

「應建立與保存來源及流向資料之醫療器材」附件

項	品項代碼	中文名稱	英文名稱	等級
1	E.0001	心血管支架	Cardiovascular stent	2,3
2	E.0006	血管內移植系統	Endovascular graft system	3
3	E.3250	血管夾	Vascular clip	2
4	E.3260	靜脈腔室夾	Vena cava clip	2
5	E.3300	動脈栓塞裝置	Arterial embolization device	3
6	E.3375	心血管之血管內過濾器	Cardiovascular intravascular filter	2
7	E.3450	血管移植彌補物	Vascular graft prosthesis	2
8	E.3460	血管內縫線系統	Endovascular Suturing System	2
9	E.3470	聚丙烯、聚乙烯、對苯二甲酸等材質製成之心內補片或小拭子	Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene	2
10	E.3545	心室血管繞道術(輔助)裝置	Ventricular bypass (assist) device	3
11	E.3610	植入式心律器之脈搏產生器	Implantable pacemaker pulse generator	3
12	E.3620	心律器導線接頭	Pacemaker lead adaptor	2
13	E.3680	心血管用永久或暫時性之心律調節器電極	Cardiovascular permanent or temporary pacemaker electrode	2,3
14	E.3710	心律調節器修復或置換之材料	Pacemaker repair or replacement material	3
15	E.3800	環狀成形術環	Annuloplasty ring	2
16	E.3850	頸動脈竇神經刺激器	Carotid sinus nerve stimulator	3
17	E.3925	心臟瓣膜置換物	Replacement heart valve	3
18	E.4450	血管夾	Vascular clamp	2
19	E.4510	心尖閉合器	Apical closure device	2
20	F.3060	牙科使用金基合金和貴重金屬合金	Gold based alloys and precious metal alloys for clinical use	2
21	F.3070	牙科用汞齊、水銀、汞齊合金	Dental amalgam, mercury, and amalgam alloy	2
22	F.3250	氫氧化鈣窩洞襯底	Calcium hydroxide cavity liner	2
23	F.3260	窩洞塗料	Cavity varnish	2
24	F.3310	樹脂充填用塗覆材料	Coating material for resin fillings	2
25	F.3640	骨內植體	Endosseous implant	3
26	F.3645	骨膜下植體材	Subperiosteal implant material	2

27	F.3680	聚四氟乙烯玻璃狀碳材料 (聚化玻璃黏著劑)	Polytetrafluoroethylene (PTFE) vitreous carbon material	2
28	F.3690	樹脂牙材	Tooth shade resin material	2
29	F.3710	卑金屬合金	Base metal alloy	2
30	F.3765	凹窩封閉劑及調節劑	Pit and fissure sealant and conditioner	2
31	F.3820	根管充填樹脂	Root canal filling resin	2,3
32	F.3890	根管固定夾板	Endodontic stabilizing splint	2
33	F.3930	牙槽修復材料	Bone grafting material	2,3
34	F.3940	全顳顎關節彌補物	Total temporomandibular joint prosthesis	3
35	F.3950	顳骨關節盂彌補物	Glenoid fossa prosthesis	3
36	F.3960	下頷髁彌補物	Mandibular condyle prosthesis	3
37	F.3970	關節間盤彌補物(內置式植 入物)	Interarticular disc prosthesis (interpositional implant)	3
38	F.4760	骨板	Bone plate	2
39	F.4880	骨內固定螺釘或金屬線	Intraosseous fixation screw or wire	2
40	F.5560	電子式唾液刺激系統	Electrical salivary stimulatory system	2
41	F.6660	牙科用瓷粉	Porcelain powder for clinical use	2
42	G.0001	人工耳蝸植入器	Cochlear implant	3
43	G.3315	鼓膜接觸式助聽器	Tympanic membrane contact hearing aid	2
44	G.3430	中耳模	Middle ear mold	2
45	G.3450	部分聽小骨置換物	Partial ossicular replacement prosthesis	2
46	G.3495	全聽小骨置換物	Total ossicular replacement prosthesis	2
47	G.3620	耳鼻喉科用合成聚合物材料	Ear, nose, and throat synthetic polymer material	2
48	G.3695	下頷骨植入式臉部彌補物	Mandibular implant facial prosthesis	2
49	G.3730	喉部彌補物(Taub 式)	Laryngeal prosthesis (Taub design)	2
50	G.3760	球囊切開術釘(Cody 氏釘)	Sacculotomy tack (Cody tack)	2
51	G.3820	內淋巴液分流器	Endolymphatic shunt	2
52	G.3850	含瓣膜式內淋巴液分流導管	Endolymphatic shunt tube with valve	2
53	G.3880	鼓室通氣管	Tympanostomy tube	2

