

衛生福利部公告

中華民國110年7月16日

衛授食字第1101104548號

主 旨：訂定「免取得醫療器材製造許可品項」，並自即日生效。

依 據：醫療器材管理法第二十二條第二項。

公告事項：免取得醫療器材製造許可品項如附件。

部 長 陳時中

**免取得醫療器材製造許可品項**

下表所列醫療器材品項未滅菌者，免取得製造許可。

序號	代碼	中文名稱	英文名稱	等級
1	A.1660	品管材料(分析與非分析)	Quality control material (assayed and unassayed)	1
2	A.2270	臨床使用的薄層色層分析系統	Thin-layer chromatography system for clinical use	1
3	B.1850	染料及化學溶液染料	Dye and chemical solution stains	1
4	C.2600	Wood氏螢光燈	Wood's fluorescent lamp	1
5	D.5220	吹氣瓶	Blow bottle	1
6	D.5280	呼吸管路支撐物	Breathing tube support	1
7	F.1820	牙科用X光片照射排列裝置	Dental x-ray exposure alignment device	1
8	F.3140	樹脂塗敷器	Resin applicator	1
9	F.3670	樹脂印模牙托材	Resin impression tray material	1
10	F.4535	牙科用鑽石器械	Dental diamond instrument	1
11	F.4565	牙科用手器械	Dental hand instrument	1
12	F.6010	研磨裝置及其附件	Abrasive device and accessories	1
13	F.6050	唾液吸收器	Saliva absorber	1
14	F.6140	咬合紙	Articulation paper	1
15	F.6200	基底塗料	Base plate shellac	1
16	F.6290	磨光劑載杯	Prophylaxis cup	1
17	F.6300	橡皮障及其附件	Rubber dam and accessories	1
18	F.6570	印模管	Impression tube	1
19	F.6870	拋棄式塗氟用牙托	Disposable fluoride tray	1
20	F.6880	成形印模牙托	Preformed impression tray	1
21	F.6890	口內牙科用臘	Intraoral dental wax	1
22	G.1100	聽力檢查耳機軟墊	Earphone cushion for audiometric testing	1
23	G.3540	聽小骨置換物修正用器械	Prosthesis modification instrument for ossicular replacement surgery	1
24	G.4350	耳鼻喉光纖光源及載具	Ear, nose, and throat fiberoptic light source and carrier	1
25	G.4770	耳鏡	Otoscope	1
26	G.5220	耳鼻喉施藥裝置及其搭配使用之物質	Ear, nose, and throat drug administration device and contained substance	1
27	G.5800	鼻外固定板	External nasal splint	1
28	H.5210	手動式灌腸組套	Enema kit	1
29	H.5250	尿液收集器及其附件	Urine collector and accessories	1
30	H.5900	造口術用袋及其附件	Ostomy pouch and accessories	1
31	H.5970	疝脫支撐器	Hernia support	1
32	I.1800	檢查鏡及其附件	Speculum and accessories	1
33	I.3800	體外美容用修復彌補物	External aesthetic restoration prosthesis	1
34	I.3910	非膨脹式四肢用夾板	Noninflatable extremity splint	1
35	I.4025	疤痕處理矽膠產品	Silicone scar management product	1
36	I.4160	外科手術用照相機及其附件	Surgical camera and accessories	1
37	I.4700	外科顯微鏡及其附件	Surgical microscope and accessories	1
38	I.4730	外科用皮膚去油劑或去黏劑	Surgical skin degreaser or adhesive tape solvent	1
39	I.5900	非充氣式止血帶	Nonpneumatic tourniquet	1
40	J.5075	彈性繃帶	Elastic bandage	1
41	J.5120	手動可調整式病床	Manual adjustable hospital bed	1
42	J.5150	非動力式治療床墊	Nonpowered flotation therapy mattress	1

