding material and basic principles, scope, performance and composition identical to the already available products. Ingredients for Bisphenol a- glycidyl dimethacrylate (Bis-GMA) and so on. For restorations such as inlays, onlays, veneers, crowns and bridges cementation or retention. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
52	Desensitizer	6863	Usually a single component or two-component liquid, paste and gel State provides. Mainly composed of polymethyl methacrylate -2-hydroxyethyl ester (2-HEMA), strontium fluoride, etc, used to seal exposed Dentinal tubules, reduces tooth sensitivity. Basic principles, scope of application, performance and composition identical to the already available products. Exemption does not include products already on the market compared to using new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
53	Alginate dressings	6864	Alginate fibers, intended use is limited to cover the wound, wound exudate absorption. Exemption situation not including: (1) indications claimed can promote epithelial of, and guide organization regeneration, and promote wound healing, and reduce pain, and antibacterial, and bleeding, and dissolved necrosis organization, and reduced scar, and anti-adhesion, role of products; (2) claimed can for body wound, and three degrees burn, and infection wound, and necrosis organization more of wound, and occurred wound pus HIV syndrome of patients, situation of products And (3) of products containing active ingredients: such as drug / pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (4) other new

			products , Such as the use of new materials, new technology, new designs or products with a new mechanism, new feature.
54	Alginate is filled	6864	Made from alginate fiber bar dressing. Intended use limited to the wound with a cavity filled after the absorption of exudate, providing micro-environment for wound healing. Exemption situation not including: (1) indications claimed can promote epithelial of, and guide organization regeneration, and promote wound healing, and reduce pain, and antibacterial, and bleeding, and dissolved necrosis organization, and reduced scar, and anti-adhesion, role of products; (2) claimed can for closed of body wound, and three degrees burn, and infection wound, and necrosis organization more of wound, and Wound sepsis patients and other products, (3) products containing active ingredients: such as drug / pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (4) other new products , Such as the use of new materials, new technology, new designs or products with a new mechanism, new feature.
55	Hydrocolloid dressings	6864	By water-soluble polymer particles (Such as sodium carboxymethyl cellulose, pectin) Components, such as rubber and Goo. Intended use is limited to protect the wound and absorbs exudate, provide a moist wound environment. Exemption situation not including: (1) indications claimed can promote epithelial of, and guide organization regeneration, and promote wound healing, and reduce pain, and antibacterial, and bleeding, and dissolved necrosis organization, and reduced scar, and anti-adhesion, role of products; (2) claimed can for body wound, and three degrees burn, and infection wound, and necrosis organization more of wound, and occurred wound pus HIV syndrome of patients, situation of products And (3) of products containing active ingredients: such as drug / pharmaceutical active ingredients, bio / bio-active

<p>ingredients, silver, disinfectants, such as and (4) other new products , Such as the use of new materials, new technology, new designs or products with a new mechanism, new feature.</p>		
<p>56</p>	<p>Hydrophilic fiber dressings</p>	<p>6864</p>
<p>Composed primarily of sodium carboxy methyl cellulose. Intended use is limited to protect the wound and absorbs exudate, provide a moist wound environment. Exemption situation not including: (1) indications claimed can promote epithelial of, and guide organization regeneration, and promote wound healing, and reduce pain, and antibacterial, and bleeding, and dissolved necrosis organization, and reduced scar, and anti-adhesion, role of products; (2) claimed can for body wound, and three degrees burn, and infection wound, and necrosis organization more of wound, and occurred wound pus HIV syndrome of patients, situation of products And (3) of products containing active ingredients: such as drug / pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (4) other new products , Such as the use of new materials, new technology, new designs or products with a new mechanism, new feature.</p>		

57	Hydrocolloid oil yarn	6864	<p>Mainly composed of Vaseline, colloidal particles of water (sodium carboxy methyl cellulose) and mesh polyester fibers. Wound drainage, cover, filling. Exemption situation not including: (1) indications claimed can promote epithelial of, and guide organization regeneration, and promote wound healing, and reduce pain, and antibacterial, and bleeding, and dissolved necrosis organization, and reduced scar, and anti-adhesion, role of products; (2) claimed can for closed of body wound, and three degrees burn, and infection wound, and necrosis organization more of wound, and Wound sepsis patients and other products, (3) products containing active ingredients: such as drug /pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (4) other new products , Such as the use of new materials, new technology, new designs or products with a new mechanism, new feature.</p>
58	Iodine liquid caps	6866	<p>Hat CAP, O -Rings, carrier, sponge, and connection pieces, containing povidone-iodine solution. Used to protect the dialysate bag outside interface connection to the outer pipe.Principle, the scope, composition, scale, content, structure, performance, and has listed the same. Exemption does not include: used for disinfection of different liquids, scope, and features special structures and other products.</p>
59	Expander	6866	<p>By expansion tubes and tube seat. Percutaneous puncture, establishing airway passage. Product rationale, scope, performance and structure identical to the already available products. Exemption does not include: using new materials containing polymers, special coating products such as drugs, biological products, and has a special structure and scope and other products.</p>

