

醫療器材管理辦法第四條附件二修正規定

附件二			
得不適用藥物製造工廠設廠標準第四編醫療器材優良製造規範之品項			
下列品項如應滅菌者，仍應符合藥物製造工廠設廠標準第四編醫療器材優良製造規範			
一、	臨床化學及臨床毒理學(除量測儀器外)		
	(CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES)		
代碼	中文名稱	英文名稱	等級
A.1030	胺基丙酸轉移酶試驗系統	Alanine amino transferase (ALT/SGPT) test system	1
A.1040	丁醛醇酵素試驗系統	Aldolase test system	1
A.1060	δ-胺基乙醯丙酸試驗系統	Delta-aminolevulinic acid test system	1
A.1065	血氨試驗系統	Ammonia test system	1
A.1075	雄烯二酮試驗系統	Androstenedione test system	1
A.1080	雄固酮試驗系統	Androsterone test system	1
A.1095	抗壞血酸試驗系統	Ascorbic acid test system	1
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
A.1115	尿中膽紅素及其結合物(非定量)試驗系統	Urinary bilirubin and its conjugates (nonquantitative) test system	1
A.1130	血量試驗系統	Blood volume test system	1
A.1135	胰島素前質 C-肽類試驗系統	C-peptides of proinsulin test system	1
A.1165	兒茶酚胺(總量)試驗系統	Catecholamines (total) test system	1
A.1175	膽固醇(總量)試驗系統	Cholesterol (total) test system	1
A.1180	胰凝乳蛋白試驗系統	Chymotrypsin test system	1
A.1185	S-化合物(11-去氧氫氧基皮質酮)試驗系統	Compound S (11-deoxycortisol) test system	1
A.1190	銅試驗系統	Copper test system	1
A.1195	腎上腺類皮質素試驗系統	Corticoids test system	1
A.1200	皮質類固酮試驗系統	Corticosterone test system	1
A.1210	肌酸試驗系統	Creatine test system	1

A.1240	胱氨酸試驗系統	Cystine test system	1
A.1245	去氫表雄固酮(游離和硫鹽)試驗系統	Dehydroepiandrosterone (free and sulfate) test system	1
A.1250	去氧皮質酮試驗系統	Deoxycorticosterone test system	1
A.1255	2,3-二磷甘油酸試驗系統	2,3-Diphosphoglyceric acid test system	1
A.1260	雌二醇試驗系統	Estradiol test system	1
A.1265	雌三醇試驗系統	Estriol test system	1
A.1270	雌激素(總量、懷孕中)試驗系統	Estrogens (total, in pregnancy) test system	1
A.1275	雌激素(總量，未懷孕)試驗系統	Estrogens (total, nonpregnancy) test system	1
A.1280	雌素酮試驗系統	Estrone test system	1
A.1285	睪丸素酮還原型試驗系統	Etiocholanolone test system	1
A.1290	脂肪酸試驗系統	Fatty acids test system	1
A.1300	卵泡刺激激素試驗系統	Follicle-stimulating hormone test system	1
A.1305	Formiminoglutamic acid, (FIGLU)試驗系統	Formiminoglutamic acid (FIGLU) test system	1
A.1310	半乳糖試驗系統	Galactose test system	1
A.1320	胃酸試驗系統	Gastric acidity test system	1
A.1325	胃泌素試驗系統	Gastrin test system	1
A.1330	球蛋白試驗系統	Globulin test system	1
A.1335	升糖素試驗系統	Glucagon test system	1
A.1360	r-麩胺醯轉移酶(GGT)和同功異構酶試驗系統	Gamma-glutamyl transpeptidase and isoenzymes test system	1
A.1365	麩甘胱試驗系統	Glutathione test system	1
A.1370	人體生長激素試驗系統	Human growth hormone test system	1
A.1375	組織氨基酸試驗系統	Histidine test system	1
A.1380	羥丁酸去氫醇素試驗系統	Hydroxybutyric dehydrogenase test system	1
A.1385	17-皮質類脂醇(17-生酮的類脂醇)試驗系統	17-Hydroxycorticosteroids (17-ketogenic steroids) test system	1
A.1390	5-羥引朵醋酸/血清素試驗系統	5-Hydroxyindole acetic acid/serotonin test system	1
A.1395	17-黃體酯酮試驗系統	17-Hydroxyprogesterone test system	1
A.1400	羥基脯氨酸試驗系統	Hydroxyproline test system	1
A.1405	免疫反應胰島素試驗系統	Immunoreactive insulin test system	1
A.1410	鐵(非血基質)試驗系統	Iron (non-heme) test system	1

A.1415	鐵結合能力試驗系統	Iron-binding capacity test system	1
A.1420	同檸檬酸去氫酵素試驗系統	Isocitric dehydrogenase test system	1
A.1430	17-酮固醇試驗系統	17-Ketosteroids test system	1
A.1435	酮(非定量)試驗系統	Ketones (nonquantitative) test system	1
A.1440	乳酸脫氫酶試驗系統	Lactate dehydrogenase test system	1
A.1450	乳酸試驗系統	Lactic acid test system	1
A.1460	白胺酸胺脢酶試驗系統	Leucine aminopeptidase test system	1
A.1465	脂肪分解酵素試驗系統	Lipase test system	1
A.1470	脂肪(總量)試驗系統	Lipid (total) test system	1
A.1475	脂蛋白試驗系統	Lipoprotein test system	1
A.1485	黃體促素試驗系統	Luteinizing hormone test system	1
A.1490	溶菌酵素試驗系統	Lysozyme (muramidase) test system	1
A.1495	鎂試驗系統	Magnesium test system	1
A.1500	蘋果酸去氫酵素試驗系統	Malic dehydrogenase test system	1
A.1505	黏多醣(非定量)試驗系統	Mucopolysaccharides (nonquantitative) test system	1
A.1510	亞硝酸鹽(非定量)試驗系統	Nitrite nonquantitative test system	1
A.1515	氮(胺基—氮)試驗系統	Nitrogen amino-nitrogen test system	1
A.1520	5'-核苷酸酵素試驗系統	5'-Nucleotidase test system	1
A.1530	血漿器官體積計測法試驗系統	Plasma oncometry test system	1
A.1535	鳥氨酸碳醯氨轉移酶試驗系統	Ornithine carbamyl transferase test system	1
A.1540	滲透壓試驗系統	Osmolality test system	1
A.1542	草酸鹽試驗系統	Oxalate test system	1
A.1550	尿酸鹼值(非定量)試驗系統	Urinary pH (nonquantitative) test system	1
A.1560	尿苯酮(非定量)試驗系統	Urinary phenylketones (nonquantitative) test system	1
A.1565	6-磷酸去氫酵素試驗系統	6-Phosphogluconate dehydrogenase test system	1
A.1570	磷酸己糖同質酵素試驗系統	Phosphohexose isomerase test system	1
A.1575	磷脂類試驗系統	Phospholipid test system	1
A.1580	亞磷酸(無機)試驗系統	Phosphorus (inorganic) test system	1
A.1590	噻咯色原質試驗系統	Porphobilinogen test system	1
A.1595	噻咯紫質試驗系統	Porphyrins test system	1
A.1605	黃體脂醇試驗系統	Pregnanediol test system	1

