

第一批实施医疗器械唯一标识的产品目录

依据《医疗器械分类目录》列出以下品种：

一、01 有源手术器械 Active Surgical Medical Devices

一级产品类别 First Level Product Category	二级产品类别 Second Level Product Category	管理类别 Class
05 冷冻手术设备及附件 Cryosurgical Unit And Accessories	02 冷冻消融针及导管 Cryoablation needle and catheter	III

二、02 无源手术器械 Passive Surgical Devices

一级产品类别 First Level Product Category	二级产品类别 Second Level Product Category	管理类别 Class
13 手术器械-吻（缝）合器械及材料 Surgical instruments-Suture instruments and materials	06 可吸收缝合线 Absorbable suture	III

三、03 神经和心血管手术器械 Neuro and cardiovascular surgical instruments

一级产品类别 First Level Product Category	二级产品类别 Second Level Product Category	管理类别 Class
13 神经和心血管手术器械-心血管介入器械	01 造影导管 Angiography Catheter	III
	02 导引导管 Guide Catheter	III

一级产品类别 First Level Product Category	二级产品类别 Second Level Product Category	管理类别 Class
Neurological and Cardiovascular Surgical Instruments - Cardiovascular interventional instrument	03 中心静脉导管 Central Venous Catheter	III
	05 灌注导管 Infusion Catheter	III
	06 球囊扩张导管 Balloon Dilatation Catheter	III
	07 切割球囊 Cutting Balloon Catheter	III
13 神经和心血管手术器械-心血管介入器械 Neurological and Cardiovascular Surgical Instruments - Cardiovascular interventional instrument	08 造影球囊 Radiography Balloon	III
	09 封堵球囊 Blocking Balloon	III
	10 血栓抽吸导管 Thrombus Aspiration Catheter	III
	11 套针外周导管 Sheath Peripheral Catheter	III
	16 导丝 Guide Wire	III
	20 心脏封堵器装载器 Cardiac occlude loader	III
	21 心脏封堵器输送线缆 Cardiac occlude delivery cable	III
	22 血管内回收装置 Cardiovascular recovery device	III

四、06 医用成像器械 Medical imaging equipment

一级产品类别 First Level Product Category	二级产品类别 Second Level Product Category	管理类别 Class
14 医用内窥镜 Endoscope	04 胶囊式内窥镜系统 Capsule endoscope system	III

五、10 输血、透析和体外循环器械 Devices for blood transfusion, dialysis and cardiopulmonary bypass

一级产品类别 First Level Product Category	二级产品类别 Second Level Product Category	管理类别 Class
04 血液净化及腹膜透析器具 Blood purification and peritoneal dialysis equipment	01 血液透析器具 Hemodialysis equipment	III
06 心肺流转器具 Cardiopulmonary circulation apparatus	01 氧合器 Oxygenator	III
	03 微栓过滤器 ADSL filters	III

六、12 有源植入器械 Active implants

一级产品类别 First Level Product Category	二级产品类别 Second Level Product Category	管理类别 Class
01 心脏节律管理设备 CRMD	01 植入式心脏起搏器 Implantable pacemaker	III
	02 植入式心律转复除颤器 Implantable defibrillator;	III

	03 临时起搏器 Temporary cardiac pacemaker	III
	04 植入式心脏起搏电极导线 Implantable pacemaker lead	III
	05 植入式心脏除颤电极导线 Implantable defibrillation electrode lead	III
	06 临时起搏电极导线 Lead of temporary pacing electrode	III
	07 植入式心脏事件监测设备 Implantable heart event monitoring device	III
02 神经调控设备 Neural control equipment	01 植入式神经刺激器 Implantable nerve stimulator	III
	02 植入式神经刺激电极 Implantable nerve stimulation electrode	III
	04 神经调控充电设备 Neural control charging equipment	III
03 辅助位听觉设备 Auxiliary position hearing equipment	01 植入式位听觉设备 Implantable hearing device	III
04 其他 Others	03 植入式药物输注设备 Implantable Drug Delivery Device	III

