



CRS
CHEMICAL INSPECTION
& REGULATION SERVICE

Catalog of high risk medical devices

Updated in 2014

No.	Risk Code	Product Name (CN)	MD Code	Generic Name (EN)	Type of Risk
1	A	高传染性产品		Highly Infectious products	
2	B	心脏或组织修补材料	6846	Materials for repairing heart and tissues	Implantable product: Animal source
3	B	眼内填充材料	6846	Intraocular tamponade materials	Implantable product: Animal source
4	B	含药产品		Drug-containing products	
5	B	动物源性产品		Animal-derived products	
6	B	生物源性		Biogenic medical devices	
7	C	脑动脉瘤夹	6846	Aneurysm Clips	Implantable product
8	C	血管吻合(夹)器	6846	Platform Vascular Closure	Implantable product
9	C	整形材料	6846	Orthopedic materials	Implantable product
10	C	神经补片	6846	Neuro-Patch	Implantable product
11	C	人工食道(食道支架)	6846	Artificial esophagus (Esophageal Stent)	Implantable product
12	C	人工血管	6846	Vascular Prosthesis	Implantable product
13	C	人工关节	6846	Modular Replacement System	Implantable product
14	C	人工尿道(尿道支持系统)	6846	Artificial urethra (Urethral Support System)	Implantable product
15	C	人工心脏瓣膜	6846	Prosthetic Heart Valves	Implantable product
16	C	人工肾	6846	artificial kidney	Implantable product
17	C	义乳(乳房植入)	6846	Breast Implant	Implantable product
18	C	人工颅骨(颅骨固定系统)	6846	Artificial skull (Cranial Fixation System)	Implantable product
19	C	人工颌骨	6846	artificial jaw bone	Implantable product
20	C	人工心脏	6846	Artificial heart	Implantable product
21	C	人工肌腱(前交叉韧带固定针系统)	6846	artificial tendon (position cruciate ligament)	Implantable product
22	C	人工耳蜗系统	6846	Cochlear Implant Systems	Implantable product
23	C	人工肛门封闭器(肛门括约肌假体)	6846	Neosphincter	Implantable product
24	C	人工皮肤	6846	Artificial skin	Implantable product
25	C	人工角膜	6846	artificial cornea	Implantable product
26	C	血管支架	6846	Vascular stents	Implantable product
27	C	前列腺支架	6846	Prostate stent	Implantable product
28	C	胆道支架	6846	Biliary Stent	Implantable product
29	C	食道支架	6846	Esophageal Stent	Implantable product
30	C	植入式助听器	6846	hearing-aids with implant	Implantable product
31	C	眼人工晶体	6822	Intra-ocular lenses	Implantable product

32	C	人工肝支持装置 (人工肝MARS分子 吸附循环系统主	6845	MARS Monitor	Medical devices used for maintaining life
33	C	植入式心脏起搏器	6821	Implantable Pulse Generator	Medical devices used for supporting and maintaining
34	C	体外心脏起搏器	6821	External Cardiac Pacemaker	Medical devices used for maintaining life
35	C	主动脉内囊反搏器	6821	aortic balloon counter pulsator	Impantable devices used for supporting and maintaining
36	C	植入体内的医用传 感器 (有创血压传 感器)	6821	Catheter tip pressure transducer	Implantable products
37	C	超声血管内介入治 疗仪 (旋磨介入治 疗仪系统)	6823	Rotablator Rotational Angioplasty System	Active interventional devices
38	C	钴60治疗机	6833	cobalt 60 therapy unit	Devices may cause great pollution to the
39	C	远距离放射性核素 治疗装置 (γ射线治 疗机)	6833	Radionuclide Radiation Therapy System	Devices may cause great pollution to the environment
40	C	核素后装近距离治 疗机 (后装治疗	6833	Afterloading therapie System	Devices may cause great pollution to the
41	C	植入放射源	6833	Implantation of radioactive sources	Devices may cause great pollution to the
42	C	人工心肺机	6845	Artificial Heart-Lung Machine	Devices used for supporting and maintaining life
43	C	鼓泡式氧合器	6845	bubble oxygenator	Devices used for supporting and maintaining life
44	C	膜式氧合器	6845	Oxygenator With Venous Hardshell Cardiotomy	Devices used for supporting and maintaining life
45	C	血泵系统	6845	Bloodpump system	Devices used for supporting and maintaining life
46	C	贮血滤血器	6845	Equipments for blood storage and hemofiltration	Devices used for supporting and maintaining life
47	C	微栓过滤器 (动脉 微栓过滤器)	6845	Arterial Blood Filter	Devices used for supporting and maintaining life
48	C	滤血器	6845	hemofilter	Devices used for supporting and maintaining life
49	C	滤水器 (超滤)	6845	Water filter (UF)	Devices used for supporting and maintaining life
50	C	血液透析装置	6845	Hemodialysis Delivery System	Devices used for supporting and maintaining life
51	C	血液透析滤过装置	6845	Hemodialysis Machine	Devices used for supporting and maintaining life
52	C	血液滤过装置	6845	Blood Autotransfusion System	Devices used for supporting and maintaining life

53	C	血液净化管路（血液净化体外循环回路附件）	6845	Drainage Connector	Devices used for supporting and maintaining life
54	C	透析血路（透析管路）	6845	Blood Tubing Line	Devices used for supporting and maintaining life
55	C	血路塑料泵管（一次性使用血泵管）	6845	Plastic pipes of blood path pump	Devices used for supporting and maintaining life
56	C	动静脉穿刺器	6845	Equipment for artery and vein puncture	Devices used for supporting and maintaining life
57	C	多层平板型透析器	6845	Multi-layer plate	Devices used for supporting and maintaining life
58	C	中空纤维透析器	6845	Hollow Fiber Dialyzer	Devices used for supporting and maintaining life
59	C	中空纤维滤过器	6845	Hemofilter for Continuous Hemofiltration	Devices used for supporting and maintaining life
60	C	吸附器（选择性血浆成份吸附器）	6845	Plasma Perfusion Column	Devices used for supporting and maintaining life
61	C	血浆分离器	6845	Plasmafilter	Devices used for supporting and maintaining life
62	C	血液解毒（灌流灌注）器	6845	Equipment for blood detoxification	Devices used for supporting and maintaining life
63	C	血液成分分离机	6845	Trima Automated Blood Collection System	Devices used for supporting and maintaining life
64	C	自体血液回输机	6845	Constavac Blood Conservation System	Devices used for supporting and maintaining life
65	C	离心式输血泵	6845	Sarns Centrifugal System	Devices used for supporting and maintaining life
66	C	灌注泵（离心泵灌注系统）	6845	Extracorporeal Blood Pumping Console	Devices used for supporting and maintaining life
67	C	单采血浆机	6845	Apheresis plasma machine	Devices used for supporting and maintaining life
68	C	血液处理机一次性使用附件	6845	Red Cells Disposable Sets	Devices used for supporting and maintaining life
69	C	腹水浓缩机	6845	Ascites Concentrator	Devices used for supporting and maintaining life
70	C	血液成份输血装置	6845	Devices for blood component transfusion	Devices used for supporting and maintaining life
71	C	医用无菌手术手套	6866	Latex Surgical Glove	Devices with large consumption may have great harmful to the public
72	C	检查用乳胶手套	6866	Latex Surgical Glove	Devices with large consumption may have great harmful to the public
73	C	避孕套	6866	Condom	Devices with large consumption may have great harmful to the public