A.1610	Pregnanetriol(化學名)試驗系統	Pregnanetriol test system	1
A.1615	孕烯醇酮試驗系統	Pregnenolone test system	1
A.1620	黃體脂酮試驗系統	Progesterone test system	1
A.1625	催乳素試驗系統	Prolactin (lactogen) test system	1
A.1630	蛋白質(化學分離法)試驗系統	Protein (fractionation) test system	1
A.1635	總蛋白質試驗系統	Total protein test system	1
A.1640	蛋白質結合碘試驗系統	Protein-bound iodine test system	1
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
A.1650	丙酮酸激酶試驗系統	Pyruvate kinase test system	1
A.1655	丙酮酸試驗系統	Pyruvic acid test system	1
A.1660	品管材料(分析與非分析)	Quality control material (assayed and unassayed)	1
A.1670	山梨糖去氫酵素試驗系統	Sorbitol dehydrogenase test system	1
A.1680	睪丸脂酮試驗系統	Testosterone test system	1
A.1705	三酸甘油脂試驗系統	Triglyceride test system	1
A.1710	總三碘甲狀腺素試驗系統	Total triiodothyronine test system	1
A.1715	三碘甲狀腺素吸收試驗系統	Triiodothyronine uptake test system	1
A.1720	丙酮磷酸同質酵素試驗系統	Triose phosphate isomerase test system	1
A.1725	胰蛋白酶試驗系統	Trypsin test system	1
A.1730	游離酪氨酸試驗系統	Free tyrosine test system	1
A.1775	尿酸試驗系統	Uric acid test system	1
A.1780	尿道結石試驗系統	Urinary calculi (stones) test system	1
A.1785	尿道尿膽素鹽(非定量)試驗系統	Urinary urobilinogen (nonquantitative) test system	1
A.1790	尿紫質試驗系統	Uroporphyrin test system	1
A.1795	梵尼蘭杏仁酸試驗系統	Vanilmandelic acid test system	1
A.1805	維生素 A 試驗系統	Vitamin A test system	1
A.1815	維生素 E 試驗系統	Vitamin E test system	1
A.1820	木糖試驗系統	Xylose test system	1
A.2270	臨床使用的薄層色層分析系統	Thin-layer chromatography system for clinical use	1
A.3050	呼吸中酒精試驗系統	Breath-alcohol test system	1
A.3110	銻試驗系統	Antimony test system	1
A.3120	砷試驗系統	Arsenic test system	1
A.3220	一氧化碳試驗系統	Carbon monoxide test system	1
A.3240	膽素酯酵素試驗系統	Cholinesterase test system	1
A.3600	汞試驗系統	Mercury test system	1
A.3750	奎寧試驗系統	Quinine test system	1

A.3850	磺胺試驗系統	Sulfonamide test system	1
二、	血液學及病理學裝置(除量測儀器外)		
	(HEMATOLOGY AND PATHOLOGY DEVICES)		
代碼	中文名稱	英文名稱	等級
B.1850	染料及化學溶液染料	Dye and chemical solution stains	1
B.1860	免疫病理組織化學試劑與套組	Immunohistochemistry reagents and kits	1
B.2220	合成細胞和組織培養基及成份	Synthetic cell and tissue culture media and components	1
B.2260	染色體培養組	Chromosome culture kit	1
B.2280	經培養之動物和人體細胞	Cultured animal and human cells	1
B.2360	黴漿菌屬偵測培養基及成份	Mycoplasma detection media and components	1
B.2800	動物和人體血清	Animal and human sera	1
B.2875	平衡鹽溶液或配方	Balanced salt solutions or formulations	1
B.4020	分析特定試劑	Analyte specific reagents	1
B.4400	酵素製劑	Enzyme preparations	1
B.5800	自動沉降速率裝置	Automated sedimentation rate device	1
B.6100	流血時間測量裝置	Bleeding time device	1
B.6150	毛細血管血液收集管	Capillary blood collection tube	1
B.6160	手動血球計數裝置	Manual blood cell counting device	1
B.6400	血球容積測量裝置	Hematocrit measuring device	1
B.6600	滲透脆性試驗	Osmotic fragility test	1
B.6700	紅血球沈澱速率試驗	Erythrocyte sedimentation rate test	1
B.7040	三磷酸腺苷釋出分析	Adenosine triphosphate release assay	1
B.7660	白血球鹼性磷酸鹽酵素試驗	Leukocyte alkaline phosphatase test	1
B.7675	白血球過氧化酵素試驗	Leukocyte peroxidase test	1
B.7900	血栓形成質產生試驗	Thromboplastin generation test	1
B.8200	血球稀釋劑	Blood cell diluent	1
B.8500	淋巴球分離培養基	Lymphocyte separation medium	1
B.8540	紅血球溶解劑	Red cell lysing reagent	1
B.8950	勒索耳氏毒蛇之蛇毒反應劑	Russell viper venom reagent	1
B.9050	血庫供應	Blood bank supplies	1

