



**CIRS**  
CHEMICAL INSPECTION  
& REGULATION SERVICE

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## Publicity List of Innovative Medical Devices collected from CMDE

NO	File NO	产品名称	Product Name	企业名称	Website Address	Publicity Time
1	Announcement on Result of Innovative Medical Device Special Approval Application (NO.1 2014)	可吸收硬脑膜封合医用胶	Absorbable Dural Sealant Medical Adhesive	山东赛克赛斯药业科技有限公司	www.successpharm.com	May 14,2014 to May 30, 2014
2	Announcement on Result of Innovative Medical Device Special Approval Application (NO.2 2014)	脑硬膜防渗医用涂敷系统	Medical impermeable coating system	北京赛奇科科技有限公司		Jun 20,2014 to Jul 03, 2014
3	Announcement on Result of Innovative Medical Device Special Approval Application (NO.2 2014)	21三体、18三体和13三体检测试剂盒	Diagnostic testing Kit of Trisomy 21,18&13.	中山大学达安基因股份有限公司	www.daangene.com	Jun 20,2014 to Jul 03, 2014
4	Announcement on Result of Innovative Medical Device Special Approval Application (NO.2 2014)	基因测序仪	DNA Sequencing instrument	深圳华因康基因科技有限公司	www.hykgene.com	Jun 20,2014 to Jul 03, 2014
5	Announcement on Result of Innovative Medical Device Special Approval Application (NO.2 2014)	具有无线程控功能的双通道植入式神经刺激系统	Dual-channel device capable of delivering bilateral stimulation with wireless programmable function	苏州景昱医疗器械有限公司	www.sceneray.com	Jun 20,2014 to Jul 03, 2014

6	Announcement on Result of Innovative Medical Device Special Approval Application (NO.2 2014)	左心耳封堵器系统	Left atrial appendage(LAA) Occluder System	先健科技(深圳)有限公司	www.lifetechmed.com	Jun 20,2014 to Jul 03, 2014
7	Announcement on Result of Innovative Medical Device Special Approval Application (NO.2 2014)	经皮介入人工心脏瓣膜系统	Percutaneous Artificial Heart Valve System	杭州启明医疗器械有限公司	www.venusmedtech.com	Jun 20,2014 to Jul 03, 2014
8	Announcement on Result of Innovative Medical Device Special Approval Application (NO.3 2014)	生物型人工角膜	Biological Artificial Cornea	广州优得清生物科技有限公司	youvisionbio.com	Aug 15,2014 to Aug 29, 2014
9	Announcement on Result of Innovative Medical Device Special Approval Application (NO.4 2014)	组织工程人角膜内皮	Tissue-engineered Human Corneal Endothelium	青岛宇明生物技术有限公司	www.yumingbio.cn	Aug 20,2014 to Sep 03, 2014
10	Announcement on Result of Innovative Medical Device Special Approval Application (NO.5 2014)	可吸收药物冠脉支架系统	Drug-eluting Bioresorbable Vascular Scaffold System	先健科技(深圳)有限公司	www.lifetechmed.com	Sep 28,2014 to Oct 15, 2014
11	Announcement on Result of Innovative Medical Device Special Approval Application (NO.5 2014)	肺动脉带瓣管道	Pulmonary Artery Conduit	武汉亚心医疗科技有限公司	www.yaxinmedical.com	Sep 28,2014 to Oct 15, 2014
12	Announcement on Result of Innovative Medical Device Special Approval Application (NO.5 2014)	锥光束乳腺CT(科宁锥光束乳腺三维成像系统)	Cone Beam Breast CT (3D Imaging Systems)	科宁(天津)医疗设备有限公司	koningcorporation.com	Sep 28,2014 to Oct 15, 2014
13	Announcement on Result of Innovative Medical Device Special Approval Application (NO.5 2014)	大肠癌甲基化基因检测试剂盒(PCR荧光探针法)	Methylated DNA Detection Kit for Colorectal Cancer(PCR Fluorescent Probe)	博尔诚(北京)科技有限公司	www.biochainbj.com	Sep 28,2014 to Oct 15, 2014

