

Article 4 Annex II of the Regulations for Governing the Management of Medical Device

Annex II		
The manufacturing of the following devices shall comply with Part 3 Chapter 3 Essential Mode of Good Manufacturing Practice (GMP) for Medical Device of the Pharmaceutical Good Manufacturing Practice Regulations.		
The manufacturing of the following devices, which need to be sterilized, shall comply with Part 3 Chapter 2 Standard Mode of Good Manufacturing Practice (GMP) for Medical Device of the Pharmaceutical Good Manufacturing Practice Regulations.		
	CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES (Devices with measurement function are excluded)	
Classification Number	Device Name	Class
A.1030	Alanine amino transferase (ALT/SGPT) test system	1
A.1040	Aldolase test system	1
A.1060	Delta-aminolevulinic acid test system	1
A.1065	Ammonia test system	1
A.1075	Androstenedione test system	1
A.1080	Androsterone test system	1
A.1095	Ascorbic acid test system	1
A.1113	Bilirubin (total and unbound) in the neonate test system	1
A.1115	Urinary bilirubin and its conjugates (nonquantitative) test system	1
A.1130	Blood volume test system	1
A.1135	C-peptides of proinsulin test system	1
A.1165	Catecholamines (total) test system	1
A.1175	Cholesterol (total) test system	1
A.1180	Chymotrypsin test system	1
A.1185	Compound S (11-deoxycortisol) test system	1
A.1190	Copper test system	1
A.1195	Corticoids test system	1
A.1200	Corticosterone test system	1
A.1210	Creatine test system	1
A.1240	Cystine test system	1
A.1245	Dehydroepiandrosterone (free and sulfate) test system	1
A.1250	Deoxycorticosterone test system	1
A.1255	2,3-Diphosphoglyceric acid test system	1

A.1260	Estradiol test system	1
A.1265	Estriol test system	1
A.1270	Estrogens (total, in pregnancy) test system	1
A.1275	Estrogens (total, nonpregnancy) test system	1
A.1280	Estrone test system	1
A.1285	Etiocholanolone test system	1
A.1290	Fatty acids test system	1
A.1300	Follicle-stimulating hormone test system	1
A.1305	Formiminoglutamic acid (FIGLU) test system	1
A.1310	Galactose test system	1
A.1320	Gastric acidity test system	1
A.1325	Gastrin test system	1
A.1330	Globulin test system	1
A.1335	Glucagon test system	1
A.1360	Gamma-glutamyl transpeptidase and isoenzymes test system	1
A.1365	Glutathione test system	1
A.1370	Human growth hormone test system	1
A.1375	Histidine test system	1
A.1380	Hydroxybutyric dehydrogenase test system	1
A.1385	17-Hydroxycorticosteroids (17-ketogenic steroids) test system	1
A.1390	5-Hydroxyindole acetic acid/serotonin test system	1
A.1395	17-Hydroxyprogesterone test system	1
A.1400	Hydroxyproline test system	1
A.1405	Immunoreactive insulin test system	1
A.1410	Iron (non-heme) test system	1
A.1415	Iron-binding capacity test system	1
A.1420	Isocitric dehydrogenase test system	1
A.1430	17-Ketosteroids test system	1
A.1435	Ketones (nonquantitative) test system	1
A.1440	Lactate dehydrogenase test system	1
A.1450	Lactic acid test system	1
A.1460	Leucine aminopeptidase test system	1
A.1465	Lipase test system	1
A.1470	Lipid (total) test system	1
A.1475	Lipoprotein test system	1
A.1485	Luteinizing hormone test system	1
A.1490	Lysozyme (muramidase) test system	1
A.1495	Magnesium test system	1
A.1500	Malic dehydrogenase test system	1
A.1505	Mucopolysaccharides(nonquantitative) test system	1