B.9125	真空血液收集系統	Vacuum-assisted blood collection system	1
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
B.9320	確定比重所用的硫酸銅溶液	Copper sulfate solution for specific gravity determinations	1
B.9550	植物凝血素及凝血前素	Lectins and protectins	1
B.9575	保存血小板濃縮液之容器	Environmental chamber for storage of platelet concentrate	1
B.9600	體外診斷用的強化培養基	Potentiating media for in vitro diagnostic use	1
B.9700	血液保存之冰箱與冷凍箱	Blood storage refrigerator and blood storage freezer	1
B.9750	加熱密封器材	Heat-sealing device	1
三、	免疫學及微生物學裝置(除量測儀器外)		
	(IMMUNOLOGY AND MICROBIOLOGY DEVICES)		
代碼	中文名稱	英文名稱	等級
C.0003	螺旋桿菌屬血清試劑	Helicobacter spp. serological reagents	1
C.2160	凝血酵素血漿	Coagulase plasma	1
C.2300	多功能培養基	Multipurpose culture medium	1
C.2320	鑑別培養基	Differential culture medium	1
C.2330	集菌培養基	Enriched culture medium	1
C.2350	微生物分析培養基	Microbiological assay culture medium	1
C.2360	選擇性培養基	Selective culture medium	1
C.2390	輸送培養基	Transport culture medium	1
C.2450	培養基之添加物	Supplement for culture media	1
C.2480	培養基的品質管制器材組	Quality control kit for culture media	1
C.2500	微滴定稀釋及分配器材	Microtiter diluting and dispensing device	1
C.2580	產氣器材	Gas-generating device	1
C.2600	Wood 氏螢光燈	Wood's fluorescent lamp	1
C.2660	微生物鑑別及測定器材	Microorganism differentiation and identification device	1
C.2900	微生物樣本收集及輸送器材	Microbiological specimen collection and transport device	1

C.3010	Acinetobacter calcoaceticus 血清試劑	Acinetobacter calcoaceticus serological reagents	1
C.3020	腺病毒血清試劑	Adenovirus serological reagents	1
C.3035	亞歷桑納屬血清試劑	Arizona spp.serological reagents	1
C.3040	麴菌屬血清試劑	Aspergillus spp. serological reagents	1
C.3060	皮炎芽生菌血清試劑	Blastomyces dermatitidis serological reagents	1
C.3065	博德氏球桿菌屬血清試劑	Bordetella spp. serological reagents	1
C.3085	布魯氏菌屬血清反應劑	Brucella spp. serological reagents	1
C.3110	胎兒彎曲畸形菌屬血清試劑	Campylobacter fetus serological reagents	1
C.3120	披衣菌屬血清試劑	Chlamydia serological reagents	1
C.3125	產檸檬酸菌屬血清試劑	Citrobacter spp.serological reagents	1
C.3135	厭酷球孢子菌血清試劑	Coccidioides immitis serological reagents	1
C.3140	棒狀桿菌屬血清試劑	Corynebacterium spp.serological reagents	1
C.3145	柯沙奇病毒血清試劑	Coxsackievirus serological reagents	1
C.3165	新形隱球菌屬血清試劑	Cryptococcus neoformans serological reagents	1
C.3200	胞虫囊血清試劑	Echinococcus spp. serological reagents	1
C.3205	Echo 病毒血清試劑	Echovirus serological reagents	1
C.3220	溶組織阿米巴血清試劑	Entamoeba histolytica serological reagents	1
C.3235	EB 病毒血清試劑	Epstein-Barr virus serological reagents	1
C.3240	馬的腦脊髓炎病毒血清試劑	Equine encephalomyelitis virus serological reagents	1
C.3250	豬丹毒桿菌血清試劑	Erysipelothrix rhusiopathiae serological reagents	1
C.3255	大腸桿菌血清試劑	Escherichia coli serological reagents	1
C.3270	黃質菌屬血清試劑	Flavobacterium spp. serological reagents	1
C.3280	土拉熱桿菌病血清試劑	Francisella tularensis serological reagents	1

C.3300	嗜血桿菌屬血清試劑	Haemophilus spp. serological reagents	1
C.3320	莢膜組織胞漿菌血清試劑	Histoplasma capsulatum serological reagents	1
C.3330	流行性感冒病毒血清試劑	Influenza virus serological reagents	1
C.3340	克雷白氏桿菌屬血清試劑	Klebsiella spp. serological reagents	1
C.3350	鉤端螺旋菌屬血清試劑	Leptospira spp. serological reagents	1
C.3355	李司特氏菌屬血清試劑	Listeria spp. serological reagents	1
C.3360	淋巴球性脈絡叢腦膜炎病毒血清試劑	Lymphocytic choriomeningitis virus serological reagents	1
C.3370	結核桿菌免疫螢光試劑	Mycobacterium tuberculosis immunofluorescent reagents	1
C.3375	黴漿菌屬血清試劑	Mycoplasma spp. serological reagents	1
C.3380	腮腺炎病毒血清試劑	Mumps virus serological reagents	1
C.3400	副流行性感冒病毒血清試劑	Parainfluenza virus serological reagents	1
C.3405	小兒麻痺病毒血清試劑	Poliovirus serological reagents	1
C.3410	變形桿菌屬(Weil-Felix)血清試劑	Proteus spp. (Weil-Felix) serological reagents	1
C.3415	假單胞菌屬血清試劑	Pseudomonas spp. serological reagents	1
C.3470	孤腸呼病毒血清試劑	Reovirus serological reagents	1
C.3480	呼吸道融合細胞病毒血清試劑	Respiratory syncytial virus serological reagents	1
C.3490	鼻病毒血清試劑	Rhinovirus serological reagents	1
C.3500	立克次體血清試劑	Rickettsia serological reagents	1
C.3520	麻疹病毒血清試劑	Rubeola (measles) virus serological reagents	1
C.3550	沙門氏菌屬血清試劑	Salmonella spp. serological reagents	1
C.3600	血吸蟲屬血清試劑	Schistosoma spp. serological reagents	1
C.3630	沙雷氏菌屬血清試劑	Serratia spp. serological reagents	1
C.3660	志賀氏桿菌屬血清試劑	Shigella spp. serological reagents	1
C.3680	申克氏孢子絲菌	Sporothrix schenckii serological reagents	1