14	Announcement on Result of Innovative Medical Device Special Approval Application (NO.6 2014)	可降解镁骨内固定螺钉	Biodegradable Magnesium Bone Fixation Screws	东莞宜安科技股份有限公司	www.e-ande.com	Nov 04,2014 to Nov 20, 2014
15	Announcement on Result of Innovative Medical Device Special Approval Application (NO.6 2014)	胸骨板	Sternal Bar	常州华森医疗器械有限公司	www.wastonmed.com	Nov 04,2014 to Nov 20, 2014
16	Announcement on Result of Innovative Medical Device Special Approval Application (NO.7 2014)	MTHFR C677T基因检测试剂盒(PCR-金磁微粒层析法)	MTHFR C677T Genotyping Kit(PCR-GoldMag Lateral Flow Assay)	西安金磁纳米生物技术有限公司	www.goldmag.com.cn	Dec 17,2014 to Dec 30, 2014
17	Announcement on Result of Innovative Medical Device Special Approval Application (NO.7 2014)	脱细胞角膜基质	Acellular Cornea Stroma	深圳艾尼尔角膜工程有限公司	www.aierfu.com	Dec 17,2014 to Dec 30, 2014
18	Announcement on Result of Innovative Medical Device Special Approval Application (NO.1 2015)	具有精确标测肾交感神经功能的消融导管和神经刺激射频消融仪	a proprietary catheter-based renal mapping and ablation system for renal denervation	苏州信迈医疗器械有限公司		Feb 03,2015 to Feb 15, 2015
19	Announcement on Result of Innovative Medical Device Special Approval Application (NO.1 2015)	恒温扩增微流控芯片核酸分析仪	Nucleic acid analyzer based on Isothermal Amplification Microfluidic	博奥生物集团有限公司	cn.capitalbio.com	Feb 03,2015 to Feb 15, 2015
20	Announcement on Result of Innovative Medical Device Special Approval Application (NO.1 2015)	儿童型智能控制洗胃机	Child Intelligent Ggastric Lavage Machine	天津市同业科技发展有限公司	www.tongye.com.cn	Feb 03,2015 to Feb 15, 2015
21	Announcement on Result of Innovative Medical Device Special Approval Application (NO.2 2015)	药物洗脱外周球囊扩张导管	Drug Coated PTA Balloon Catheter	北京先瑞达医疗科技有限公司	www.acotec.cn	Mar 16,2015 to Mar 30, 2015

22	Announcement on Result of Innovative Medical Device Special Approval Application (NO.2 2015)	SMN1基因外显子缺失检测试剂盒(荧光定量PCR法)	Diagnostic Kit for Deletions of SMN1 exon(Fluorescence quantitative PCR)	上海五色石医学研究有限公司	chromysky.net	Mar 16,2015 to Mar 30, 2015
23	Announcement on Result of Innovative Medical Device Special Approval Application (NO.2 2015)	全吸收式生物血管支架系统	Absorption Biological Stent System	Abbott Vascular	www.abbottvascular.com	Mar 16,2015 to Mar 30, 2015
24	Announcement on Result of Innovative Medical Device Special Approval Application (NO.3 2015)	三维心脏电生理标测系统	3D Cardiac Electrophysiological device	上海微创电生理医疗科技有限公司	www.microport.com.cn	Apr 14,2015 to Apr 27, 2015
25	Announcement on Result of Innovative Medical Device Special Approval Application (NO.3 2015)	三层仿生小口径人造血管	Three-layer weaved Small-caliber Artificial Blood Vessel	武汉杨森生物技术有限公司	www.youngsen.cn	Apr 14,2015 to Apr 27, 2015
26	Announcement on Result of Innovative Medical Device Special Approval Application (NO.3 2015)	人工晶状体	Intraocular Lens (IOL)	爱博诺德(北京)医疗科技有限公司	www.ebmedical.com	Apr 14,2015 to Apr 27, 2015
27	Announcement on Result of Innovative Medical Device Special Approval Application (NO.3 2015)	介入人工生物心脏瓣膜	Bioprosthetic Heart Valves	苏州杰成医疗科技有限公司		Apr 14,2015 to Apr 27, 2015
28	Announcement on Result of Innovative Medical Device Special Approval Application (NO.4 2015)	3aPCS型角膜基质替代物	3-Apcs type Corneal Substitute	青岛中皓生物工程有 限公司	www.ctec-cn.com	Jun 03,2015 to Jun 16, 2015
29	Announcement on Result of Innovative Medical Device Special Approval Application (NO.4 2015)	正电子发射断层成像装置	Positron Emission Tomography Imaging Apparatus	明峰医疗系统股份有 限公司	www.fmimed.com.cn	Jun 03,2015 to Jun 16, 2015

30	Announcement on Result of Innovative Medical Device Special Approval Application (NO.4 2015)	红细胞寿命测定仪	RBC Life Measuring Instrument	深圳市先亚生物科技有限公司	www.seekya.cn	Jun 03,2015 to Jun 16, 2015
31	Announcement on Result of Innovative Medical Device Special Approval Application (NO.4 2015)	外科手术机器人定位系统	Surgery Robot Positioning System	北京天智航医疗科技股份有限公司	www.tinavi.com.cn	Jun 03,2015 to Jun 16, 2015
32	Announcement on Result of Innovative Medical Device Special Approval Application (NO.5 2015)	血管内动脉瘤密封系统(NELLIX® EndoVascular Aneurysm Sealing System)	EndoVascular Aneurysm Sealing System	Endologix International Holdings B.V.	www.endologix.com	Jun 26,2015 to Jul 09, 2015
33	Announcement on Result of Innovative Medical Device Special Approval Application (NO.5 2015)	外科生物补片（膀胱、腹壁修补专用）	Biologic Surgery Graft (Bladder, Abdominal Repair dedicated)	上海松力生物技术有限公司	www.shsongli.com	Jun 26,2015 to Jul 09, 2015
34	Announcement on Result of Innovative Medical Device Special Approval Application (NO.5 2015)	医用人工神经移植术	Medical Artificial Nerve Graft	江苏益通生物科技有限公司		Jun 26,2015 to Jul 09, 2015