54	G.3930	含半通透膜鼓室通氣管	Tympanostomy tube with semipermeable membrane	2
55	H.3350	膨脹式陰莖植入物	Penile inflatable implant	3
56	H.3630	硬式陰莖植入物	Penile rigidity implant	2
57	H.3750	睪丸彌補物	Testicular prosthesis	3
58	H.4620	輸尿管支架	Ureteral stent	2
59	H.5015	胰液引流支架與施放系統	Pancreatic drainage stent	2
60	H.5140	膀胱殘餘尿淨空用尿道置入式幫浦	Urethral insert with pump for bladder drainage	2
61	H.5270	植入式電子排尿自制裝置	Implanted electrical urinary continence device	3
62	H.5280	植入式機械/水壓式排尿自制裝置	Implanted mechanical/hydraulic urinary continence device	3
63	H.5530	植入式前列腺組織夾取系統	Implantable transprostatic tissue retractor system	2
64	H.5540	血液通路裝置及其附件	Blood access device and accessories	2
65	H.5930	女性下泌尿道症用直腸控制系統	Rectal control system	2
66	I.0002	膠原蛋白植入劑	Collagen implant	3
67	I.0007	玻尿酸植入物	Hyaluronic Acid Implants	3
68	I.0010	抗沾黏屏障材料	Adhesion Barrier Material	3
69	I.3300	外科用網片	Surgical mesh	2
70	I.3500	含碳纖維合成物之聚四氟乙烯之植入物材料	Polytetrafluoroethylene with carbon fibers composite implant material	2
71	I.3530	可充填生理食鹽水之矽膠乳房彌補物	Silicone inflatable breast prosthesis	3
72	I.3540	矽膠充填之乳房彌補物	Silicone gel-filled breast prosthesis	3
73	I.3550	下巴彌補物	Chin prosthesis	2
74	I.3590	耳朵彌補物	Ear prosthesis	2
75	I.3610	食道彌補物	Esophageal prosthesis	2
76	I.3680	鼻彌補物	Nose prosthesis	2
77	I.3720	氣管彌補物	Tracheal prosthesis	2
78	I.4010	組織黏著劑	Tissue adhesive	2,3
79	I.4015	含聚二甲基二烯丙基氯化銨 (pDADMAC)成分之創傷覆蓋材	Wound dressing with poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive	2
80	I.4300	可植入式夾子	Implantable clip	2

81	I.4490	可吸收性止血劑及敷料	Absorbable hemostatic agent and dressing	3
82	I.4493	可吸收性多醣體交脂類外科用縫合線	Absorbable poly(glycolide/L-lactide) surgical suture	2
83	I.4494	基因重組技術製造之可吸收聚羥基丁酸酯外科縫線	Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology	2
84	I.4495	不銹鋼縫合線	Stainless steel suture	2
85	I.4520	聚四氟乙烯注射物	Polytetrafluoroethylene injectable	3
86	I.4750	植入式縫合釘	Implantable staple	2
87	I.4830	可吸收性腸縫合線	Absorbable surgical gut suture	2
88	I.4840	可吸收性聚對二氧環己酮外科縫合線	Absorbable polydioxanone surgical suture	2
89	I.5000	不可吸收性聚對苯二甲酸乙二酯縫合線	Nonabsorbable poly(ethylene terephthalate)surgical suture	2
90	I.5010	不可吸收性聚丙烯縫合線	Nonabsorbable polypropylene surgical suture	2
91	I.5020	不可吸收性聚醯胺縫合線	Nonabsorbable polyamide surgical suture	2
92	I.5030	不可吸收性絲縫合線	Natural nonabsorbable silk surgical suture	2
93	I.5035	非吸收式膨體聚四氟乙烯手術縫合線	Nonabsorbable expanded polytetrafluoroethylene surgical suture	2
94	K.1330	深度電極	Depth electrode	2
95	K.5030	動脈瘤縫合術用甲基丙烯酸甲酯	Methyl methacrylate for aneurysmorrhaphy	2
96	K.5150	血管內閉塞導管	Intravascular occluding catheter	3
97	K.5175	頸動脈夾	Carotid artery clamp	2
98	K.5200	動脈瘤夾	Aneurysm clip	2
99	K.5225	植入式可展延夾	Implanted malleable clip	2
100	K.5275	神經環帶	Nerve cuff	2
101	K.5300	頭顱造型術用甲基丙烯酸甲酯	Methyl methacrylate for cranioplasty	2
102	K.5320	預成形可變式頭顱造型板	Preformed alterable cranioplasty plate	2
103	K.5330	預成形不可變式頭顱造型板	Preformed nonalterable cranioplasty plate	2