C.3700	金黃色葡萄球菌血清試劑	Staphylococcus aureus serological reagents	1
C.3720	鏈球菌屬外酵素試劑	Streptococcus spp. exoenzyme reagents	1
C.3740	鏈球菌屬血清試劑	Streptococcus spp. serological reagents	1
C.3850	旋毛虫血清試劑	Trichinella spiralis serological reagents	1
C.3870	錐虫屬血清試劑	Trypanosoma spp. serological reagents	1
C.3930	霍亂弧菌血清試劑	Vibrio cholerae serological reagents	1
C.4100	補體試劑	Complement reagent	1
C.5040	白蛋白免疫試驗系統	Albumin immunological test system	1
C.5060	前白蛋白免疫試驗系統	Prealbumin immunological test system	1
C.5065	人體同種異型標記免疫試驗系統	Human allotypic marker immunological test system	1
C.5160	β -球蛋白免疫試驗系統	Beta-globulin immunological test system	1
C.5170	母乳免疫試驗系統	Breast milk immunological test system	1
C.5200	醣脫水酵素 B 及 C 免疫試驗系統	Carbonic anhydrase B and C immunological test system	1
C.5220	Cohn fraction II(一種蛋白質分離法)免疫試驗系統	Cohn fraction II immunological test system	1
C.5230	初乳免疫試驗系統	Colostrum immunological test system	1
C.5320	破壞素 B 因子免疫試驗系統	Properdin factor B immunological test system	1
C.5330	第十三, A, S, 因子免疫試驗系統	Factor XIII, A, S, immunological test system	1
C.5360	Cohn fraction IV 免疫試驗系統	Cohn fraction IV immunological test system	1
C.5370	Cohn fraction V 免疫試驗系統	Cohn fraction V immunological test system	1
C.5380	游離分泌補體免疫試驗系統	Free secretory component immunological test system	1
C.5400	α -球蛋白免疫試驗系統	Alpha-globulin immunological test system	1

C.5420	α -1-醣蛋白免疫試驗系統	Alpha-1-glycoproteins immunological test system	1
C.5425	α -2-醣蛋白免疫試驗系統	Alpha-2-glycoproteins immunological test system	1
C.5430	β -2-醣蛋白 I 免疫試驗系統	Beta-2-glycoprotein I immunological test system	1
C.5440	β -2-醣蛋白 III 免疫試驗系統	Beta-2-glycoprotein III immunological test system	1
C.5460	結合球蛋白免疫試驗系統	Haptoglobin immunological test system	1
C.5490	凝血酵素免疫試驗系統	Hemopexin immunological test system	1
C.5520	免疫球蛋白 G(Fab 特定片段)免疫試驗系統	Immunoglobulin G (Fab fragment specific) immunological test system	1
C.5530	免疫球蛋白 G(Fc 特定片段)免疫試驗系統	Immunoglobulin G (Fc fragment specific) immunological test system	1
C.5540	免疫球蛋白 G(Fd 特定片段)免疫試驗系統	Immunoglobulin G (Fd fragment specific) immunological test system	1
C.5560	乳酸去氫免疫試驗系統	Lactic dehydrogenase immunological test system	1
C.5570	乳膽鐵質免疫試驗系統	Lactoferrin immunological test system	1
C.5590	脂蛋白 X 免疫試驗系統	Lipoprotein X immunological test system	1
C.5700	人類全血漿或血清免疫試驗系統	Whole human plasma or serum immunological test system	1
C.5715	胞漿素原免疫試驗系統	Plasminogen immunological test system	1
C.5735	前凝血酵素免疫試驗系統	Prothrombin immunological test system	1
C.5765	核黃素結合蛋白免疫試驗系統	Retinol-binding protein immunological test system	1
C.5800	精液(精子)免疫試驗系統	Seminal fluid (sperm) immunological test system	1
C.5860	全脊髓液免疫試驗系統	Total spinal fluid immunological test system	1

C.5890	α 間胰蛋白抑制劑免疫試驗系統	Inter-alpha trypsin inhibitor immunological test system	1
四、	麻醉學科用裝置		
	(ANESTHESIOLOGY DEVICES)		
代碼	中文名稱	英文名稱	等級
D.1100	動脈血液取樣組	Arterial blood sampling kit	1
D.1575	氣體收集容器	Gas collection vessel	1
D.1910	食道聽診器	Esophageal stethoscope	1
D.1930	食道聽診器探頭	Stethoscope head	1
D.5100	鼻咽氣道管	Nasopharyngeal airway	1
D.5110	口咽氣道管	Oropharyngeal airway	1
D.5220	吹氣瓶	Blow bottle	1
D.5240	麻醉呼吸管路	Anesthesia breathing circuit	1
D.5280	呼吸管路支撐物	Breathing tube support	1
D.5300	二氧化碳吸收劑	Carbon dioxide absorbent	1
D.5310	二氧化碳吸收器	Carbon dioxide absorber	1
D.5320	儲氣囊	Reservoir bag	1
D.5340	經鼻氧氣套管	Nasal oxygen cannula	1
D.5350	經鼻氧氣導管	Nasal oxygen catheter	1
D.5375	熱及濕氣凝結器(人工鼻)	Heat and moisture condenser (artificial nose)	1
D.5460	家用治療潮濕器	Therapeutic humidifier for home use	1
D.5530	可彎曲式喉頭鏡	Flexible laryngoscope	1
D.5540	硬式喉頭鏡	Rigid laryngoscope	1
D.5550	麻醉氣體面罩	Anesthetic gas mask	1
D.5560	氣體面罩頭套帶	Gas mask head strap	1
D.5570	非重吸入式呼吸面罩	Nonrebreathing mask	1
D.5580	氧氣面罩	Oxygen mask	1
D.5590	排氣面罩	Scavenging mask	1
D.5600	Venturi 面罩	Venturi mask	1
D.5620	呼吸咬嘴	Breathing mouthpiece	1
D.5640	非呼吸用醫藥噴霧器	Medicinal nonventilatory nebulizer (atomizer)	1
D.5675	再吸入裝置	Rebreathing device	1
D.5700	非動力式氧氣帳	Nonpowered oxygen tent	1
D.5770	氣管管路固定裝置	Tracheal tube fixation device	1
D.5780	管路導引鉗	Tube introduction forceps	1