A.1510	Nitrite nonquantitative test system	1
A.1515	Nitrogen amino-nitrogen test system	1
A.1520	5'-Nucleotidase test system	1
A.1530	Plasma oncometry test system	1
A.1535	Ornithine carbamyl transferase test system	1
A.1540	Osmolality test system	1
A.1542	Oxalate test system	1
A.1550	Urinary pH (nonquantitative) test system	1
A.1560	Urinary phenylketones (nonquantitative) test system	1
A.1565	6-Phosphogluconate dehydrogenase test system	1
A.1570	Phosphohexose isomerase test system	1
A.1575	Phospholipid test system	1
A.1580	Phosphorus (inorganic) test system	1
A.1590	Porphobilinogen test system	1
A.1595	Porphyrins test system	1
A.1605	Pregnanediol test system	1
A.1610	Pregnanetriol test system	1
A.1615	Pregnenolone test system	1
A.1620	Progesterone test system	1
A.1625	Prolactin (lactogen) test system	1
A.1630	Protein (fractionation) test system	1
A.1635	Total protein test system	1
A.1640	Protein-bound iodine test system	1
A.1645	Urinary protein or albumin (nonquantitative) test system	1
A.1650	Pyruvate kinase test system	1
A.1655	Pyruvic acid test system	1
A.1660	Quality control material (assayed and unassayed)	1
A.1670	Sorbitol dehydrogenase test system	1
A.1680	Testosterone test system	1
A.1705	Triglyceride test system	1
A.1710	Total triiodothyronine test system	1
A.1715	Triiodothyronine uptake test system	1
A.1720	Triose phosphate isomerase test system	1
A.1725	Trypsin test system	1
A.1730	Free tyrosine test system	1
A.1775	Uric acid test system	1
A.1780	Urinary calculi (stones) test system	1
A.1785	Urinary urobilinogen (nonquantitative) test system	1
A.1790	Uroporphyrin test system	1
A.1795	Vanilmandelic acid test system	1

A.1805	Vitamin A test system	1
A.1815	Vitamin E test system	1
A.1820	Xylose test system	1
A.2270	Thin-layer chromatography system for clinical use	1
A.3050	Breath-alcohol test system	1
A.3110	Antimony test system	1
A.3120	Arsenic test system	1
A.3220	Carbon monoxide test system	1
A.3240	Cholinesterase test system	1
A.3600	Mercury test system	1
A.3750	Quinine test system	1
A.3850	Sulfonamide test system	1
二、	HEMATOLOGY AND PATHOLOGY DEVICES (Devices with measurement function are excluded)	
Classification Number	Classification Name	Class
B.1850	Dye and chemical solution stains	1
B.1860	Immunohistochemistry reagents and kits	1
B.2220	Synthetic cell and tissue culture media and components	1
B.2260	Chromosome culture kit	1
B.2280	Cultured animal and human cells	1
B.2360	Mycoplasma detection media and components	1
B.2875	Balanced salt solutions or formulations	1
B.4020	Analyte specific reagents	1
B.4400	Enzyme preparations	1
B.5800	Automated sedimentation rate device	1
B.6100	Bleeding time device	1
B.6150	Capillary blood collection tube	1
B.6160	Manual blood cell counting device	1
B.6400	Hematocrit measuring device	1
B.6600	Osmotic fragility test	1
B.6700	Erythrocyte sedimentation rate test	1
B.7040	Adenosine triphosphate release assay	1
B.7660	Leukocyte alkaline phosphatase test	1
B.7675	Leukocyte peroxidase test	1
B.7900	Thromboplastin generation test	1
B.8200	Blood cell diluent	1
B.8500	Lymphocyte separation medium	1

B.8540	Red cell lysing reagent	1
B.8950	Russell viper venom reagent	1
B.9050	Blood bank supplies	1
B.9125	Vacuum-assisted blood collection system	1
B.9225	Cell-freezing apparatus and reagents for in vitro diagnostic use	1
B.9320	Copper sulfate solution for specific gravity determinations	1
B.9550	Lectins and protectins	1
B.9575	Environmental chamber for storage of platelet concentrate	1
B.9600	Potentiating media for in vitro diagnostic use	1
B.9700	Blood storage refrigerator and blood storage freezer	1
B.9750	Heat-sealing device	1
三、	IMMUNOLOGY AND MICROBIOLOGY DEVICES (Devices with measurement function are excluded)	
Classification Number	Classification Name	Class
C.0003	Helicobacter spp. Serological reagents	1
C.2160	Coagulase plasma	1
C.2300	Multipurpose culture medium	1
C.2320	Differential culture medium	1
C.2330	Enriched culture medium	1
C.2350	Microbiological assay culture Medium	1
C.2360	Selective culture medium	1
C.2390	Transport culture medium	1
C.2450	Supplement for culture media	1
C.2480	Quality control kit for culture media	1
C.2500	Microtiter diluting and dispensing device	1
C.2580	Gas-generating device	1
C.2600	Wood's fluorescent lamp	1
C.2660	Microorganism differentiation and identification device	1
C.2900	Microbiological specimen collection and transport device	1
C.3010	Acinetobacter calcoaceticus serological reagents	1
C.3020	Adenovirus serological reagents	1
C.3035	Arizona spp.serological reagents	1
C.3040	Aspergillus spp. serological reagents	1
C.3060	Blastomyces dermatitidis serological reagents	1
C.3065	Bordetella spp. serological reagents	1
C.3085	Brucella spp. serological reagents	1
C.3110	Campylobacter fetus serological reagents	1

