

「應以登錄方式取得上市許可之醫療器材品項」草案

序號	代碼	中文名稱	英文名稱	等級
1	A.1030	丙胺酸轉胺酶試驗系統	Alanine amino transferase (ALT/SGPT) test system	1
2	A.1065	血氨試驗系統	Ammonia test system	1
3	A.1113	新生兒膽紅素(總量及未結合的)試驗系統	Bilirubin (total and unbound) in the neonate test system	1
4	A.1135	胰島素前質C-肽類試驗系統	C-peptides of proinsulin test system	1
5	A.1175	膽固醇(總量)試驗系統	Cholesterol (total) test system	1
6	A.1260	雌二醇試驗系統	Estradiol test system	1
7	A.1300	卵泡刺激激素試驗系統	Follicle-stimulating hormone test system	1
8	A.1310	半乳糖試驗系統	Galactose test system	1
9	A.1360	r-麩胺醯轉移酶(GGT)和同功酶試驗系統	Gamma-glutamyl transpeptidase and isoenzymes test system	1
10	A.1410	鐵(非血基質)試驗系統	Iron (non-heme) test system	1
11	A.1415	鐵結合能力試驗系統	Iron-binding capacity test system	1
12	A.1435	酮(非定量)試驗系統	Ketones (nonquantitative) test system	1
13	A.1440	乳酸脫氫酶試驗系統	Lactate dehydrogenase test system	1
14	A.1450	乳酸試驗系統	Lactic acid test system	1
15	A.1465	脂肪分解酵素試驗系統	Lipase test system	1
16	A.1475	脂蛋白試驗系統	Lipoprotein test system	1
17	A.1485	黃體激素試驗系統	Luteinizing hormone test system	1
18	A.1495	鎂試驗系統	Magnesium test system	1
19	A.1550	尿酸鹼值(非定量)試驗系統	Urinary pH (nonquantitative) test system	1
20	A.1580	磷酸(無機)試驗系統	Phosphorus (inorganic) test system	1
21	A.1630	蛋白質(化學分離法)試驗系統	Protein (fractionation) test system	1
22	A.1635	總蛋白質試驗系統	Total protein test system	1
23	A.1645	尿蛋白質或白蛋白(非定量)試驗系統	Urinary protein or albumin (nonquantitative) test system	1
24	A.1680	睪丸脂酮試驗系統	Testosterone test system	1
25	A.1705	三酸甘油脂試驗系統	Triglyceride test system	1
26	A.1775	尿酸試驗系統	Uric acid test system	1
27	A.2150	臨床使用的連續流動式多項化學分析儀	Continuous flow sequential multiple chemistry analyzer for clinical use	1
28	A.2160	臨床使用的個別式光度量測化學分析儀	Discrete photometric chemistry analyzer for clinical use	1
29	A.2260	臨床使用的高壓液相層析儀	High pressure liquid chromatography system for clinical use	1
30	A.2300	臨床使用的色度計、光度計或分光光度計	Colorimeter, photometer, or spectrophotometer for clinical use	1

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31	A.2485	臨床使用的電泳設備	Electrophoresis apparatus for clinical use	1
32	A.2500	臨床使用的酵素分析儀	Enzyme analyzer for clinical use	1
33	A.2560	臨床使用的螢光儀	Fluorometer for clinical use	1
34	A.2900	自動尿液分析系統	Automated urinalysis system	1
35	A.3240	膽素酯酵素試驗系統	Cholinesterase test system	1
36	B.1850	染料及化學溶液染料	Dye and chemical solution stains	1
37	B.2220	合成細胞和組織培養基及成份	Synthetic cell and tissue culture media and components	1
38	B.5800	自動沉降速率裝置	Automated sedimentation rate device	1
39	B.6150	毛細管血液收集管	Capillary blood collection tube	1
40	B.6160	手動血球計數裝置	Manual blood cell counting device	1
41	B.6400	血球容積測量裝置	Hematocrit measuring device	1