D.5790	氣管內管探針	Tracheal tube stylet	1
D.5810	氣道連接器	Airway connector	1
D.5860	壓力管路及其附件	Pressure tubing and accessories	1
D.5975	呼吸器管路	Ventilator tubing	1
D.5995	T 形引流器(集水器)	Tee drain (water trap)	1
D.6810	氣管支氣管抽吸導管	Tracheobronchial suction catheter	1
D.6885	醫用氣體接頭組	Medical gas yoke assembly	1
五、	心臟血管用裝置		
	(CARDIOVASCULAR DEVICES)		
代碼	中文名稱	英文名稱	等級
E.1875	聽診器	Stethoscope	1
E.3650	心律調節器之聚合物網狀袋	Pacemaker polymeric mesh bag	1
E.3730	心律調節器維修工具	Pacemaker service tools	1
E.3935	心臟瓣膜彌補物之支撐物	Prosthetic heart valve holder	1
E.4200	心肺血管繞道術輔助設備	Cardiopulmonary bypass accessory equipment	1
E.4500	心臟血管外科器械	Cardiovascular surgical instruments	1
六、	牙科裝置		
	(DENTAL DEVICES)		
代碼	中文名稱	英文名稱	等級
F.0001	排齦線	Retraction cord	1
F.1730	牙髓測試器用電極膠	Electrode gel for pulp tester	1
F.1820	牙科用 X 光片照射排列裝置	Dental x-ray exposure alignment device	1
F.1840	牙科用 X 光片位置指示裝置	Dental x-ray position indicating device	1
F.1850	鉛線位置指示器	Lead-lined position indicator	1
F.2050	牙科超音波描記裝置	Dental sonography device	1
F.2060	頷骨輪廓標記裝置	Jaw tracking device	1
F.3100	牙科用和汞器	Dental amalgamator	1
F.3110	牙科用汞齊膠囊	Dental amalgam capsule	1
F.3130	成型鉤	Preformed anchor	1
F.3140	樹脂塗敷器	Resin applicator	1
F.3165	精密接著體	Precision attachment	1

F.3240	牙科用圓頭銼	Dental bur	1
F.3275	牙科用水泥(士敏汀)	Dental cement	1
F.3285	預成型牙鉤	Preformed clasp	1
F.3330	成型牙冠	Preformed crown	1
F.3350	黃金或不銹鋼咬頭	Gold or stainless steel cusp	1
F.3360	成型咬頭	Preformed cusp	1
F.3400	梧桐膠合硼酸鈉含或不含阿拉伯樹膠	Karaya and sodium borate with or without acacia denture adhesive	1
F.3410	氧化乙烯聚合物和/或羧基甲基纖維素鈉假牙黏著劑	Ethylene oxide homopolymer and/or carboxymethyl-cellulose sodium denture adhesive	1
F.3450	氧化乙烯聚合物或印度樹膠假牙黏著劑	Ethylene oxide homopolymer and/or karaya denture adhesive	1
F.3490	胺基甲基纖維素鈉、和/或聚乙烯甲基醚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
F.3520	不需處方之假牙清潔劑	OTC denture cleanser	1
F.3530	機械式假牙清潔器	Mechanical denture cleaner	1
F.3540	假牙襯墊	OTC denture cushion or pad	1
F.3580	成形金屬假牙床	Preformed gold denture tooth	1
F.3670	樹脂印模牙托材	Resin impression tray material	1
F.3740	保持釘和固定夾板	Retentive and splinting pin	1
F.3810	根管中心柱釘	Root canal post	1
F.3830	根管紙針	Endodontic paper point	1
F.3840	根管銀針	Endodontic silver point	1
F.3850	馬來膠	Gutta percha	1
F.3900	有金屬鑲嵌的人工後牙	Posterior artificial tooth with a metal insert	1
F.3910	人工牙的底和面	Backing and facing for an artificial tooth	1
F.3980	牙齒骨內植入物附件	Endosseous dental implant accessories	1
F.4130	口內牙鑽頭	Intraoral dental drill	1
F.4200	牙科手機及其附件	Dental handpiece and accessories	1
F.4535	牙科用鑽石器械	Dental diamond instrument	1
F.4565	牙科手用器械	Dental hand instrument	1
F.4620	光纖維牙科用光源	Fiber optic dental light	1
F.4630	牙科用手術燈	Dental operating light	1
F.4730	牙科用注射針	Dental injecting needle	1

F.5410	牙科矯正裝置及其附件	Orthodontic appliance and accessories	1
F.5525	成形牙齒定位器	Preformed tooth positioner	1
F.6010	研磨裝置及其附件	Abrasive device and accessories	1
F.6030	口腔研磨磨光劑	Oral cavity abrasive polishing agent	1
F.6050	唾液吸收器	Saliva absorber	1
F.6100	麻醉劑加溫器	Anesthetic warmer	1
F.6140	咬合紙	Articulation paper	1
F.6200	基底塗料	Base plate shellac	1
F.6250	牙科治療椅及其附件	Dental chair and accessories	1
F.6290	預防杯形物	Prophylaxis cup	1
F.6300	橡皮障及其附件	Rubber dam and accessories	1
F.6475	漂白牙齒的熱源	Heat source for bleaching teeth	1
F.6570	印模管	Impression tube	1
F.6640	牙科手術裝置及其附件	Dental operative unit and accessories	1
F.6710	水熱式滅菌器	Boiling water sterilizer	1
F.6870	拋棄式塗氟用牙托	Disposable fluoride tray	1
F.6880	成形印模牙托	Preformed impression tray	1
F.6890	口內牙科用臘	Intraoral dental wax	1
七、	耳鼻喉科用裝置		
	(EAR,NOSE,AND THORAT DEVICES)		
代碼	中文名稱	英文名稱	等級
G.1100	聽力檢查耳機軟墊	Earphone cushion for audiometric testing	1
G.1600	嗅覺測試裝置	Olfactory test device	1
G.1925	Toynbee 氏耳咽管功能診斷管	Toynbee diagnostic tube	1
G.3300	助聽器	Hearing aid	1
G.3540	聽小骨置換物修正用器械	Prosthesis modification instrument for ossicular replacement surgery	1
G.3900	鼻腔擴大器	Nasal dilator	1
G.4100	止鼻血用氣球	Epistaxis balloon	1
G.4140	耳鼻喉科用圓銼	Ear, nose, and throat bur	1
G.4175	鼻咽部導管	Nasopharyngeal catheter	1
G.4350	耳鼻喉光纖光源及載具	Ear, nose, and throat fiberoptic light source and carrier	1

