

List of Innovative Medical Devices Approved by the State Food and Drug Administration

	Product name	Production enterprise	Approved date	Location	Registration number
1	Gene sequencer	Shenzhen Huayinkang Gene Technology Co., Ltd.	2014-12-10	Guangdong	National Machinery Note 20143402171
2	Constant temperature amplification microfluidic chip nucleic acid analyzer	Boao Biological Group Co., Ltd.	2015-4-20	Beijing	National Machinery Note 20153400580
3	Dual-channel implantable deep brain stimulation pulse generator kit	Suzhou Jingyu Medical Equipment Co., Ltd.	2015-6-9	Jiangsu	National Machinery Note 20153210970
4	Implantable deep brain stimulation electrode lead kit	Suzhou Jingyu Medical Equipment Co., Ltd.	2015-6-9	Jiangsu	National Machinery Note 20153210971
5	Implantable deep brain stimulation extension lead kit	Suzhou Jingyu Medical Equipment Co., Ltd.	2015-6-9	Jiangsu	National Machinery Note 20153210972
6	MTHFR C677T gene detection kit (PCR- gold magnetic particle chromatography)	Xi'an Gold Magnetic Nano Biotechnology Co., Ltd.	2015-7-3	Shaanxi	National Machinery Note 20153401148
7	Acellular corneal stroma	Shenzhen Ainier Corneal Engineering Co., Ltd.	2015-4-22	Guangdong	National Machinery Note 20153460581
8	Septin9 gene methylation detection kit (PCR fluorescent probe method)	Boercheng (Beijing) Technology Co., Ltd.	2015-8-24	Beijing	National Machinery Note 20153401481
9	Mammary X -ray digital tomography equipment	Corning (Tianjin) Medical Equipment Co., Ltd.	2015-11-20	Tianjin	National Machinery Note 20153302052
10	Survival Motor Neuron Gene 1 (SMN1) Exon Deletion Detection Kit (Fluorescence Quantitative PCR Method)	Shanghai Wise Stone Medical Research Co., Ltd.	2015-12-22	Shanghai	National Machinery Note 20153402293
11	Three-dimensional cardiac electrophysiological mapping system	Shanghai MicroPort Electrophysiology Medical Technology Co., Ltd.	2016-2-26	Shanghai	National Machinery Note 20163770387
12	Respiratory tract pathogenic bacteria nucleic acid detection kit	Boao Biological Group Co., Ltd.	2016-2-17	Beijing	National Machinery Note 20163400327

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	(constant temperature amplification chip method)				
13	Acellular corneal graft	Guangzhou Youdeqing Biological Technology Co., Ltd.	2016-3-28	Guangdong	National Machinery Note 20163460573
14	Implantable vagus nerve stimulation pulse generator kit	Beijing Pinchi Medical Equipment Co., Ltd.	2016-5-16	Beijing	National Machinery Note 20163210989
15	Implantable vagus nerve stimulation electrode lead kit	Beijing Pinchi Medical Equipment Co., Ltd.	2016-5-16	Beijing	National Machinery Note 20163210990
16	Drug-eluting peripheral balloon dilatation catheter	Beijing Xianruida Medical Technology Co., Ltd.	2016-5-25	Beijing	National Machinery Note 20163771020
17	Cold saline perfusion radiofrequency ablation catheter	Shanghai MicroPort Electrophysiology Medical Technology Co., Ltd.	2016-5-31	Shanghai	National Machinery Note 20163771040
18	Sternum plate	Changzhou Huasen Medical Equipment Co., Ltd.	2016-10-8	Jiangsu	National Machinery Note 20163461582
19	Positron emission and X-ray computed tomography imaging device	Mingfeng Medical System Co., Ltd.	2016-10-17	Zhejiang	National Machinery Note 20163332156
20	Intraocular lens	Aibo Nord (Beijing) Medical Technology Co., Ltd.	2016-11-21	Beijing	National Machinery Note 20163221747
21	Orthopedic surgery navigation and positioning system	Beijing Tianzhihang Medical Technology Co., Ltd.	2016.11.14	Beijing	National Machinery Note 20163542280
22	Cryogenic cryoablation surgery system	Hygeia (Beijing) Medical Devices Co., Ltd.	2017-2-14	Beijing	National Machinery Note 20173583088
23	Sterile cryoablation needle for single use	Hygeia (Beijing) Medical Devices Co., Ltd.	2017-2-14	Beijing	National Machinery Note 20173583089
24	Variable-angle dual-probe single-photon emission computer tomography equipment	Beijing Yongxin Medical Equipment Co., Ltd.	2017-4-26	Beijing	National Machinery Note 20173330681