104	K.5360	頭顱造形板固定器	Cranioplasty plate fastener	2
105	k.5805	重複式經顱磁刺激(rTMS)治療系統	Repetitive transcranial magnetic stimulation system	2
106	K.5820	植入式小腦刺激器	Implanted cerebellar stimulator	3
107	K.5830	植入式膈膜/膈神經刺激器	Implanted diaphragmatic/phrenic nerve stimulator	3
108	K.5840	疼痛舒緩用植入式大腦內/皮質下刺激器	Implanted intracerebral/subcortical stimulator for pain relief	3
109	K.5850	膀胱排空用植入式脊髓刺激器	Implanted spinal cord stimulator for bladder evacuation	3
110	K.5860	植入式神經肌肉刺激器	Implanted neuromuscular stimulator	3
111	K.5870	疼痛舒緩用植入式週邊神經刺激器	Implanted peripheral nerve stimulator for pain relief	2
112	K.5880	疼痛舒緩用植入式脊髓刺激器	Implanted spinal cord stimulator for pain relief	2,3
113	K.5900	預成形頭顱骨接合帶	Preformed craniosynostosis strip	2
114	K.5910	硬膜替代物	Dura substitute	2
115	K.5940	電痙攣治療裝置	Electroconvulsive therapy device	3
116	K.5950	人工栓塞裝置	Artificial embolization device	3
117	L.0004	可吸收性防沾黏材質	Absorbable adhesion barrier	3
118	L.3650	輸卵管彌補物	Fallopian tube prosthesis	2
119	L.3900	陰道支架	Vaginal stent	2
120	L.5360	子宮內避孕器及放置器	Contraceptive intrauterine device (IUD) and introducer	3
121	L.5380	輸卵管閉合避孕器及放置器	Contraceptive tubal occlusion device (TOD) and introducer	3
122	L.5980	經陰道骨盆腔器官脫垂治療用手術網片	Surgical mesh for transvaginal pelvic organ prolapse repair	3
123	M.0002	囊袋環	Endocapsular ring	3
124	M.3100	眼科用鉭製夾	Ophthalmic tantalum clip	2
125	M.3300	可吸收之植入物(鞏膜扣環法)	Absorbable implant (scleral buckling method)	2
126	M.3320	眼球植入物	Eye sphere implant	2
127	M.3340	眼外部眼眶植入物	Extraocular orbital implant	2
128	M.3400	角膜彌補物	Keratoprosthesis	2
129	M.3600	人工水晶體	Intraocular lens	3
130	M.3920	眼房水閥植入物	Eye valve implant	2