G.4420	耳鼻喉手動式外科器械	Ear, nose, and throat manual surgical instrument	1
G.4750	喉頭閃頻內視鏡	Laryngostroboscope	1
G.4770	耳鏡	Otoscope	1
G.4780	鼻腔內固定夾板	Intranasal splint	1
G.4800	骨粒子收集器	Bone Particle collector	1
G.5220	耳鼻喉佈施藥裝置	Ear, nose, and throat drug administration device	1
G.5300	耳鼻喉檢查及治療檯	Ear, nose, and throat examination and treatment unit	1
G.5550	動力式鼻沖洗器	Powered nasal irrigator	1
G.5800	鼻外固定板	External nasal splint	1
G.5840	口吃矯正器材	Antistammering device	1
八、	胃腸病學-泌尿學科用裝置		
	(GASTROENTROLOGY-UROLOGY DEVICES)		
代碼	中文名稱	英文名稱	等級
H.1075	腸胃科-泌尿科生檢器械	Gastroenterology-urology biopsy instrument	1
H.4530	胃腸科-泌尿科光纖牽引器	Gastroenterolgy-urology fiberoptic retractor	1
H.4560	肋骨障	Ribdam	1
H.4590	連接尿道用探條	Interlocking urethral sound	1
H.4730	手動式胃腸科-泌尿科手術器械及其附件	Manual gastroenterolgoy-urology surgical instrument and accessories	1
H.4890	泌尿手術檯及其附件	Urological table and accessories	1
H.5030	自制式迴腸造口術用導管	Continent ileostomy catheter	1
H.5090	恥骨上位的導尿管及其附件	Suprapubic urological catheter and accessories	1
H.5130	泌尿導管及其附件	Urological catheter and accessories	1
H.5160	男性尿道夾	Urological clamp for males	1
H.5210	灌腸組套	Enema kit	1
H.5450	直腸擴張器	Rectal dilator	1
H.5520	尿道擴張器	Urethral dilator	1
H.5900	造口術用袋及其附件	Ostomy pouch and accessories	1
H.5970	疝脫支撐器	Hernia support	1
H.5980	胃腸管及其附件	Gastrointestinal tube and accessories	1

九、	一般及整型外科手術裝置		
	(GENERAL AND PLASTIC SURGERY DEVICES)		
代碼	中文名稱	英文名稱	等級
I.1800	檢查鏡及其附件	Speculum and accessories	1
I.3250	體外顏面骨折固定裝置	External facial fracture fixation appliance	1
I.3750	體外彌補物之黏貼物	External prosthesis adhesive	1
I.3800	體外美容用修復彌補物	External aesthetic restoration prosthesis	1
I.3900	膨脹式四肢用夾板	Inflatable extremity splint	1
I.3910	非膨脹式四肢用夾板	Noninflatable extremity splint	1
I.3925	整形外科手術組套及其附件	Plastic surgery kit and accessories	1
I.4014	外部使用非吸收式紗布或海綿球	Nonresorbable gauze/sponge for external use	1
I.4018	親水性創傷覆蓋材	Hydrophilic wound dressing	1
I.4020	閉合用傷口/燒燙傷敷料	Occlusive wound/burn dressing	1
I.4025	矽膠片	Silicone sheeting	1
I.4022	水性創傷與燒傷覆蓋材	Hydrogel wound dressing and burn dressing	1
I.4040	外科手術用衣物（外科手術衣及面罩）	Surgical apparel(Surgical gowns and surgical masks)	1
I.4100	器官袋	Organ bag	1
I.4160	外科手術用照相機及其附件	Surgical camera and accessories	1
I.4200	導入/引流導管及其附件	Introduction/drainage catheter and accessories	1
I.4320	可拆除式皮膚夾	Removable skin clip	1
I.4380	覆巾用黏貼物	Drape adhesive	1
I.4440	眼墊(Eye pad)	Eye pad	1
I.4450	體內用不被吸收紗布	Nonabsorbable gauze for internal use	1
I.4470	手術用手套乳劑	Surgeon's gloving cream	1
I.4660	皮膚標記用筆	Skin marker	1
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
I.4700	外科顯微鏡及其附件	Surgical microscope and accessories	1
I.4730	外科用皮膚去油劑或去黏劑	Surgical skin degreaser or adhesive tape solvent	1
I.4760	可拆除式皮膚縫合釘	Removable skin staple	1

I.4800	一般手術用手動式器械	Manual surgical instrument for general use	1
I.4820	手術用器具馬達與配件或附件	Surgical instrument motors and accessories/attachments	1
I.4930	縫線置留裝置	Suture retention device	1
I.4950	手動式外科手術抬、手術椅及其附件	Manual operating table and accessories and manual operating chair and accessories	1
I.4960	電動或氣動式外科手術抬、手術椅及其附件	Operating tables and accessories and operating chairs and accessories	1
I.5350	探針式除毛機	Needle-type epilator	1
I.5360	拔毛鉗式除毛機	Tweezer-type epilator	1
I.5900	非充氣式止血帶	Nonpneumatic tourniquet	1
I.5910	充氣式止血帶	Pneumatic tourniquet	1
十、	一般醫院及個人使用裝置		
	(GENERAL HOSPITAL AND PERSONAL USE DEVICES)		
代碼	名稱		等級
J.2200	前額液晶體溫片	Liquid crystal forehead temperature strip	1
J.2900	臨床變色體溫計	Clinical color change thermometer	1
J.5075	彈性繃帶	Elastic bandage	1
J.5090	液體性繃帶	Liquid bandage	1
J.5110	水壓可調整式病床	Hydraulic adjustable hospital bed	1
J.5120	手動可調整式病床	Manual adjustable hospital bed	1
J.5150	非動力式治療床墊	Nonpowered flotation therapy mattress	1
J.5160	醫療用束帶	Therapeutic medical binder	1
J.5180	灼傷片	Burn sheet	1
J.5210	血管內導管固定裝置	Intravascular catheter securement device	1
J.5240	醫療用黏性膠帶及黏性繃帶	Medical adhesive tape and adhesive bandage	1
J.5270	新生兒用眼罩	Neonatal eye pad	1
J.5300	醫療用吸收纖維	Medical absorbent fiber	1
J.5420	輸血袋用壓力器	Pressure infusor for an I.V. bag	1
J.5510	非交流電力式病患升降機	Non-AC-powered patient lift	1