42	B.8200	血球稀釋劑	Blood cell diluent	1
43	B.8500	淋巴球分離培養基	Lymphocyte separation medium	1
44	B.8540	紅血球溶解劑	Red cell lysing reagent	1
45	B.9195	血液混合器及血液重量分析裝置	Blood mixing devices and blood weighing devices	1
46	B.9225	體外診斷用的細胞冷凍設備及反應劑	Cell-freezing apparatus and reagents for in vitro diagnostic use	1
47	B.9275	體外診斷用血庫離心機	Blood bank centrifuge for in vitro diagnostic use	1
48	B.9575	保存血小板濃縮液之環境控制箱	Environmental chamber for storage of platelet concentrate	1
49	B.9600	體外診斷用的強化培養基	Potentiating media for in vitro diagnostic use	1
50	B.9700	血液保存之冰箱與冷凍箱	Blood storage refrigerator and blood storage freezer	1
51	B.9750	加熱密封器材	Heat-sealing device	1
52	C.0003	螺旋桿菌屬血清試劑	Helicobacter spp. serological reagents	1
53	C.2300	多功能培養基	Multipurpose culture medium	1
54	C.2320	鑑別培養基	Differential culture medium	1
55	C.2330	強化培養基	Enriched culture medium	1
56	C.2360	選擇性培養基	Selective culture medium	1
57	C.2500	微滴定稀釋及分配器材	Microtiter diluting and dispensing device	1
58	C.2560	微生物成長監視器	Microbial growth monitor	1
59	C.2580	產氣器材	Gas-generating device	1
60	C.2660	微生物鑑別及測定器材	Microorganism differentiation and identification device	1
61	C.2900	微生物樣本收集及輸送器材	Microbiological specimen collection and transport device	1
62	C.3020	腺病毒血清試劑	Adenovirus serological reagents	1

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63	C.3120	披衣菌血清試劑	Chlamydia serological reagents	1
64	C.3145	柯沙奇病毒血清試劑	Coxsackievirus serological reagents	1
65	C.3165	新型隱球菌屬血清試劑	Cryptococcus neoformans serological reagents	1
66	C.3220	痢疾阿米巴血清試劑	Entamoeba histolytica serological reagents	1
67	C.3255	大腸桿菌血清試劑	Escherichia coli serological reagents	1
68	C.3300	嗜血桿菌屬血清試劑	Haemophilus spp. serological reagents	1
69	C.3350	鉤端螺旋菌屬血清試劑	Leptospira spp. serological reagents	1
70	C.3370	結核桿菌免疫螢光試劑	Mycobacterium tuberculosis immunofluorescent reagents	1
71	C.3375	黴漿菌屬血清試劑	Mycoplasma spp. serological reagents	1
72	C.3380	腮腺炎病毒血清試劑	Mumps virus serological reagents	1
73	C.3405	小兒麻痺病毒血清試劑	Poliovirus serological reagents	1
74	C.3480	呼吸道融合細胞病毒血清試劑	Respiratory syncytial virus serological reagents	1
75	C.3500	立克次體血清試劑	Rickettsia serological reagents	1
76	C.3520	麻疹病毒血清試劑	Rubeola (measles) virus serological reagents	1
77	C.3550	沙門氏菌屬血清試劑	Salmonella spp. serological reagents	1
78	C.3660	志賀氏桿菌屬血清試劑	Shigella spp. serological reagents	1
79	C.3700	金黃色葡萄球菌血清試劑	Staphylococcus aureus serological reagents	1
80	C.3720	鏈球菌屬胞外酶試劑	Streptococcus spp. exoenzyme reagents	1
81	C.3740	鏈球菌屬血清試劑	Streptococcus spp. serological reagents	1
82	C.4540	免疫比濁計	Immunonephelometer equipment	1