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25	Fully degradable sinus drug stent system	Puyi (Shanghai) Biotechnology Co., Ltd.	2017-4-25	Shanghai	National Machinery Note 20173460679
26	Percutaneous interventional artificial heart valve system	Hangzhou Qiming Medical Devices Co., Ltd.	2017-4-25	Zhejiang	National Machinery Note 20173460680
27	Interventional artificial heart valve	Suzhou Jiecheng Medical Technology Co., Ltd.	2017-4-28	Jiangsu	National Machinery Note 20173460698
28	Disposable absorbable nail intradermal stapler	Beijing Yihe Hengrui Medical Technology Co., Ltd.	2017-5-31	Beijing	National Machinery Note 20173650874
29	Left atrial appendage occluder system	Lifotech Technology (Shenzhen) Co., Ltd.	2017-6-2	Guangdong	National Machinery Note 20173770881
30	Branch type aorta stent graft and delivery system	Shanghai MicroPort Medical Equipment (Group) Co., Ltd.	2017-6-26	Shanghai	National Machinery Note 20173463241
31	Foldable artificial vitreous balloon	Guangzhou Satellite TV Bo Biological Technology Co., Ltd.	2017-7-25	Guangdong	National Machinery Note 20173223296
32	Abdominal Aorta Stent Graft System	Beijing Huamai Taike Medical Equipment Co., Ltd.	2017-10-17	Beijing	National Machinery Note 20173461434
33	Implantable pacemaker	Lifotech Technology (Shenzhen) Co., Ltd.	2017-12-11	Guangdong	National Machinery Note 20173211570
34	Human EGFR gene mutation detection kit (multiplex fluorescent PCR method)	Xiamen Aide Biomedical Technology Co., Ltd.	2018-1-18	Fujian	National Machinery Note 20183400014
35	Absorbable dura mater sealing medical glue	Shandong Saikesaisi Pharmaceutical Technology Co., Ltd.	2018-1-25	Shandong	National Machinery Note 20183650031
36	Vascular reconstruction device	MicroPort Shentong Medical Technology (Shanghai) Co., Ltd.	2018-3-15	Shanghai	National Machinery Note 20183770102

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37	miR-92a detection kit (fluorescence RT-PCR method)	Shenzhen Jinbaihui Biological Co., Ltd.	2018-3-27	Guangdong	National Machinery Note 20183400108
38	Hepatitis C virus nucleic acid determination kit (PCR- fluorescent probe method)	Beijing Najie Diagnostic Reagent Co., Ltd.	2018-4-20	Beijing	National Machinery Note 20183400157
39	Cerebral thrombus removal device	Jiangsu Nico Medical Equipment Co., Ltd.	2018-5-08	Jiangsu	National Machinery Note 20183770186
40	Quantitative blood flow fraction measurement system	Bodong Medical Imaging Technology (Shanghai) Co., Ltd.	2018-7-12	Shanghai	National Machinery Note 20183210282
41	People EGFR/ALK/BRAF/KRAS gene mutation combined detection kit (reversible terminal termination sequencing method)	Guangzhou Burning Rock Medical Laboratory Co., Ltd.	2018-7-18	Guangdong	National Machinery Note 20183400286
42	Automatic chemiluminescence immunoassay analyzer	Beijing Lianzhong Tech Technology Co., Ltd.	2018-8-11	Beijing	National Machinery Note 20183220293
43	Human EGFR , KRAS , BRAF , PIK3 CA , ALK , ROS1 gene mutation detection kit (semiconductor sequencing method)	Tianjin Nuohe Zhiyuan Biological Information Technology Co., Ltd.	2018-8-11	Tianjin	National Machinery Note 20183400294
44	Composite hernia repair patch	Shanghai Songli Biotechnology Co., Ltd.	2018-8-12	Shanghai	National Machinery Note 20183130292
45	Positron emission tomography and magnetic resonance imaging system	Shanghai United Imaging Medical Technology Co., Ltd.	2018-8-29	Shanghai	National Machinery Note 20183060337
46	EGFR/ALK/ROS1/BRAF/KRAS/HER 2 gene mutation detection kit (reversible terminal termination sequencing method)	Nanjing Shihe Medical Equipment Co., Ltd.	2018-9-28	Jiangsu	National Machinery Note 20183400408
47	Implantable sacral nerve stimulation electrode lead kit	Beijing Pinchi Medical Equipment Co., Ltd.	2018-9-28	Beijing	National Machinery Note 20183120409
48	Implantable sacral nerve stimulator kit	Beijing Pinchi Medical Equipment Co., Ltd.	2018-9-28	Beijing	National Machinery Note 20183120410
49	Human SDC2 Gene Methylation Detection Kit (Fluorescence PCR Method)	Guangzhou Kang Liming Biological Technology Co., Ltd.	2018-11-16	Guangdong	National Machinery Note 20183400506