60	Traditional disposable infusion set	6866	<p>Performance, structure, composition, purpose, belonging to GB 8368 The infusion sets for single use of gravity infusions can be completely covered and raw materials in line with GB15593 , Related standard requirements of traditional type one-time using infusion device, by Cork puncture device and the protection sets, and with air filter device and plug of intake mouth, and liquid channel, and dropper, and drops bucket, and liquid filter device, and pipeline, and flow regulator, and injection pieces, and outside cone joint and the protection sets composition, and infusion container, and infusion needle distribution with, for vein infusion, can with infusion posted (is located in single packaging within), Cork puncture device can for double head or bulls. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature, such as (1) non- PVC materials of the product, (2) materials with non- DEHP plasticizer, Photophobic, physical products, (3) with automatic hydraulic, automatic exhaust structure design of a new type of product. (4) products containing active ingredients: such as drug /pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (5) other new products.</p>
61	Traditional-type infusion sets for single use With needle	6866	<p>Performance, structure, composition, purpose, belonging to GB 8368 The disposable infusion of gravity infusions, GB 18671 Can be completely covered by the disposable intravenous needles and raw material complies with GB15593 Classic related standards such as infusion sets for single use, brought up by Cork puncturing devices and protective cover, air filter and plug the intake, fluid channels, eyedropper, drop, liquid filter, pipe, flow regulators, injection parts, the outer cone joints, protective cover, needle (nominal outside diameter 0.36—1.2mm),</p> <p>The needle handle, hoses, connections and protective cap formed, equipped with containers, infusion and transfusion needle, used for intravenous infusion. Infusion paste (located within a single package), Cork puncture for two-headed or bull. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature, such as (1) non- PVC materials of the product, (2) materials with non- DEHP Physical products such as plasticizers, photophobic, (3) With automatic hydraulic, automatic exhaust structure design of a</p>

new type of product. (4) products containing active ingredients: such as drug / pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (5) other new products.

62 Infusion extension tube 6866

Performance, structure, composition, purpose, belonging to GB 8368 The infusion sets for single use of gravity infusions can be completely covered and raw materials in line with GB15593 Disposable infusion related standards such as extension tubes, conical couplings, liquid filter (optional), piping, and equipped with containers, infusion and transfusion needle, intravenous infusion, type can be straight type, Y Type. Liquid filter nominal pore size of 2um, and3um, and5um, and15um. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature, such as (1) non- PVC materials of the product, (2) materials with non- DEHP Physical products such as plasticizers, photophobic, (3) With automatic hydraulic, automatic exhaust structure design of a new type of product. (4) products containing active ingredients: such as drug / pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (5) other new products.

63	One-time use of precise filtering infusion apparatus With needle	6866	<p>Performance, structure, composition, purpose, belonging to YY0286.1-2007 The special infusion 1 part: single use of precise filtering infusion apparatus, and GB 18671 disposable intravenous needles could be completely covered and raw materials in accordance with GB15593 standards, such as traditional-type infusion sets for single use, Brought up by Cork puncturing devices and protective cover, air filter and plug the intake, liquid channels, eyedropper, drop pipe, liquid filter (2um, and 3um, and 5um), pipe, flow regulators, injection, outer cone attachment, protective cover, needle (nominal outside diameter 0.36-1.2mm), the needle handle, hoses, connections and protective cap formed, equipped with containers, infusion and transfusion needle, used for intravenous infusion. Infusion paste (located within a single package), Cork puncture for two-headed or bull. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature, such as (1) non- PVC materials of the product, (2) materials with non- DEHP Physical products such as plasticizers, photophobic, (3) With automatic hydraulic, automatic exhaust structure design of a new type of product. (4) products containing active ingredients: such as drug /pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (5) other new products.</p>
64	-Disposable bottle bag and infusion With needle	6866	<p>Performance, structure, composition, purpose, belonging to YY0286.8-2008 The special infusion 5 parts: bottle and bag infusion for single use, and GB 18671 disposable intravenous needles could be completely covered and raw materials in accordance with GB15593 standards, such as traditional-type infusion sets for single use, Brought up by Cork puncturing devices and protective cover, air filter and plug the intake, liquid channels, eyedropper, drop pipe, liquid filter (2um, and 3um, and 5um, and 15um), pipe , Hose, bottle (or liquid), flow regulators, injection, outer cone attachment, protective cover, needle (nominal diameter 0.36-1.2mm), the needle handle, hoses, connections and protective cap formed, equipped with containers, infusion and transfusion needle, used for intravenous infusion.</p> <p>Infusion paste (located within a single package), Cork puncture for two-headed or bull. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature, such as (1)</p>

