

衛生福利部公告

中華民國 109 年 9 月 24 日

衛授食字第 1091607998 號

主 旨：預告訂定「應建立與保存來源及流向資料之醫療器材」及「應申報來源及流向資料之醫療器材品項」草案。

依 據：行政程序法第一百五十四條第一項。

公告事項：

- 一、訂定機關：衛生福利部。
- 二、訂定依據：醫療器材管理法第十九條第一項及第二項。
- 三、「應建立與保存來源及流向資料之醫療器材」為醫療器材分類分級管理辦法所定第二等級及第三等級植入式醫療器材如附件。
- 四、「應申報來源及流向資料之醫療器材品項」依醫療器材分類分級管理辦法所定如下：
 - (一) E.3610 植入式心律器之脈搏產生器。
 - (二) I.3540 矽膠充填之乳房彌補物。
 - (三) L.5980 經陰道骨盆腔器官脫垂治療用手術網片。
- 五、本案另載於行政院公報資訊網、本部網站「衛生福利法規檢索系統」下「法規草案」網頁、本部食品藥物管理署網站「公告資訊」下「本署公告」網頁及國家發展委員會「公共政策網路參與平臺－眾開講」網頁（<https://join.gov.tw/policies/>）。
- 六、對於公告內容有任何意見或修正建議者，可於本公告刊登公報之隔日起 60 日內，至前揭「衛生福利法規檢索系統」或「公共政策網路參與平臺－眾開講」網頁陳述意見或洽詢：
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部 長 陳時中

附件

應建立與保存來源及流向資料之醫療器材

項	分類分級代碼	中文品名	英文品名	管理等級
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	牙科使用黃金基底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	樹脂充填用覆蓋材料	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	基底金屬合金	Base metal alloy	2
30	F.3750	牙齒矯正托架黏著樹脂及調節劑	Bracket adhesive resin and tooth conditioner	2
31	F.3765	凹窩封閉劑及調節劑	Pit and fissure sealant and conditioner	2
32	F.3820	根管充填樹脂	Root canal filling resin	2,3
33	F.3890	根管固定夾板	Endodontic stabilizing splint	2
34	F.3930	牙槽修復材料	Bone grafting material	2,3
35	F.3940	全顳顎關節彌補物	Total temporomandibular joint prosthesis	3
36	F.3950	顳骨關節盂彌補物	Glenoid fossa prosthesis	3
37	F.3960	下顎髁彌補物	Mandibular condyle prosthesis	3
38	F.3970	關節間盤彌補物(內置式植入物)	Interarticular disc prosthesis (interpositional implant)	3
39	F.4760	骨板	Bone plate	2
40	F.4880	骨內固定螺絲或金屬線	Intraosseous fixation screw or wire	2
41	F.5560	電子式唾液刺激系統	Electrical salivary stimulatory system	2
42	F.6660	牙科用瓷粉	Porcelain powder for clinical use	2
43	G.0001	人工耳蝸植入器	Cochlear implant	3
44	G.3315	鼓膜接觸式助聽器	Tympanic membrane contact hearing aid.	2
45	G.3430	中耳模	Middle ear mold	2
46	G.3450	部分人工聽小骨置換物	Partial ossicular replacement prosthesis	2
47	G.3495	全人工聽小骨置換物	Total ossicular replacement prosthesis	2
48	G.3620	耳鼻喉科用合成聚合物材料	Ear, nose, and throat synthetic polymer material	2
49	G.3695	下頷骨植入式臉部彌補物	Mandibular implant facial prosthesis	2
50	G.3730	喉部彌補物(Taub 式)	Laryngeal prosthesis (Taub design)	2
51	G.3760	球囊切開術釘(Cody 氏釘)	Sacculotomy tack (Cody tack)	2
52	G.3820	內淋巴液分流器	Endolymphatic shunt	2
53	G.3850	含瓣膜式內淋巴液分流導管	Endolymphatic shunt tube with valve	2
54	G.3880	鼓室通氣管	Tympanostomy tube	2