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50	Human 10 gene mutation joint detection kit (reversible end termination sequencing method)	Xiamen Aide Biomedical Technology Co., Ltd.	2018-11-16	Fujian	National Machinery Note 20183400507
51	Medical electron linear accelerator	Guangdong Zhongneng Accelerator Technology Co., Ltd.	2018-11-28	Guangdong	National Machinery Note 20183050520
52	Valvuloplasty ring	Kings Biotechnology (Changshu) Co., Ltd.	2018-12-07	Jiangsu	National Machinery Note 20183130534
53	Neurosurgery Navigation and Positioning System	Huake Precision (Beijing) Medical Technology Co., Ltd.	2018-12-21	Beijing	National Machinery Note 20183010598
54	Medical linear accelerator system	Shanghai United Imaging Medical Technology Co., Ltd.	2018-12-24	Shanghai	National Machinery Note 20183050599
55	Porous tantalum bone filling material	Chongqing Runze Pharmaceutical Co., Ltd.	2019-1-7	Chongqing	National Machinery Note 20193130001
56	Bioabsorbable coronary artery rapamycin eluting stent system	Lepu (Beijing) Medical Equipment Co., Ltd.	2019-2-22	Beijing	National Machinery Note 20193130093
57	Patient monitor	Shenzhen Mindray Biomedical Electronics Co., Ltd.	2019-3-12	Guangdong	National Machinery Note 20193070154
58	Abdominal aorta stent graft and delivery system	MicroPort Cardiovascular Medical Technology (Shanghai) Co., Ltd.	2019-3-19	Shanghai	National Machinery Note 20193130182
59	Left atrial appendage closure system	Beijing Meditop Medical Technology Co., Ltd.	2019-4-30	Beijing	National Machinery Note 20193130278
60	Left atrial appendage occluder system	Shanghai Pushi Medical Equipment Technology Co., Ltd.	2019-5-5	Shanghai	National Machinery Note 20193130279
61	Intensity Modulated Radiation Therapy Planning System Software	Zhongke Superfine (Anhui)	2019-5-6	Anhui Hefei	National Machinery Note 20193210281