83	C.5040	白蛋白免疫試驗系統	Albumin immunological test system	1
84	C.5060	前白蛋白免疫試驗系統	Prealbumin immunological test system	1
85	C.5420	$\alpha$ -1-醣蛋白免疫試驗系統	Alpha-1-glycoproteins immunological test system	1
86	C.5460	血紅素結合蛋白免疫試驗系統	Haptoglobin immunological test system	1
87	D.2320	無補償式管流量計	Uncompensated thorpe tube flowmeter	1
88	D.2340	補償式管流量計	Compensated thorpe tube flowmeter	1
89	D.2610	氣體壓力計	Gas pressure gauge	1
90	D.2700	壓力調節器	Pressure regulator	1
91	D.5100	鼻咽氣道管	Nasopharyngeal airway	1
92	D.5110	口咽氣道管	Oropharyngeal airway	1
93	D.5240	麻醉呼吸管路	Anesthesia breathing circuit	1
94	D.5300	二氧化碳吸收劑	Carbon dioxide absorbent	1
95	D.5320	儲氣囊	Reservoir bag	1
96	D.5340	經鼻氧氣套管	Nasal oxygen cannula	1
97	D.5350	經鼻氧氣導管	Nasal oxygen catheter	1
98	D.5375	熱及濕氣凝結器(人工鼻)	Heat and moisture condenser (artificial nose)	1
99	D.5460	家用治療潮濕器	Therapeutic humidifier for home use	1
100	D.5530	可彎曲式喉頭鏡	Flexible laryngoscope	1
101	D.5540	硬式喉頭鏡	Rigid laryngoscope	1
102	D.5550	麻醉氣體面罩	Anesthetic gas mask	1
103	D.5560	氣體面罩頭套帶	Gas mask head strap	1

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104	D.5570	非重吸入式呼吸面罩	Nonbreathing mask	1
105	D.5600	Venturi面罩	Venturi mask	1
106	D.5620	呼吸咬嘴	Breathing mouthpiece	1
107	D.5770	氣管管路固定裝置	Tracheal tube fixation device	1
108	D.5790	氣管內管探針	Tracheal tube stylet	1
109	D.5810	氣道連接器	Airway connector	1
110	D.5860	壓力管路及其附件	Pressure tubing and accessories	1
111	D.5975	呼吸器管路	Ventilator tubing	1
112	D.5995	T形引流器(集水器)	Tee drain (water trap)	1
113	D.6810	氣管支氣管抽吸導管	Tracheobronchial suction catheter	1
114	D.6885	醫用氣體接頭組	Medical gas yoke assembly	1
115	E.4500	心臟血管外科器械	Cardiovascular surgical instruments	1
116	F.1820	牙科用X光片照射排列裝置	Dental x-ray exposure alignment device	1
117	F.3100	牙科用和汞器	Dental amalgamator	1
118	F.3110	牙科用汞齊膠囊	Dental amalgam capsule	1
119	F.3140	樹脂塗敷器	Resin applicator	1
120	F.3165	精密接著體	Precision attachment	1
121	F.3240	牙科用鑽針	Dental bur	1
122	F.3330	成型牙冠	Preformed crown	1
123	F.3490	胺基甲基纖維素鈉、和/或聚乙烯甲基醌 順丁烯二酸鈣鈉複鹽假牙黏著劑	Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive	1
124	F.3520	不需處方之假牙清潔劑	OTC dental appliance Cleanser	1
125	F.3580	成形金屬假牙床	Preformed gold denture tooth	1
126	F.3661	CAD/CAM光學取模系統	Optical Impression Systems for CAD/CAM	1
127	F.3670	樹脂印模牙托材	Resin impression tray material	1
128	F.3810	根管中心柱釘	Root canal post	1
129	F.3830	根管紙針	Endodontic paper point	1
130	F.3850	馬來膠	Gutta percha	1
131	F.3910	人工牙的底和面	Backing and facing for an artificial tooth	1
132	F.3980	牙齒骨內植入物附件	Endosseous dental implant accessories	1
133	F.4130	口內牙鑽頭	Intraoral dental drill	1