	<p>non- PVC materials of the product, (2) materials with non- DEHP Physical products such as plasticizers, photophobic, (3) With automatic hydraulic, automatic exhaust structure design of a new type of product. (4) products containing active ingredients: such as drug/ pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (5) other new products.</p>
<p>65 Traditional transfusion sets for single use With needle 6866</p>	<p>Performance, structure, composition, purpose, belonging to GB 8369 The transfusion sets for single use, and GB 18671 Can be completely covered by the disposable intravenous needles and raw material complies with GB15593 Classic related standards such as infusion sets for single use, puncture trocar sleeve by corks, bottle caps or puncture needles and parts, air filters, air intake hose, applicator (Two, three) , Drop pipe, flow regulators, filters, injection, blood and blood components outside the cone joint (Screw type connector, or straight connector) , Supporting use of disposable intravenous needle, intravenous blood transfusions. Infusion paste (located within a single package).Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature, such as (1) non- PVC materials of the product, (2) materials with non- DEHP Physical products such as plasticizers, photophobic, (3) With automatic hydraulic, automatic exhaust structure design of a new type of product. (4) products containing active ingredients: such as drug /pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (5) other new products.</p>

66	Burette-type infusion sets for single use With needle	6866	<p>Performance, structure, composition, purpose, belonging to YY0286.2-2006 The special infusion 2 parts: disposable burette-type infusion gravity infusions, GB 18671 can be completely covered by the disposable intravenous needles and raw materials in line with GB15593 Classic related standards such as infusion sets for single use, brought up by Cork puncturing devices and protective cover, air filter and plug the intake, fluid channels, eyedropper, drop, liquid filter (Nominal pore size of filter media 2.0 μ m, and 3.0 μ m, and 5.0 μ m, and 15 μ m), Piping, flow regulators, injection, outer cone attachment, protective cover, needle (nominal outside diameter 0.36—1.2mm), The needle handle, hoses, connections and protective cap formed, equipped with containers, infusion and transfusion needle, used for intravenous infusion.</p> <p>Infusion paste (located within a single package), Cork puncture for two-headed or bull. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature, such as (1) non- PVC materials of the product, (2) materials with non-DEHP Physical products such as plasticizers, photophobic, (3) With automatic hydraulic, automatic exhaust structure design of a new type of product. (4) products containing active ingredients: such as drug / pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (5) other new products.</p>
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67	Flow set fine-infusion for single use With needle	6866	<p>Performance, structure, composition, purpose, belonging to YY0286.6-2009 The special infusion 6 section: special infusion 6parts: disposable flow set of fine-infusion,GB 18671of the one-time use of intravenous infusion needle Fully covered and raw materials in accordance with GB15593 standards, such as conventional disposable infusion set from Cork puncture protection sleeve, aspiration, control switches (not worthy), air filter, two, three, drop bucket, eyedropper, piping, precision drug liquid filter (nominal pore size of filter media 2.0 μ m, and3.0 μ m, and5.0 μ m, and15 μ m), the flow rate setting device (20~ 125ml/h), outer cone connectors, caps, injection and intravenous infusion needle for single use. Infusion paste (located within a single package), Cork puncture for two-headed or bull. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature, such as (1) non- PVC materials of the product, (2) materials with non- DEHP Physical products such as plasticizers, photophobic, (3) With automatic hydraulic, automatic exhaust structure design of a new type of product. (4) products containing active ingredients: such as drug /pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (5) other new products.</p>
68	Disposable infusion devices	6866	<p>Performance, structure, composition, purpose, belonging to YY 0286.4-2006 The special infusion 4 parts: disposable infusion device for pressure infusion device could be completely covered and raw materials in accordance with GB15593 standards, such as conventional disposable infusion set, brought up by Cork puncturing devices and protective cover, air filter and plug the intake channel, liquid, dropper, bucket drops, liquid filter, pipe, Flow regulators, injection of external components and tapered joints, protective cover, filter and backflow valves and other components, containers, infusion and transfusion needle use, used for intravenous infusion, infusion paste, corks puncture for two-headed or bull. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature, such as (1) non- PVC materials of the product, (2) materials with non- DEHP Physical products such as plasticizers, photophobic, (3) With automatic hydraulic, automatic exhaust structure design of a new type of product. (4) products containing active ingredients: such as drug / pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (5) other new products.</p>