J.5550	交替式壓力氣墊床	Alternating pressure air flotation mattress	1
J.5560	溫度調節式水床墊	Temperature regulated water mattress	1
J.5680	小兒姿勢固定器	Pediatric position holder	1
J.5740	蛇咬用傷口吸引組	Suction snakebite kit	1
J.5780	醫用輔助襪	Medical support stocking	1
J.5820	治療用陰囊支撐器	Therapeutic scrotal support	1
J.5950	臍帶閉合器	Umbilical occlusion device	1
J.6025	吸收性尖端塗藥器	Absorbent tipped applicator	1
J.6150	醫療器械用超音波洗淨機	Ultrasonic cleaner for medical instruments	1
J.6230	壓舌板	Tongue depressor	1
J.6280	醫用鞋墊	Medical insole	1
J.6375	病患用潤滑劑	Patient lubricant	1
J.6430	液體藥物給藥器	Liquid medication dispenser	1
J.6450	皮膚壓力保護器	Skin pressure protectors	1
J.6760	保護性限制帶	Protective restraint	1
J.6775	動力式病患輸送裝置	Powered patient transfer device	1
J.6785	手動病患輸送裝置	Manual patient transfer device	1
J.6820	醫用可拋棄式剪刀	Medical disposable scissors	1
J.6890	一般醫療器械用消毒劑	General purpose disinfectants	1
J.6900	手提式擔架	Hand-carried stretcher	1
J.6910	輪式擔床	Wheeled stretcher	1
J.6960	灌洗注射筒	Irrigating syringe	1
J.6970	液晶靜脈定位器	Liquid crystal vein locator	1
J.6980	靜脈固定器	Vein stabilizer	1
J.6990	注射架	Infusion stand	1
十一、	神經學科用裝置		
	(NEUROLOGICAL DEVICES)		
代碼	中文名稱	英文名稱	等級
K.1200	兩點式判讀儀	Two-point discriminator	1
K.1500	觸覺計	Esthesiometer	1
K.1525	調音叉	Tuning fork	1
K.4030	顱骨板鐵砧	Skull plate anvil	1
K.4060	腦室套管	Ventricular cannula	1
K.4125	神經外科用椅	Neurosurgical chair	1
K.4190	夾成形/切割器械	Clip forming/cutting instrument	1

K.4200	去夾器械	Clip removal instrument	1
K.4325	頭顱鑽手機	Cranial drill handpiece(brace)	1
K.4500	頭顱造型術用材料形成工具	Cranioplasty material forming instrument	1
K.4525	顯微手術器械	Microsurgical instrument	1
K.4535	非動力式神經外科用器械	Nonpowered neurosurgical instrument	1
K.4545	分流系統植入用器械	Shunt system implantation instrument	1
K.4600	額葉白質刀	Leukotome	1
K.4650	神經外科用縫合針	Neurosurgical suture needle	1
K.4750	顱骨打洞器	Skull punch	1
K.4900	顱骨板起子	Skullplate screwdriver	1
十二、	婦產科用裝置		
	(OBSTETRICAL AND GYNECOLOGICAL DEVICES)		
代碼	中文名稱	英文名稱	等級
L.1640	陷凹鏡及其附件	Culdoscope and accessories	1
L.1690	子宮鏡及其附件	Hysteroscope and accessories	1
L.1700	子宮鏡灌入器	Hysteroscopic insufflator	1
L.1720	婦產科用腹腔鏡及其附件	Gynecologic laparoscope and accessories	1
L.1730	腹腔鏡灌入器	Laparoscopic insufflator	1
L.2900	胎兒聽診器	Fetal stethoscope	1
L.4520	婦產科用一般手動器械	Obstetric-gynecologic general manual instrument	1
L.4530	婦產科專用手動器械	Obstetric-gynecologic specialized manual instrument	1
L.5900	治療用陰道灌洗器	Therapeutic vaginal douche apparatus	1
L.5920	陰道吹藥器	Vaginal insufflator	1
L.6190	輔助生殖顯微鏡及其附件	Assisted reproductive microscopes and microscope accessories	1
十三、	眼科用裝置		
	(OPHTHALMIC DEVICES)		
代碼	中文名稱	英文名稱	等級

M.1040	眼球觸覺計	Ocular esthesiometer	1
M.1070	色盲檢查器	Anomaloscope	1
M.1090	Haidlinger 刷	Haidlinger brush	1
M.1140	眼科用椅	Ophthalmic chair	1
M.1160	色覺板照明器	Color vision plate illuminator	1
M.1200	眼球運動鼓狀器	Optokinetic drum	1
M.1250	直視鏡	Euthyscope	1
M.1290	固定裝置	Fixation device	1
M.1320	穹窿鏡	Fornixscope	1
M.1350	角膜鏡	Keratoscope	1
M.1375	Bagolini 鏡片	Bagolini lens	1
M.1380	診斷用聚光鏡片	Diagnostic condensing lens	1
M.1390	診斷用彈性 Fresnel 鏡片	Flexible diagnostic Fresnel lens	1
M.1395	診斷用 Hruby 眼底鏡片	Diagnostic Hruby fundus lens	1
M.1400	Maddox 鏡	Maddox lens	1
M.1405	眼科試驗鏡片組	Ophthalmic trial lens set	1
M.1410	眼科試驗鏡片夾	Ophthalmic trial lens clip	1
M.1435	馬克斯威氏點	Maxwell spot	1
M.1460	立體感測量器	Stereopsis measuring instrument	1
M.1605	視野鏡	Perimeter	1
M.1650	眼科用棒狀稜鏡	Ophthalmic bar prism	1
M.1655	眼科用 Fresnel 稜鏡	Ophthalmic Fresnel prism	1
M.1660	視軸角度稜鏡	Gonioscopic prism	1
M.1665	眼科旋轉稜鏡	Ophthalmic rotary prism	1
M.1680	眼科用投影機	Ophthalmic projector	1
M.1690	瞳孔圖儀	Pupillograph	1
M.1700	瞳孔計	Pupillometer	1
M.1750	視網膜檢影器架	Skiascopic rack	1
M.1790	近點尺	Nearpoint ruler	1
M.1800	Schirmer 試紙	Schirmer strip	1
M.1810	切線幕(視野計)	Tangent screen (campimeter)	1
M.1870	立體鏡	Stereoscope	1
M.1905	眼球震顫帶	Nystagmus tape	1
M.1910	視覺分離試驗系統	Spectacle dissociation test system	1
M.1940	眼壓計消毒器	Tonometer sterilizer	1
M.1945	透照器	Transilluminator	1
M.3200	義眼	Artificial eye	1
M.4070	動力式角膜鑽孔器	Powered corneal burr	1
M.4250	眼科用電解器	Ophthalmic electrolysis unit	1
M.4300	人工水晶體導引器	Intraocular lens guide	1
M.4335	手術用頭燈	Operating headlamp	1