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		Technology Co., Ltd.			
62	Digital mammography X-ray imaging system	Shanghai United Imaging Medical Technology Co., Ltd.	2019-5-6	Shanghai	National Machinery Note 20193060280
63	Positron emission and X-ray computed tomography scanning system	Hubei Ruishi Digital Medical Imaging Technology Co., Ltd.	2019-5-31	Hubei	National Machinery Note 20193060364
64	Transcatheter leadless implantable pacing system Micra Transcatheter Leadless Pacemaker system	Medtronic Medtronic Inc.	2019-6-11	United States	National Machinery Injection into 20193120297
65	Transcatheter Aortic Valve System	Shanghai MicroPort Xintong Medical Technology Co., Ltd.	2019-7-10	Shanghai	National Machinery Note 20193130494
66	Single-use intravascular imaging catheter	Nanjing Wolfman Medical Technology Co., Ltd.	2019-8-19	Jiangsu Nanjing	National Machinery Note 20193060601
67	Non-invasive blood glucose meter	Bobang Fangzhou Medical Technology (Beijing) Co., Ltd.	2019-8-26	Beijing	National Machinery Note 20193070602
68	Implantable left ventricular assist system	Chongqing Yongrenxin Medical Equipment Co., Ltd.	2019-8-26	Chongqing	National Machinery Note 20193120603
69	Acellular corneal graft	Qingdao Zhonghao Biological Engineering Co., Ltd.	2019-9-12	Shandong	National Machinery Note 20193160679
70	Coronary angiography blood flow reserve fraction measurement system	Suzhou Runmad Medical Technology Co., Ltd.	2019-12-09	Suzhou	National Machinery Note 20193070969
71	One-time use invasive pressure sensor	Suzhou Runmad Medical Technology Co., Ltd.	2019-12-9	Suzhou	National Machinery Note 20193070970
72	Positron emission and X-ray computed tomography scanning system	Shanghai United Imaging Medical Technology Co., Ltd.	2019-12-17	Shanghai	National Machinery Note 20193060998

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73	Nucleic acid amplification detection analyzer	Hangzhou Ustar Biotechnology Co., Ltd.	2019-12-23	Hangzhou	National Machinery Note 20193061026
74	Puncture surgery navigation equipment	Yida Polestar Medical Technology (Suzhou) Co., Ltd.	2020-01-14	Suzhou	National Machinery Note 20203010034
75	Coronary blood flow reserve fraction calculation software	Beijing Kunlun Medical Cloud Technology Co., Ltd.	2020-01-14	Beijing	National Machinery Note 20203210035
76	Human EGFR/KRAS/BRAF/HER2/ALK/ROS1 gene mutation detection kit (semiconductor sequencing method)	Xiamen Feishuo Biotechnology Co., Ltd.	2020-01-22	Xiamen	National Machinery Note 20203400094
77	Preimplantation chromosome aneuploidy detection kit (semiconductor sequencing method)	Suzhou Beikang Medical Devices Co., Ltd.	2020-02-21	Suzhou	National Machinery Note 20203400181
78	Bioabsorbable coronary rapamycin eluting stent system	Shandong Huaan Biological Technology Co., Ltd.	2020-3-4	Jinan	National Machinery Note 20203130197
79	Drug balloon dilatation catheter	Shanghai MicroPort Xinmai Medical Technology Co., Ltd.	2020-4-26	Shanghai	National Machinery Note 20203130445
80	Cardiovascular optical coherence tomography equipment and accessories	Shenzhen Zhongke Microlight Medical Device Technology Co., Ltd.	2020-04-28	Shenzhen	National Machinery Note 20203060446
81	RNF180/Septin9 gene methylation detection kit (PCR fluorescent probe method)	Boercheng (Beijing) Technology Co., Ltd.	2020-04-28	Beijing	National Machinery Note 20203400447
82	Plasma surgery equipment	Hunan Jingyi Medical Technology Co., Ltd.	2020-05-08	Hunan	National Machinery Note 20203010474
83	Tumor electric field treatment instrument	NovoCure Ltd.	2020-05-11	Israel	National Machinery Injection 20203090269
84	Transcatheter Aortic Valve System	Edwards Lifesciences LLC	2020-06-05	United States	National Machinery Injection 20203130291
85	Transcatheter mitral valve clamp and steerable guiding catheter	Abbott Vascular	2020-06-15	United States	National Machinery Injection 20203130325