69	Disposable pressure extension tube	6866	<p>Disposable pressure extension tube by inner and outer tapered Luer connector, extension tube and / Or three-way valves, and enters the body when blood vessels connected to the catheter. Intended use for the interventions used in the connecting pipe and equipment, provide liquid infusion access and / or use of invasive blood pressure monitoring. Raw materials shall conform to GB15593 standards and other related requirements. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature, such as (1) non- PVC materials of the product, (2) materials with non- DEHP Physical products such as plasticizers, photophobic, (3) products containing active ingredients: such as drug / pharmaceutical active ingredients, bio / bio-active ingredients, silver, disinfectants, such as and (4) Other new products.</p>
70	Infusion tube Accessories: filters	6866	<p>Filters, silicone discs , The Ruhr , Composed of Luer connectors and caps , Used for matching with the temperature, and liquid instrument temperature fluid connections, use the 3 Hours change, gravity-type infusion, excluding produce porous bubbles when heating liquids, excluding filter particles or bacteria. Product performance using applicable parts of the following standards, such as:GB8368-2005 disposable infusion of gravity infusions;YY 0585.3-2005 Pressure infusion device with disposable fluid and annex 3 section: filter</p>
71	One-time use of intravenous indwelling needle	6866	<p>Performance, structure, composition, uses industry standard to be released belong to the one-time use of venous indwelling needle itself can be completely covered by product, intended use may include " Blood specimen collection " Function. Products are generally composed of ductal components and syringe components, and component consists of catheters, Catheter, catheter extension tube (if any) and any one of the Joint Assembly, and component is made up of needles and needle needle seat and / or other one of the accessories of the assemblies. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature , such as products with anti-acupuncture and functional.</p>

72	High pressure contrast injections extension tube	6866	Products from the catheter , Rotating Luer connectors and O -Ring /Fix Luer connector , Seat. Products for disposable products ,sterile supply. The product during angiography as a bolus contrast piping. Such as products with specific properties or structures (such as self-destruction, acupuncture, etc) cannot be exempted, such as clinical. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
73	Contrast-enhanced high pressure syringe for single use and accessories	6866	By syringe, connecting pipe, J -Suction tube and so on. Intended use: for supporting CT high-pressure injection pumps,MRI high-pressure injection pumps,DSA high pressure injection pump and Cardiovascular Angiography injection of contrast agent device ,without touching the body. Such as products with specific properties or structures cannot be exempted from clinic.Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
74	Connecting pipe	6866	Connecting pipe by connecting pipe and joint. Used to connect a syringe and catheter, injected contrast agents for angiography or used to connect devices in the Interventional pathway and extending fluid. Such as products with specific properties or structures cannot be exempted from clinic. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
75	T-cock	6866	This product by the cock, knob and screw-type interface. Sterile and pyrogen-free. For one-time use. Such as products with specific properties or structures cannot be exempted from clinic. Exemption does not include the use of new materials, active ingredients, new technology, new designs or products with a new mechanism, new feature.
76	Disposable human arterial blood specimen collection device	6866	Disposable human arterial blood specimen collection consists of storage device, blood sampling needle and needle CAP, ventilation hood, needle cases, cubical plastic blocks. For arterial blood sample collection and storage of collected blood samples for blood gas analysis.