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

82	I.4490	可吸收性止血劑及敷料	Absorbable hemostatic agent and dressing	3
83	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
84	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
85	I.4495	不銹鋼縫合線	Stainless steel suture	2
86	I.4520	聚四氟乙烯注射物	Polytetrafluoroethylene injectable	3
87	I.4750	植入式縫合釘	Implantable staple	2
88	I.4830	可吸收性腸縫合線	Absorbable surgical gut suture	2
89	I.4840	可吸收性聚對二氧環己酮外科縫合線	Absorbable polydioxanone surgical suture	2
90	I.5000	不可吸收性聚乙烯縫合線	Nonabsorbable poly(ethylene terephthalate)surgical suture	2
91	I.5010	不可吸收性聚丙烯縫合線	Nonabsorbable polypropylene surgical suture	2
92	I.5020	不可吸收性聚醯胺縫合線	Nonabsorbable polyamide surgical suture	2
93	I.5030	不可吸收性絲縫合線	Natural nonabsorbable silk surgical suture	2
94	I.5035	非吸收式已展開之聚四氟乙烯手術縫合線	Nonabsorbable expanded polytetrafluoroethylene surgical suture	2
95	K.1330	深度電極	Depth electrode	2
96	K.5030	動脈瘤縫合術用甲基丙烯酸甲酯	Methyl methacrylate for aneurysmorrhaphy	2
97	K.5150	血管內閉塞導管	Intravascular occluding catheter	3
98	K.5175	頸動脈夾	Carotid artery clamp	2
99	K.5200	動脈瘤夾	Aneurysm clip	2
100	K.5225	植入式可展延夾	Implanted malleable clip	2
101	K.5275	神經環帶	Nerve cuff	2
102	K.5300	頭顱造型術用甲基丙烯酸甲酯	Methyl methacrylate for cranioplasty	2
103	K.5320	預成形可變式頭顱造型板	Preformed alterable cranioplasty plate	2
104	K.5330	預成形不可變式頭顱造型板	Preformed nonalterable cranioplasty plate	2

105	K.5360	頭顱造形板固定器	Cranioplasty plate fastener	2
106	K.5805	重複式經顱磁刺激(rTMS)治療系統	Repetitive transcranial magnetic stimulation system	2
107	K.5820	植入式小腦刺激器	Implanted cerebellar stimulator	3
108	K.5830	植入式膈膜/膈神經刺激器	Implanted diaphragmatic/phrenic nerve stimulator	3
109	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
110	K.5850	膀胱排空用植入式脊髓刺激器	Implanted spinal cord stimulator for bladder evacuation	3
111	K.5860	植入式神經肌肉刺激器	Implanted neuromuscular stimulator	3
112	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
113	K.5880	疼痛舒緩用植入式脊髓刺激器	Implanted spinal cord stimulator for pain relief.	2,3
114	K.5900	預成形頭顱骨接合帶	Preformed craniosynostosis strip	2
115	K.5910	硬膜替代物	Dura substitute	2
116	K.5940	電痙攣治療裝置	Electroconvulsive therapy device	3
117	K.5950	人工栓塞裝置	Artificial embolization device	3
118	L.0004	可吸收性防沾黏材質	Absorbable adhesion barrier	3
119	L.3650	輸卵管彌補物	Fallopian tube prosthesis	2
120	L.3900	陰道支架	Vaginal stent	2
121	L.5360	子宮內避孕器及放置器	Contraceptive intrauterine device (IUD) and introducer	3
122	L.5380	輸卵管閉合避孕器及放置器	Contraceptive tubal occlusion device (TOD) and introducer	3
123	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
124	M.0002	囊袋環	Capsular Tension Ring	3
125	M.3100	眼科用鉭製夾	Ophthalmic tantalum clip	2
126	M.3300	可吸收之植入物(鞏膜扣環法)	Absorbable implant (scleral buckling method)	2
127	M.3320	眼球植入物	Eye sphere implant	2
128	M.3340	眼外部眼框植入物	Extraocular orbital implant	2
129	M.3400	角膜彌補物	Keratoprosthesis	2
130	M.3600	人工水晶體	Intraocular lens	3
131	M.3920	眼房水閥植入物	Eye valve implant	2
132	M.4155	鞏膜塞	Scleral plug	2