131	M.4155	鞏膜塞	Scleral plug	2
132	M.4270	眼內充填用氣體	Intraocular gas	3
133	M.4275	眼內充填用液體	Intraocular fluid	3
134	N.0003	關節腔玻尿酸植入物	Intraarticular hyaluronic acid implants	3
135	N.3010	骨固定環	Bone fixation cerclage	2
136	N.3015	骨頭異體移植片	Bone heterograft	3
137	N.3020	骨髓內固定桿	Intramedullary fixation rod	2
138	N.3023	體內固化式髓內固定桿	In vivo cured intramedullary fixation rod	2
139	N.3025	被動式肌腱彌補物	Passive tendon prosthesis	2
140	N.3027	PMMA 骨水泥	Polymethylmethacrylate (PMMA) bone cement	2
141	N.3030	單一或多重之金屬類骨固定裝置及附件	Single/multiple component metallic bone fixation appliance and accessories	2
142	N.3040	平滑或螺紋之金屬類骨固定物	Smooth or threaded metallic bone fixation fastener	2
143	N.3045	可吸收鈣鹽骨洞填充裝置	Resorbable calcium salt bone void filler device	2,3
144	N.3050	椎弓板間之脊椎矯正固定物	Spinal interlaminar fixation orthosis	2
145	N.3060	椎體間之脊椎矯正固定物	Spinal intervertebral body fixation orthosis	2
146	N.3070	椎弓螺釘系統	Pedicle screw spinal system	2
147	N.3080	椎體間融合裝置	Intervertebral body fusion device	2,3
148	N.3100	半限制型踝關節之金屬類/複合物類骨水泥式彌補物	Ankle joint metal/composite semi-constrained cemented prosthesis	2
149	N.3110	半限制型踝關節之金屬類/聚合物類骨水泥式彌補物	Ankle joint metal/polymer semi-constrained cemented prosthesis	2
150	N.3120	非限制型踝關節之金屬類/聚合物類骨水泥式彌補物	Ankle joint metal/polymer non-constrained cemented prosthesis	3
151	N.3150	限制型肘關節之金屬類/金屬類或金屬類/聚合物類骨水泥式彌補物	Elbow joint metal/metal or metal/polymer constrained cemented prosthesis	2
152	N.3160	半限制型肘關節之金屬類/聚合物類骨水泥式彌補物	Elbow joint metal / polymer semi-constrained cemented prosthesis	2
153	N.3170	肘關節橈骨(半肘)聚合物類彌補物	Elbow joint radial (hemi-elbow) polymer prosthesis	2

154	N.3180	肘關節肱骨(半肘)金屬類無骨水泥式彌補物	Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	3
155	N.3200	限制型指關節之金屬類/金屬類無骨水泥式彌補物	Finger joint metal / metal constrained uncemented prosthesis	3
156	N.3210	限制型指關節之金屬類/金屬類骨水泥式彌補物	Finger joint metal / metal constrained cemented prosthesis	3
157	N.3220	限制型指關節之金屬類/聚合物類骨水泥式彌補物	Finger joint metal / polymer constrained cemented prosthesis	3
158	N.3230	限制型指關節之聚合物類彌補物	Finger joint polymer constrained prosthesis	2
159	N.3300	限制型髖關節之金屬類骨水泥式或無骨水泥式彌補物	Hip joint metal constrained cemented or uncemented prosthesis	3
160	N.3310	限制型髖關節之金屬類/聚合物類骨水泥式或無骨水泥式彌補物	Hip joint metal/polymer constrained cemented or uncemented prosthesis	2
161	N.3320	半限制型髖關節金屬類/金屬類含骨水泥式髖臼窩組件之彌補物	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis	3
162	N.3330	半限制型髖關節金屬/金屬類含非骨水泥式髖臼窩組件之彌補物	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis	3
163	N.3340	半限制型髖關節金屬類/複合物類骨水泥式彌補物	Hip joint metal/composite semi-constrained cemented prosthesis	2
164	N.3350	半限制型髖關節金屬類/聚合物類骨水泥式彌補物	Hip joint metal/polymer semi-constrained cemented prosthesis	2
165	N.3353	半限制型髖關節之金屬類/陶瓷類/聚合物類骨水泥或無孔塗佈無骨水泥式彌補物	Hip joint metal / ceramic / polymer semi-constrained cemented or nonporous uncemented prosthesis	2
166	N.3358	半限制型髖關節金屬類/聚合物類/金屬類多孔塗佈無骨水泥式彌補物	Hip joint metal / polymer / metal semi-constrained porous-coated uncemented prosthesis	2
167	N.3360	髖關節股骨(半髖)金屬骨水泥或無骨水泥式彌補物	Hip joint femoral(hemi-hip) metallic cemented or uncemented prosthesis	2
168	N.3370	髖關節(半髖)髖臼金屬骨水泥式彌補物	Hip joint (hemi-hip) acetabular metal cemented prosthesis	3
169	N.3380	髖關節股骨(半髖)骨幹軸承金屬類/多縮醛類骨水泥式彌補物	Hip joint femoral(hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis	3