134	F.4200	牙科手機及其附件	Dental handpiece and accessories	1
135	F.4535	牙科用鑽石器械	Dental diamond instrument	1
136	F.4565	牙科手用器械	Dental hand instrument	1
137	F.4620	光纖維牙科用光源	Fiber optic dental light	1

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138	F.4630	牙科用手術燈	Dental operating light	1
139	F.6010	研磨裝置及其附件	Abrasive device and accessories	1
140	F.6030	口腔研磨磨光劑	Oral cavity abrasive polishing agent	1
141	F.6050	唾液吸收器	Saliva absorber	1
142	F.6140	咬合紙	Articulation paper	1
143	F.6250	牙科治療椅及其附件	Dental chair and accessories	1
144	F.6290	磨光劑載杯	Prophylaxis cup	1
145	F.6300	橡皮障及其附件	Rubber dam and accessories	1
146	F.6475	漂白牙齒的熱源	Heat source for bleaching teeth	1
147	F.6570	印模管	Impression tube	1
148	F.6640	牙科手術裝置及其附件	Dental operative unit and accessories	1
149	F.6710	水熱式滅菌器	Boiling water sterilizer	1
150	F.6880	成形印模牙托	Preformed impression tray	1
151	F.6890	口內牙科用臘	Intraoral dental wax	1
152	G.3900	鼻腔擴大器	Nasal dilator	1
153	G.4140	耳鼻喉科用圓銼	Ear, nose, and throat bur	1
154	G.4350	耳鼻喉光纖光源及載具	Ear, nose, and throat fiberoptic light source and carrier	1
155	G.4420	耳鼻喉手動式外科器械	Ear, nose, and throat manual surgical instrument	1
156	G.4750	喉頭閃頻內視鏡	Laryngostroboscope	1
157	G.4770	耳鏡	Otoscope	1
158	G.5300	耳鼻喉檢查及治療檯	Ear, nose, and throat examination and treatment unit	1
159	G.5550	動力式鼻沖洗器	Powered nasal irrigator	1
160	H.1400	胃的酸鹼度電極	Stomach pH electrode	1
161	H.1620	尿液動力測量系統	Urodynamics measurement system	1
162	H.1800	尿液流量或容積測量系統	Urine flow or volume measuring system	1
163	H.4680	輸尿管結石移除器	Ureteral stone dislodger	1
164	H.4730	手動式胃腸科-泌尿科手術器械及其附件	Manual gastroenterology-urology surgical instrument and accessories	1
165	H.5210	手動式灌腸組套	Enema kit	1
166	H.5450	直腸擴張器	Rectal dilator	1
167	H.5900	造口術用袋及其附件	Ostomy pouch and accessories	1
168	H.5970	疝脫支撐器	Hernia support	1
169	I.1800	檢查鏡及其附件	Speculum and accessories	1
170	I.3800	體外美容用修復彌補物	External aesthetic restoration prosthesis	1

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171	I.3900	膨脹式四肢用夾板	Inflatable extremity splint	1
172	I.3910	非膨脹式四肢用夾板	Noninflatable extremity splint	1
173	I.4025	疤痕處理矽膠產品	Silicone scar management product	1
174	I.4160	外科手術用照相機及其附件	Surgical camera and accessories	1
175	I.4200	導入/引流導管及其附件	Introduction/drainage catheter and accessories	1
176	I.4440	眼墊	Eye pad	1
177	I.4450	體內用不被吸收紗布	Nonabsorbable gauze for internal use	1
178	I.4660	皮膚標記用筆	Skin marker	1
179	I.4680	非動力式，單一病人使用，可攜帶式之抽吸器具	Nonpowered, single patient, portable suction apparatus	1
180	I.4700	外科顯微鏡及其附件	Surgical microscope and accessories	1
181	I.4730	外科用皮膚去油劑或去黏劑	Surgical skin degreaser or adhesive tape solvent	1