七、13 无源植入器械 Passive implants

一级产品类别 First Level Product Category	二级产品类别 Second Level Product Category	管理类别 Class
01 骨结合植入物 Osseointegrated implants	02 单/多部件可吸收骨固定器械 Single / multi-component absorbable bone fixation apparatus	III
03 脊柱植入物 Spinal Implants	02 脊柱椎体间固定/置换系统 Spinal Internal Fixation System / Vertebral Body Replacement System	III
04 关节置换植入物 Joint replacement implant	01 髋关节假体 Hip prosthesis	III
	02 膝关节假体 Knee prosthesis	III
	03 肩关节假体 Shoulder prosthesis	III
	04 肘关节假体 Elbow prosthesis	III
04 关节置换植入物 Joint replacement implant	05 指关节假体 Phalanx prosthesis	III
	06 腕关节假体 Wrist prosthesis	III
	07 踝关节假体 Ankle prosthesis	III
	08 颞下颌关节假体 Temporomandibular joint prosthesis	III
06 神经内/外科植入物 Intraneural / surgical implants	04 硬脑（脊）膜补片 Hard brain (ridge) membrane patch	III
	06 颅内支架系统 Intracranial stent system	III
	07 颅内栓塞器械 Intracranial stent system	III
	08 颅内弹簧圈系统	III

一级产品类别 First Level Product Category	二级产品类别 Second Level Product Category	管理类别 Class
	Intracranial coil system	
	09 人工颅骨 Artificial skull	III
	10 脑积水分流器及组件 Hydrocephalus shunt and components	III
	11 颅内动脉瘤血流导向装置 Flow guide device for intracranial aneurysm	III
07 心血管植入物 Cardiovascular implants;	01 血管内假体 Endovascular prosthesis	III
	02 血管支架 Vascular Stent	III
	03 腔静脉滤器 Vena cava filter	III
	04 人工血管 Vascular prosthesis/ AV graft	III
	05 心血管补片 Cardiovascular patch	III
	06 人工心脏瓣膜及瓣膜修复器械 Prosthetic heart valves and prosthetic devices	III
	07 心脏封堵器 Cardiac occluder	III
	08 心血管栓塞器械 Cardiovascular embolism device	III
08 耳鼻喉植入物 ENT Implants	02 耳内假体 Ear-insertion Prosthesis	III

一级产品类别 First Level Product Category	二级产品类别 Second Level Product Category	管理类别 Class
09 整形及普通外科植入物 Implantable access ports and accessories	01 整形填充材料 Plastic filling material	III
	02 整形用注射填充物 Plastic injection filler	III
	03 乳房植入物 Breast implants;	III
	04 外科补片/外科修补网 Surgical patch / mesh	III
	06 非血管支架 Non vascular stent	III
	07 支气管内活瓣 Endobronchial valve;	III
	09 阴茎假体 Penile Prosthesis	III

八、14 注输、护理和防护器械 Infusion, recovery and protective devices

一级产品类别 First Level Product Category	二级产品类别 Second Level Product Category	管理类别 Class
02 血管内输液器械 Intravascular infusion apparatus	10 植入式给药器械 Implantable drug delivery device	III
05 非血管内导(插)管 Non intravascular catheter	05 输尿管支架 Ureteral stent;	III
08 可吸收外科敷料(材料) Surgical Absorbable Dressing (or Material)	01 可吸收外科止血材料 Surgical Absorbable Hemostatic Material	III

九、16 眼科器械 Ophthalmic instruments

一级产品类别 First Level Product Category	二级产品类别 Second Level Product Category	管理类别 Class
07 眼科植入物及辅助器械 Ophthalmic implants and auxiliary devices	01 人工晶状体 Intraocular Lens	III