133	M.4270	眼內充填用氣體	Intraocular gas	3
134	M.4275	眼內充填用液體	Intraocular fluid	3
135	N.0003	關節腔玻尿酸植入物	Intraarticular hyaluronic acid implants	3
136	N.3010	骨固定環	Bone fixation cerclage	2
137	N.3015	骨頭異體移植片	Bone heterograft	3
138	N.3020	骨髓內固定桿	Intramedullary fixation rod	2
139	N.3023	體內固化式髓內固定棒	In vivo cured intramedullary fixation rod	2
140	N.3025	被動式肌腱彌補物	Passive tendon prosthesis	2
141	N.3027	PMMA 骨水泥	Polymethylmethacrylate (PMMA) bone cement	2
142	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
143	N.3040	平滑或螺紋之金屬類骨固定物	Smooth or threaded metallic bone fixation fastener	2
144	N.3045	再吸收鈣鹽骨洞填充裝置	Resorbable calcium salt bone void filler device	2
145	N.3050	椎弓板間之脊椎矯正固定物	Spinal interlaminar fixation orthosis	2
146	N.3060	椎體間之脊椎矯正固定物	Spinal intervertebral body fixation orthosis	2
147	N.3070	椎弓螺釘系統	Pedicle screw spinal system.	2,3
148	N.3080	椎體間融合裝置	Intervertebral body fusion device	2,3
149	N.3100	半限制型踝關節之金屬類/合成物類骨水泥式彌補物	Ankle joint metal/composite semi-constrained cemented prosthesis	2
150	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
151	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
152	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
153	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

154	N.3170	肘關節橈骨(半肘)聚合物類彌補物	Elbow joint radial (hemi-elbow) polymer prosthesis	2
155	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
156	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
157	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
158	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
159	N.3230	限制型指關節之聚合物類彌補物	Finger joint polymer constrained prosthesis	2
160	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
161	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
162	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
163	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
164	N.3340	半限制型髖關節金屬類/合成物類骨水泥式彌補物	Hip joint metal/composite semi-constrained cemented prosthesis	2
165	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
166	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
167	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
168	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

169	N.3370	髖關節(半髖)髖白金屬骨水泥式彌補物	Hip joint (hemi-hip) acetabular metal cemented prosthesis	3
170	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
171	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/polymerl cemented or uncemented prosthesis	2
172	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
173	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
174	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
175	N.3490	非限制型膝關節股脛骨金屬類/合成物類骨水泥式彌補物	Knee joint femorotibial metal/composite non-constrained cemented prosthesis	2
176	N.3500	半限制型膝關節股脛骨金屬類/合成物類骨水泥式彌補物	Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	2
177	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
178	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
179	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
180	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
181	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
182	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	Knee joint patellofemorotibial polymer/metal/metal constrained	3

		式彌補物	cemented prosthesis	
183	N.3560	半限制型膝關節髌股脛骨聚合物類/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
184	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
185	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
186	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
187	N.3590	膝關節脛骨(半膝)金屬類重鋪面非骨水泥式彌補物	Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis	2
188	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
189	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
190	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
191	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
192	N.3680	肩關節肩窩(半肩)金屬類骨水泥式彌補物	Shoulder joint glenoid (hemi-shoulder)metallic cemented prosthesis	3
193	N.3690	肩關節肱骨(半肩)金屬類非骨水泥式彌補物	Shoulder joint humeral (hemi-shoulder)metallic uncemented prosthesis	2
194	N.3720	限制型趾關節聚合物類彌補物	Toe joint polymer constrained prosthesis	2
195	N.3730	趾關節趾骨(半趾)聚合物類彌補物	Toe joint phalangeal (hemi-toe)polymer prosthesis	2

196	N.3750	腕關節腕半月骨聚合物類彌補物	Wrist joint carpal lunate polymer prosthesis	2
197	N.3760	腕關節腕舟狀骨聚合物類彌補物	Wrist joint carpal scaphoid polymer prosthesis	2
198	N.3770	腕關節腕多角骨聚合物類彌補物	Wrist joint carpal trapezium polymer prosthesis	2
199	N.3780	限制型腕關節聚合物類彌補物	Wrist joint polymer constrained prosthesis	2
200	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
201	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
202	N.3810	腕關節尺骨(半腕)聚合物類彌補物	Wrist joint ulnar(hemi-wrist) polymer prosthesis	2
203	P.5725	可吸收式肛門直腸周邊阻隔器	Absorbable perirectal spacer	2