182	I.4760	可拆除式皮膚縫合釘	Removable skin staple	1
183	I.4800	一般手術用手動式器械	Manual surgical instrument for general use	1
184	I.4950	手動式外科手術檯、手術椅及其附件	Manual operating table and accessories and manual operating chair and accessories	1
185	I.4960	電動或氣動式外科手術檯、手術椅及其附件	Operating tables and accessories and operating chairs and accessories	1
186	I.5350	探針式除毛機	Needle-type epilator	1
187	I.5900	非充氣式止血帶	Nonpneumatic tourniquet	1
188	I.5910	充氣式止血帶	Pneumatic tourniquet	1
189	J.5100	交流電力可調整式病床	AC-powered adjustable hospital bed	1
190	J.5120	手動可調整式病床	Manual adjustable hospital bed	1
191	J.5140	小兒病床	Pediatric hospital bed	1
192	J.5150	非動力式治療床墊	Nonpowered flotation therapy mattress	1
193	J.5160	醫療用束帶	Therapeutic medical binder	1
194	J.5210	血管內導管固定裝置	Intravascular catheter securement device	1
195	J.5300	醫療用吸收纖維	Medical absorbent fiber	1
196	J.5420	靜脈輸液袋用壓力器	Pressure infusor for an I.V. bag	1
197	J.5475	噴射灌洗器	Jet lavage	1
198	J.5510	非交流電力式病患升降機	Non-AC-powered patient lift	1
199	J.5550	交替式壓力氣墊床	Alternating pressure air flotation mattress	1
200	J.5560	溫度調節式水床墊	Temperature regulated water mattress	1

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201	J.5950	臍帶閉合器	Umbilical occlusion device	1
202	J.6025	吸收性尖端塗藥器	Absorbent tipped applicator	1
203	J.6150	醫療器械用超音波洗淨機	Ultrasonic cleaner for medical instruments	1
204	J.6230	壓舌板	Tongue depressor	1
205	J.6280	醫用鞋墊	Medical insole	1
206	J.6450	皮膚壓力保護器	Skin pressure protectors	1
207	J.6740	真空動力式體液吸收器具	Vacuum-powered body fluid suction apparatus	1
208	J.6785	手動病患輸送裝置	Manual patient transfer device	1
209	J.6900	手提式擔架	Hand-carried stretcher	1
210	J.6910	輪式擔床	Wheeled stretcher	1
211	J.6960	灌洗注射筒	Irrigating syringe	1
212	J.6970	液晶靜脈定位器	Liquid crystal vein locator	1
213	K.4525	顯微手術器械	Microsurgical instrument	1
214	K.4535	非動力式神經外科用器械	Nonpowered neurosurgical instrument	1
215	L.4520	婦產科用一般手動器械	Obstetric-gynecologic general manual instrument	1
216	L.6190	輔助生殖顯微鏡及其附件	Assisted reproductive microscopes and microscope accessories	1
217	M.1140	眼科用椅	Ophthalmic chair	1
218	M.1350	角膜鏡	Keratoscope	1
219	M.1380	診斷用聚光鏡片	Diagnostic condensing lens	1
220	M.1405	眼科試驗鏡片組	Ophthalmic trial lens set	1
221	M.1460	立體感測量器	Stereopsis measuring instrument	1
222	M.1605	視野鏡	Perimeter	1
223	M.1680	眼科用投影機	Ophthalmic projector	1
224	M.1700	瞳孔計	Pupillometer	1
225	M.1760	眼科驗光機	Ophthalmic refractometer	1
226	M.1770	手動式驗光儀	Manual refractor	1
227	M.1800	Schirmer試紙	Schirmer strip	1
228	M.1870	立體鏡	Stereoscope	1
229	M.4300	人工水晶體導引器	Intraocular lens guide	1
230	M.4350	手動式眼科手術器械	Manual ophthalmic surgical instrument	1