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86	Diabetic retinopathy analysis software	Shanghai Yingtong Medical Technology Co., Ltd.	2020-08-07	Shanghai	National Machinery Note 20203210686
87	Diabetic retinopathy fundus image-aided diagnosis software	Shenzhen Siji Intelligent Technology Co., Ltd.	2020-08-07	Shenzhen City	National Machinery Note 20203210687
88	Hip Joint Coated Ball Head	Zhongao Huicheng Technology Co., Ltd.	2020-08-20	Beijing	National Machinery Note 20203130707
89	Bolt removal bracket	Zhuhai Tongqiao Medical Technology Co., Ltd.	2020-09-07	Guangdong Province	National Machinery Note 20203030728
90	Blood flow reserve fraction measuring equipment	Shenzhen Beixin Life Technology Co., Ltd.	2020-09-29	Shenzhen City	National Machinery Note 20203070774
91	Pressure microcatheter	Shenzhen Beixin Life Technology Co., Ltd.	2020-09-29	Shenzhen City	National Machinery Note 20203070775
92	Hydrogen and oxygen atomizer	Shanghai Rumei Medical Technology Co., Ltd.	2020-02-02	Shanghai	National Machinery Note 20203080066
93	Memory alloy nail foot holder	Lanzhou Ximai Memory Alloy Co., Ltd.	2020.10.26	Gansu	National Machinery Note 20203130823
94	Coronary CT angiography image vascular stenosis auxiliary triage software	Yukun (Beijing) Network Technology Co., Ltd.	2020-11-03	Beijing	National Machinery Note 20203210844
95	KRAS gene mutation and BMP3/NDRG4 gene methylation and fecal occult blood combined detection kit (PCR fluorescent probe method - colloidal gold method)	Hangzhou Nuohui Health Technology Co., Ltd.	2020-11-09	Hangzhou	National Machinery Note 20203400845
96	Drug-eluting PTA balloon dilatation catheter	Zhejiang Guichuang Medical Equipment Co., Ltd.	2020.11.9	Zhejiang Province	National Machinery Note 20203030857
97	Peripheral nerve repair graft	Jiangsu Yitong Biological Technology Co., Ltd.	2020.11.17	Jiangsu Province	National Machinery Note 20203130898
98	CT image-assisted detection software for pulmonary nodules	Hangzhou Shenrui Bolian Technology Co., Ltd.	2020-11-30	Hangzhou City	National Machinery Note 20203210920

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99	Vertebral artery rapamycin targeting eluting stent system	MicroPort Shentong Medical Technology (Shanghai) Co., Ltd.	2020-12-17	Shanghai	National Machinery Note 20203130971
100	Iliac artery bifurcation stent system	Lifetech Technology (Shenzhen) Co., Ltd.	2021/1/12	Guangdong	National Machinery Note 20213130022
101	Anchored balloon dilatation catheter	Hunan Epte Medical Equipment Co., Ltd.	2021/1/13	Hunan	National Machinery Note 202113030023
102	Single-use intravascular imaging catheter	Suzhou Argus Medical Technology Co., Ltd.	2021/3/9	Jiangsu	National Machinery Note 202113060169
103	Single-use electronic ureter and renal pelvis endoscope	Beijing North Tengda Technology Development Co., Ltd.	2021/3/16	Beijing	National Machinery Note 202113060175
104	Helicobacter pylori 23S rRNA gene mutation detection kit (PCR- fluorescent probe method)	Shanghai Xinchao Biotechnology Co., Ltd.	2021-4-1	Shanghai	National Machinery Note 20113400227
105	Coronary CT blood flow reserve score calculation software	Shenzhen Ruixin Intelligent Medical Technology Co., Ltd.	2021-4-14	Shenzhen	National Machinery Note 20213210270
106	Transcatheter Aortic Valve System	Peijia Medical Technology (Suzhou) Co., Ltd.	2021.4.19	Jiangsu Province	National Machinery Note 20113130275
107	Temporary pacemaker	Shenzhen Xianjian Xinkang Medical Electronics Co., Ltd.	2021-4-26	Guangdong	National Machinery Injection Standard 20113120299
108	Paclitaxel-eluting PTCA balloon dilatation catheter	Zhejiang Batai Medical Technology Co., Ltd.	2021-4-30	Zhejiang Province	National Machinery Note 202113030297
109	Peripheral nerve socket	Beijing Huifukang Medical Technology Co., Ltd.	2021-4-30	Beijing	National Machinery Note 20113130298