C.3120	Chlamydia serological reagents	1
C.3125	Citrobacter spp.serological reagents	1
C.3135	Coccidioides immitis serological reagents	1
C.3140	Corynebacterium spp.serological reagents	1
C.3145	Coxsackievirus serological reagents	1
C.3165	Cryptococcus neoformans serological reagents	1
C.3200	Echinococcus spp. serological reagents	1
C.3205	Echovirus serological reagents	1
C.3220	Entamoeba histolytica serological reagents	1
C.3235	Epstein-Barr virus serological reagents	1
C.3240	Equine encephalomyelitis virus serological reagents	1
C.3250	Erysipelothrix rhusiopathiae serological reagents	1
C.3255	Escherichia coli serological reagents	1
C.3270	Flavobacterium spp. serological reagents	1
C.3280	Francisella tularensis serological reagents	1
C.3300	Haemophilus spp. serological reagents	1
C.3320	Histoplasma capsulatum serological reagents	1
C.3330	Influenza virus serological reagents	1
C.3340	Klebsiella spp. serological reagents	1
C.3350	Leptospira spp. serological reagents	1
C.3355	Listeria spp. serological reagents	1
C.3360	Lymphocytic choriomeningitis virus serological reagents	1
C.3370	Mycobacterium tuberculosis immunofluorescent reagents	1
C.3375	Mycoplasma spp. serological reagents	1
C.3380	Mumps virus serological reagents	1
C.3400	Parainfluenza virus serological reagents	1
C.3405	Poliovirus serological reagents	1
C.3410	Proteus spp. (Weil-Felix) serological reagents	1
C.3415	Pseudomonas spp. serological reagents	1
C.3470	Reovirus serological reagents	1
C.3480	Respiratory syncytial virus serological reagents	1
C.3490	Rhinovirus serological reagents	1
C.3500	Rickettsia serological reagents	1
C.3520	Rubeola (measles) virus serological reagents	1
C.3550	Salmonella spp. serological reagents	1
C.3600	Schistosoma spp. serological reagents	1
C.3630	Serratia spp. serological reagents	1
C.3660	Shigella spp.serological reagents	1
C.3680	Sporothrix schenckii serological reagents	1
C.3700	Staphylococcus aureus serological reagents	1
C.3720	Streptococcus spp. exoenzyme reagents	1

C.3740	Streptococcus spp. serological reagents	1
C.3850	Trichinella spiralis serological reagents	1
C.3870	Trypanosoma spp. serological reagents	1
C.3930	Vibrio cholerae serological reagents	1
C.4100	Complement reagent	1
C.5040	Albumin immunological test system	1
C.5060	Prealbumin immunological test system	1
C.5065	Human allotypic marker immunological test system	1
C.5160	Beta-globulin immunological test system	1
C.5170	Breast milk immunological test system	1
C.5200	Carbonic anhydrase B and C immunological test system	1
C.5220	Cohn fraction II immunological test system	1
C.5230	Colostrum immunological test system	1
C.5320	Properdin factor B immunological test system	1
C.5330	Factor XIII, A, S, immunological test system	1
C.5360	Cohn fraction IV immunological test system	1
C.5370	Cohn fraction V immunological test system	1
C.5380	Free secretory component immunological test system	1
C.5400	Alpha-globulin immunological test system	1
C.5420	Alpha-1-glycoproteins immunological test system	1
C.5425	Alpha-2-glycoproteins immunological test system	1
C.5430	Beta-2-glycoprotein I immunological test system	1
C.5440	Beta-2-glycoprotein III immunological test system	1
C.5460	Haptoglobin immunological test system	1
C.5490	Hemopexin immunological test system	1
C.5520	Immunoglobulin G (Fab fragment specific) immunological test system	1
C.5530	Immunoglobulin G (Fc fragment specific) immunological test system	1
C.5540	Immunoglobulin G (Fd fragment specific) immunological test system	1
C.5560	Lactic dehydrogenase immunological test system	1
C.5570	Lactoferrin immunological test system	1
C.5590	Lipoprotein X immunological test system	1
C.5700	Whole human plasma or serum immunological test system	1
C.5715	Plasminogen immunological test system	1
C.5735	Prothrombin immunological test system	1
C.5765	Retinol-binding protein immunological test system	1
C.5800	Seminal fluid (sperm) immunological test system	1
C.5860	Total spinal fluid immunological test system	1
C.5890	Inter-alpha trypsin inhibitor immunological test system	1
四、	ANESTHESIOLOGY DEVICES	