170	N.3390	髖關節股骨(半髖)金屬類/聚合物類骨水泥或無骨水泥式彌補物	Hip joint femoral(hemi-hip) metal/polymer cemented or uncemented prosthesis	2
171	N.3400	髖關節股骨(半髖)金屬類重鋪面骨彌補物	Hip joint femoral(hemi-hip) metallic resurfacing prosthesis	2
172	N.3410	半限制型髖關節金屬類/聚合物類重鋪面式骨水泥彌補物	Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis	3
173	N.3480	限制型膝關節股脛骨金屬類骨水泥式彌補物	Knee joint femorotibial metallic constrained cemented prosthesis	3
174	N.3490	非限制型膝關節股脛骨金屬類/複合物類骨水泥式彌補物	Knee joint femorotibial metal/composite non-constrained cemented prosthesis	2
175	N.3500	半限制型膝關節股脛骨金屬類/複合物類骨水泥式彌補物	Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	2
176	N.3510	限制型膝關節股脛骨金屬類/聚合物類骨水泥式彌補物	Knee joint femorotibial metal/polymer constrained cemented prosthesis	2
177	N.3520	非限制型膝關節股脛骨金屬類/聚合物類骨水泥式彌補物	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis	2
178	N.3530	半限制型膝關節股脛骨金屬類/聚合物類骨水泥式彌補物	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis	2
179	N.3535	膝關節股脛骨(單側)金屬類/聚合物類多孔塗佈無骨水泥式彌補物	Knee joint femorotibial unicompartmental metal/polymer porous-coated uncemented prosthesis	2
180	N.3540	半限制型膝關節膑股骨聚合物類/金屬類骨水泥式彌補物	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	2
181	N.3550	限制型膝關節膑股脛骨聚合物類/金屬類/金屬類骨水泥式彌補物	Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis	3
182	N.3560	半限制型膝關節膑股脛骨聚合物類/金屬類/聚合物類骨水泥式彌補物	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis	2



183	N.3565	膝關節髌股骨金屬類/聚合物類多孔塗佈無骨水泥式彌補物	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis	2
184	N.3570	膝關節股骨(半膝)金屬類無骨水泥式彌補物	Knee joint femoral (hemi-knee) metallic uncemented prosthesis	3
185	N.3580	膝關節髌骨(半膝)金屬類重鋪面無骨水泥式彌補物	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis	2,3
186	N.3590	膝關節脛骨(半膝)金屬類重鋪面無骨水泥式彌補物	Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis	2
187	N.3640	限制型肩關節金屬類/金屬類或金屬類/聚合物類骨水泥式彌補物	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	3
188	N.3650	非限制型肩關節金屬類/聚合物類骨水泥式彌補物	Shoulder joint metal / polymer non-constrained cemented prosthesis	2
189	N.3660	半限制型肩關節金屬類/聚合物類骨水泥式彌補物	Shoulder joint metal/polymer semi-constrained cemented prosthesis	2
190	N.3670	肩關節金屬類/聚合物類非限制型或半限制型多孔塗佈無骨水泥式彌補物	Shoulder joint metal/polymer/metal nonconstrained or semiconstrained porous-coated uncemented prosthesis	2
191	N.3680	肩關節盂(半肩)金屬類骨水泥式彌補物	Shoulder joint glenoid (hemi-shoulder)metallic cemented prosthesis	3
192	N.3690	肩關節肱骨(半肩)金屬類無骨水泥式彌補物	Shoulder joint humeral (hemi-shoulder)metallic uncemented prosthesis	2
193	N.3720	限制型趾關節聚合物類彌補物	Toe joint polymer constrained prosthesis	2
194	N.3730	趾關節趾骨(半趾)聚合物類彌補物	Toe joint phalangeal (hemi-toe)polymer prosthesis	2
195	N.3750	腕關節腕半月骨聚合物類彌補物	Wrist joint carpal lunate polymer prosthesis	2
196	N.3760	腕關節腕舟狀骨聚合物類彌補物	Wrist joint carpal scaphoid polymer prosthesis	2
197	N.3770	腕關節腕多角骨聚合物類彌補物	Wrist joint carpal trapezium polymer prosthesis	2

198	N.3780	限制型腕關節聚合物類彌補物	Wrist joint polymer constrained prosthesis	2
199	N.3790	限制型腕關節金屬類骨水泥式彌補物	Wrist joint metal constrained cemented prosthesis	3
200	N.3800	半限制型腕關節金屬類/聚合物類骨水泥式彌補物	Wrist joint metal/polymer semi-constrained cemented prosthesis	2
201	N.3810	腕關節尺骨(半腕)聚合物類彌補物	Wrist joint ulnar(hemi-wrist) polymer prosthesis	2
202	P.5725	可吸收式肛門直腸周邊阻隔器	Absorbable perirectal spacer	2