231	M.4360	眼睛手術灌注裝置	Ocular surgery irrigation device	1
232	M.4370	角膜刀	Keratome	1
233	M.4570	眼科手術標記器	Ophthalmic surgical marker	1
234	M.4750	眼科用眼罩	Ophthalmic eye shield	1

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235	M.4770	眼科用手術眼鏡(放大鏡)	Ophthalmic operating spectacles (loupes)	1
236	M.5844	矯正鏡片	Corrective spectacle lens	1
237	N.4200	骨水泥分配器	Cement dispenser	1
238	N.4210	臨床用骨水泥攪拌器	Cement mixer for clinical use	1
239	N.4540	手動式骨科手術器械	Orthopedic manual surgical instrument	1
240	N.4800	臨床用樣板	Template for clinical use	1
241	N.5850	非動力式骨科牽引器及配件	Nonpowered orthopedic traction apparatus and accessories	1
242	N.5960	石膏拆除器械	Cast removal instrument	1
243	O.0006	連續式被動關節活動器	Continuous Passive Motion Device	1
244	O.1575	測力板	Force-measuring platform	1
245	O.1925	等速肌力試驗評估系統	Isokinetic Testing and Evaluation System	1
246	O.3025	義肢及裝具用附件	Prosthetic and orthotic accessory	1
247	O.3075	醫療用手杖	Cane	1
248	O.3100	機械椅	Mechanical chair	1
249	O.3150	醫療用拐杖	Crutch	1
250	O.3175	浮動坐墊	Flotation cushion	1
251	O.3410	體外肢體裝具用組件	External limb orthotic component	1
252	O.3420	體外肢體義肢用組件	External limb prosthetic component	1
253	O.3475	肢體裝具	Limb orthosis	1
254	O.3490	軀幹裝具	Truncal orthosis	1
255	O.3500	體外組裝下肢義肢	External assembled lower limb prosthesis	1
256	O.3520	治療檯	Plinth	1
257	O.3640	手臂吊帶	Arm sling	1
258	O.3750	機械式治療檯	Mechanical table	1
259	O.3760	動力式治療檯	Powered table	1
260	O.5125	非動力式坐浴	Nonpowered sitz bath	1
261	O.5170	動力式氣流漂浮治療床	Powered flotation therapy bed	1
262	O.5225	動力式病人翻身床	Powered patient rotation bed	1
263	O.5700	醫療用冷敷裝置	Cold pack	1
264	O.5710	醫療用可丟棄式的冷熱敷包	Hot or cold disposable pack	1
265	O.5720	醫療用水循環式冷熱敷包	Water circulating hot or cold pack	1
266	O.5730	醫療用濕熱敷包	Moist heat pack	1
267	O.5740	動力式熱敷墊	Powered heating pad	1



序號	代碼	中文名稱	英文名稱	等級
268	O.5925	牽引用附件	Traction accessory	1
269	P.1320	核醫攝取探頭	Nuclear uptake probe	1
270	P.1640	放射性影片標記系統	Radiographic film marking system	1
271	P.1700	診斷用X光機高壓產生器	Diagnostic x-ray high voltage generator	1
272	P.1760	診斷用X光球管套組件	Diagnostic x-ray tube housing assembly	1
273	P.1830	放射科病患用支架	Radiologic patient cradle	1
274	P.1840	放射線影片	Radiographic film	1
275	P.1910	放射線柵板	Radiographic grid	1
276	P.1920	放射線造影頭部固定器	Radiographic head holder	1
277	P.1960	放射線強化螢幕	Radiographic intensifying screen	1
278	P.1980	放射線檯	Radiographic table	1
279	P.2010	醫學影像儲存裝置	Medical image storage device	1
280	P.2020	醫學影像傳輸裝置	Medical image communication device	1
281	P.5780	病患定位光束指示器	Light beam patient position indicator	1
282	P.6500	個人用防護罩	Personnel protective shield	1