77	Ureteral stent	6866	Ureteral stent Bracket, locators, and other components. Products are sterilized, disposable. The products and Endoscope into the renal pelvis, ureter and bladder, ureteral obstruction, stenosis or occlusion of hydronephrosis caused by a temporary drainage .Exemption does not include: use of new materials using non- DEHPplasticizer containing special coating such as functional polymer, pharmaceutical, bio-products, containing active ingredients, new technology, new design or new mechanisms, as well as with special structures, the scope of products.
78	Percutaneous dilation apparatus	6866	When used for percutaneous puncture of renal pelvis, dilated renal parenchyma in subcutaneous tissue, muscle, in order to establish and maintain a percutaneous access.
79	Percutaneous nephrostomy for devices	6866	For percutaneous nephrostomy for surgery, dilators, puncture needle, wire, composed of catheter sheaths and Balloon dilatation catheter. Products material mature mechanism of clear, and have been registered in the products have the same nature. New structural design and mechanism of exception except for medical device combination products.
80	Radiotherapy recording and validation software	6870	Before radiation therapy treatment parameter validation and treatment parameters recorded in the treatment process.
81	Outline of radiation therapy software	6870	Used in radiation treatment planning prior to tumors and relevant organs and organizations of the outline.
82	Guide wire	6877	Flexible instruments that guide the catheters inserted into the blood vessel and locate. Can core wire, wire wrapped, safety components such as wires, sheathed, with attachments, can be coated with a coating, you can include extension of the Guide wire. Products material mature mechanism of clear, and have been registered in the products have the same nature. New structural design and mechanism of exception except for medical device combination products; except for Neurovascular Guidewire.
83	Guiding catheter	6877	Establishment of vascular access in operation. By tube and seat components, with attachments, can be coated with a coating. Products material mature mechanism of clear, and have been registered in the products have the same nature. New structural

			design and mechanism except for medical device combination products except for nerves and vessels except the guiding catheter.
84	Angiographic catheter	6877	For injection or input control media and / Or a liquid. By tube and seat components, with attachments, can be coated with a coating. Products material mature mechanism of clear, and have been registered in the products have the same nature. New structural design and mechanism of exception except for medical device combination products; except for neuro-vascular catheter.
85	Micro-ducts	6877	For injection or input control media and / Or liquid and / Or materials, from the tube and seat components, with attachments, can be coated with a coating. Products material mature mechanism of clear, and have been registered in the products have the same nature. New structural design and mechanism of exception except for medical device combination products; except for neuro-vascular catheter.
86	Catheter sheath	6877	For the auxiliary transmission diagnosis / Therapy equipment into the heart Chamber. Sheaths, tubes and components such as collateral, with attachments, can be coated with a coating. Products material mature mechanism of clear, and have been registered in the products have the same nature. New structural design and mechanism of exception except for medical device combination products; except for neuro-vascular catheter sheath.
87	Balloon dilatation catheters	6877	Arterio-venous stenosis or stents (used to support the vascular lumen Implantable tubular structure) treatment. By balloon, catheters, catheter detectability and rays tokens, with attachments, can be coated with a coating. Products material mature mechanism of clear, and have been registered in the products have the same nature. New structural design and mechanism except for medical device combination products except for nerves and vessels except the Balloon dilatation catheter.
88	Y Shape connector	6877	Auxiliary devices for percutaneous angioplasty. By y -shaped connectors, Luer fittings, o -shaped gaskets and other components. Products material mature mechanism of clear, and have been registered in the products have the same nature.

89	The bleeding valve	6877	Auxiliary devices for percutaneous angioplasty. Hemostatic valve housings, valve, locking connectors, components such as side pipes, t-cock. Products material mature mechanism of clear, and have been registered in the products have the same nature.
90	Intravascular extraction device	6877	For transcatheter capture off after failure of intravascular Interventional devices in and out of foreign bodies such as brackets, faults the catheter and guide wire. From the tube, basket and handles and other components, with attachments, can be coated with a coating. Products material mature mechanism of clear, and have been registered in the products have the same nature. New structural design and mechanism except for medical device combination products except for Neurovascular apparatus except.
91	Expansion of sheath	6877	Expansion sheath formed by the inner sheath and the outer sheath.Suitable for percutaneous dilatational cardiac pacing around, indwelling catheters and foreign organizations. Product principle, scope, performance and structure identical to the already available products. Exemption does not include: using new materials containing polymers, special coating products such as drugs, biological products, and has a special structure and scope and other products.
92	Heart defects with Occluder delivery device	6877	Through the femoral vein / Transportation of femoral artery congenital heart defects with occluder. Loader, push and so on. Products material mature mechanism of clear, and have been registered in the products have the same nature. New structural design and mechanism of exception except for medical device combination products.