

第四條附件二修正規定

附件二			
應適用藥物優良製造準則第三編第三章精要模式之品項			
下列品項如已經滅菌者，仍須符合藥物優良製造準則第三編第二章標準模式			
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	白胺酸胺肱酶試驗系統	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'-核甘酸酵素試驗系統	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	噶咯色原質試驗系統	Porphobilinogen test system	1
A.1595	噶咯紫質試驗系統	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	山梨糖去氫醇素試驗系統	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	丙糖磷酸同質醇素試驗系統	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	膽素酯醇素試驗系統	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.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	莢膜組織孢漿菌血清試劑	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	鈎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 chorimeningitis 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.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.0006	連續式被動關節活動器	Continuous Passive Motion Device	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