M.4350	手動式眼科手術器械	Manual ophthalmic surgical instrument	1
M.4360	眼睛手術灌注裝置	Ocular surgery irrigation device	1
M.4370	角膜刀	Keratome	1
M.4570	眼科手術標記器	Ophthalmic surgical marker	1
M.4750	眼科用眼罩	Ophthalmic eye shield	1
M.4770	眼科用手術眼鏡(放大鏡)	Ophthalmic operating spectacles (loupes)	1
M.5600	上眼瞼下垂支持器	Ptosis crutch	1
M.5844	矯正鏡片	Corrective spectacle lens	1
十四、	骨科用裝置		
	(ORTHOPEDIC DEVICES)		
代碼	中文名稱	英文名稱	等級
N.1100	關節鏡	Arthroscope	1
N.3000	骨臼帽	Bone cap	1
N.4200	骨水泥分配器	Cement dispenser	1
N.4210	臨床用骨水泥攪拌器	Cement mixer for clinical use	1
N.4220	骨水泥單體蒸氣排除器	Cement monomer vapor evacuator	1
N.4230	骨水泥通風管	Cement ventilation tube	1
N.4540	手動式骨科手術器械	Orthopedic manual surgical instrument	1
N.5850	非動力式骨科牽引器及配件	Nonpowered orthopedic traction apparatus and accessories	1
N.5890	非侵入式牽引組件	Noninvasive traction component	1
N.5940	石膏類產品	Cast component	1
N.5960	石膏拆除器械	Cast removal instrument	1
N.5980	手動式打石膏及拆石膏器械	Manual cast application and removal instrument	1
十五、	物理醫學科用裝置		
	(PHYSICAL MEDICINE DEVICES)		
代碼	中文名稱	英文名稱	等級
O.0003	皮膚局部冷凍劑	Topical refrigerant (vapocoolant)	1
O.1175	電極線	Electrode cable	1
O.3025	義肢及裝具用附件	Prosthetic and orthotic accessory	1
O.3075	醫療用手杖	Cane	1

O.3100	機械椅	Mechanical chair	1
O.3150	醫療用拐杖	Crutch	1
O.3175	浮動坐墊	Flotation cushion	1
O.3410	體外肢體裝具用組件	External limb orthotic component	1
O.3420	體外肢體義肢用組件	External limb prosthetic component	1
O.3475	肢體裝具	Limb orthosis	1
O.3490	軀幹裝具	Truncal orthosis	1
O.3500	體外組裝下肢義肢	External assembled lower limb prosthesis	1
O.3520	治療檯	Plinth	1
O.3640	手臂吊帶	Arm sling	1
O.3665	先天性髖關節移位外展夾板	Congenital hip dislocation abduction splint	1
O.3675	丹尼布朗夾板	Denis Brown splint	1
O.3750	機械式治療檯	Mechanical table	1
O.3760	動力式治療檯	Powered table	1
O.3825	機械式助行器	Mechanical walker	1
O.3850	機械式輪椅	Mechanical wheelchair	1
O.5125	非動力式坐浴	Nonpowered sitz bath	1
O.5160	氣流床	Air-fluidized bed	1
O.5170	動力式氣流漂浮治療床	Powered flotation therapy bed	1
O.5180	手動式病人翻身床	Manual patient rotation bed	1
O.5225	動力式病人翻身床	Powered patient rotation bed	1
O.5700	醫療用冷敷包	Cold pack	1
O.5710	醫療用可丟棄式的冷熱敷包	Hot or cold disposable pack	1
O.5720	醫療用水循環式冷熱敷包	Water circulating hot or cold pack	1
O.5730	醫療用濕熱敷包	Moist heat pack	1
O.5765	壓力供應裝置	Pressure-applying device	1
O.5925	牽引用附件	Traction accessory	1
十六、	放射學科用裝置		
	(RADIOLOGY DEVICES)		
代碼	中文名稱	英文名稱	等級
P.1350	核醫掃描台	Nuclear scanning bed	1
P.1400	核醫密封校正源	Nuclear sealed calibration source	1
P.1410	核醫心電圖同步器	Nuclear electrocardiograph synchronizer	1
P.1640	放射性影片標記系統	Radiographic film marking system	1

P.1760	診斷用 X 光球管套組件	Diagnostic x-ray tube housing assembly	1
P.1830	放射科病患用支架	Radiologic patient cradle	1
P.1840	放射線影片	Radiographic film	1
P.1910	放射線柵板	Radiographic grid	1
P.1920	放射線造影頭部固定器	Radiographic head holder	1
P.1960	放射線強化螢幕	Radiographic intensifying screen	1
P.1970	放射線心電圖/呼吸器同步器	Radiographic ECG/respirator synchronizer	1
P.2010	醫學影像儲存裝置	Medical image storage device	1
P.2020	醫學影像傳輸裝置	Medical image communication device	1
P.5740	放射核種遠端治療源	Radionuclide teletherapy source	1
P.5780	病患定位光束指示器	Light beam patient position indicator	1
P.6500	個人用防護罩	Personnel protective shield	1
十七、	其他經中央衛生主管機關認定者		
	(OTHER CATEGORIES SPECIFIED BY THE CENTRAL COMPETENT HEALTH AUTHORITY)		
代碼	中文名稱	英文名稱	
B.0002	血液成份壓取裝置	Blood component extractor	1