43	J.5160	醫療用束帶	Therapeutic medical binder	1
44	J.5210	血管內導管固定裝置	Intravascular catheter securement device	1
45	J.5240	醫療用黏性膠帶及黏性繃帶	Medical adhesive tape and adhesive bandage	1
46	J.5270	新生兒用眼罩	Neonatal eye pad	1
47	J.5300	醫療用吸收纖維	Medical absorbent fiber	1
48	J.5780	醫用輔助襪	Medical support stocking	1
49	J.5820	治療用陰囊支撐器	Therapeutic scrotal support	1
50	J.6025	吸收性尖端塗藥器	Absorbent tipped applicator	1
51	J.6230	壓舌板	Tongue depressor	1
52	J.6375	病患用潤滑劑	Patient lubricant	1
53	J.6430	液體藥物給藥器	Liquid medication dispenser	1
54	J.6450	皮膚壓力保護器	Skin pressure protectors	1
55	J.6785	手動病患輸送裝置	Manual patient transfer device	1
56	J.6900	手提式擔架	Hand-carried stretcher	1
57	J.6960	灌洗注射筒	Irrigating syringe	1
58	J.6970	液晶靜脈定位器	Liquid crystal vein locator	1
59	J.6980	靜脈固定器	Vein stabilizer	1
60	K.1200	兩點式判讀儀	Two-point discriminator	1
61	K.1500	觸覺計	Esthesiometer	1
62	K.1525	調音叉	Tuning fork	1
63	K.4190	夾成形/切割器械	Clip forming/cutting instrument	1
64	K.4200	去夾器械	Clip removal instrument	1
65	L.5900	治療用陰道灌洗器	Therapeutic vaginal douche apparatus	1
66	M.1090	黃斑部色素光學密度儀	Haidinger brush	1
67	M.1140	眼科用椅	Ophthalmic chair	1
68	M.1200	眼球運動鼓狀器	Optokinetic drum	1
69	M.1320	穹窿鏡	Fornixscope	1
70	M.1350	角膜鏡	Keratoscope	1
71	M.1375	Bagolini鏡片	Bagolini lens	1
72	M.1380	診斷用聚光鏡片	Diagnostic condensing lens	1
73	M.1390	診斷用彈性Fresnel鏡片	Flexible diagnostic Fresnel lens	1
74	M.1395	診斷用Hruby眼底鏡片	Diagnostic Hruby fundus lens	1
75	M.1400	瑪竇氏鏡	Maddox lens	1
76	M.1405	眼科試驗鏡片組	Ophthalmic trial lens set	1
77	M.1410	眼科試驗鏡片夾	Ophthalmic trial lens clip	1
78	M.1460	立體感測量器	Stereopsis measuring instrument	1
79	M.1605	視野鏡	Perimeter	1
80	M.1650	眼科用棒狀稜鏡	Ophthalmic bar prism	1
81	M.1655	眼科用Fresnel稜鏡(壓貼鏡片)	Ophthalmic Fresnel prism	1
82	M.1665	眼科旋轉稜鏡	Ophthalmic rotary prism	1
83	M.1680	眼科用投影機	Ophthalmic projector	1
84	M.1700	瞳孔計	Pupillometer	1
85	M.1750	視網膜檢影鏡架	Skiascopic rack	1
86	M.1790	近點尺	Nearpoint ruler	1
87	M.1810	切線幕(視野計)	Tangent screen (campimeter)	1
88	M.1870	立體鏡	Stereoscope	1
89	M.1905	眼球震顫帶	Nystagmus tape	1
90	M.1910	視覺分離試驗系統	Spectacle dissociation test system	1

91	M.1945	透照器	Transilluminator	1
92	M.4335	手術用頭燈	Operating headlamp	1
93	M.4750	眼科用眼罩	Ophthalmic eye shield	1
94	M.4770	眼科用手術眼鏡(放大鏡)	Ophthalmic operating spectacles (loupes)	1
95	M.5600	上眼瞼下垂支持器	Ptosis crutch	1
96	M.5844	矯正鏡片	Corrective spectacle lens	1
97	N.1250	非動力式肌力計	Nonpowered dynamometer	1
98	N.1520	非動力式測角計	Nonpowered goniometer	1
99	N.5850	非動力式骨科牽引器及配件	Nonpowered orthopedic traction apparatus and accessories	1
100	N.5890	非侵入式牽引組件	Noninvasive traction component	1
101	N.5940	石膏類產品	Cast component	1
102	N.5980	手動式打石膏及拆石膏器械	Manual cast application and removal instrument	1
103	O.0006	連續式被動關節活動器	Continuous Passive Motion Device	1
104	O.3025	義肢及裝具用附件	Prosthetic and orthotic accessory	1
105	O.3075	醫療用手杖	Cane	1
106	O.3150	醫療用拐杖	Crutch	1
107	O.3175	浮動坐墊	Flotation cushion	1
108	O.3410	體外肢體裝具用組件	External limb orthotic component	1
109	O.3420	體外肢體義肢用組件	External limb prosthetic component	1
110	O.3475	肢體裝具	Limb orthosis	1
111	O.3490	軀幹裝具	Truncal orthosis	1
112	O.3520	治療檯	Plinth	1
113	O.3640	手臂吊帶	Arm sling	1
114	O.3665	先天性髖關節移位外展夾板	Congenital hip dislocation abduction splint	1
115	O.3675	丹尼布朗夾板	Denis Brown splint	1
116	O.3750	機械式治療檯	Mechanical table	1
117	O.3825	機械式助行器	Mechanical walker	1
118	O.5125	非動力式坐浴	Nonpowered sitz bath	1
119	O.5700	醫療用冷敷裝置	Cold pack	1
120	O.5710	醫療用可丟棄式的冷熱敷包	Hot or cold disposable pack	1
121	O.5720	醫療用水循環式冷熱敷包	Water circulating hot or cold pack	1
122	O.5730	醫療用濕熱敷包	Moist heat pack	1
123	O.5925	牽引用附件	Traction accessory	1
124	P.1920	放射線造影頭部固定器	Radiographic head holder	1
125	P.6500	個人用防護罩	Personnel protective shield	1