Classification Number	Classification Name	Class
D.1100	Arterial blood sampling kit	1
D.1575	Gas collection vessel	1
D.1910	Esophageal stethoscope	1
D.1930	Stethoscope head	1
D.5100	Nasopharyngeal airway	1
D.5110	Oropharyngeal airway	1
D.5220	Blow bottle	1
D.5240	Anesthesia breathing circuit	1
D.5280	Breathing tube support	1
D.5300	Carbon dioxide absorbent	1
D.5310	Carbon dioxide absorber	1
D.5320	Reservoir bag	1
D.5340	Nasal oxygen cannula	1
D.5350	Nasal oxygen catheter	1
D.5375	Heat and moisture condenser (artificial nose)	1
D.5460	Therapeutic humidifier for home use	1
D.5530	Flexible laryngoscope	1
D.5540	Rigid laryngoscope	1
D.5550	Anesthetic gas mask	1
D.5560	Gas mask head strap	1
D.5570	Nonrebreathing mask	1
D.5580	Oxygen mask	1
D.5590	Scavenging mask	1
D.5600	Venturi mask	1
D.5620	Breathing mouthpiece	1
D.5640	Medicinal nonventilatory nebulizer (atomizer)	1
D.5675	Rebreathing device	1
D.5700	Nonpowered oxygen tent	1
D.5770	Tracheal tube fixation device	1
D.5780	Tube introduction forceps	1
D.5790	Tracheal tube stylet	1
D.5810	Airway connector	1
D.5860	Pressure tubing and accessories	1
D.5975	Ventilator tubing	1
D.5995	Tee drain (water trap)	1
D.6810	Tracheobronchial suction catheter	1
D.6885	Medical gas yoke assembly	1



五、	CARDIOVASCULAR DEVICES		
Classification Number	Classification Name		Class
E.1875	Stethoscope		1
E.3650	Pacemaker polymeric mesh bag		1
E.3730	Pacemaker service tools		1
E.3935	Prosthetic heart valve holder		1
E.4200	Cardiopulmonary bypass accessory equipment		1
E.4500	Cardiovascular surgical instruments		1
六、	DENTAL DEVICES		
Classification Number	Classification Name		Class
F.0001	Retraction cord		1
F.1730	Electrode gel for pulp tester		1
F.1820	Dental x-ray exposure alignment device		1
F.1840	Dental x-ray position indicating device		1
F.1850	Lead-lined position indicator		1
F.2050	Dental sonography device		1
F.2060	Jaw tracking device		1
F.3100	Dental amalgamator		1
F.3110	Dental amalgam capsule		1
F.3130	Preformed anchor		1
F.3140	Resin applicator		1
F.3165	Precision attachment		1
F.3240	Dental bur		1
F.3275	Dental cement		1
F.3285	Preformed clasp		1
F.3330	Preformed crown		1
F.3350	Gold or stainless steel cusp		1
F.3360	Preformed cusp		1
F.3400	Karaya and sodium borate with or without acacia denture adhesive		1
F.3410	Ethylene oxide homopolymer and/or carboxymethyl-cellulose sodium denture adhesive		1
F.3450	Ethylene oxide homopolymer and/or karaya denture adhesive		1

F.3490	Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive	1
F.3520	OTC denture cleanser	1
F.3530	Mechanical denture cleaner	1
F.3540	OTC denture cushion or pad	1
F.3580	Preformed gold denture tooth	1
F.3670	Resin impression tray material	1
F.3740	Retentive and splinting pin	1
F.3810	Root canal post	1
F.3830	Endodontic paper point	1
F.3840	Endodontic silver point	1
F.3850	Gutta percha	1
F.3900	Posterior artificial tooth with a metal insert	1
F.3910	Backing and facing for an artificial tooth	1
F.3980	Endosseous dental implant accessories	1
F.4130	Intraoral dental drill	1
F.4200	Dental handpiece and accessories	1
F.4535	Dental diamond instrument	1
F.4565	Dental hand instrument	1
F.4620	Fiber optic dental light	1
F.4630	Dental operating light	1
F.4730	Dental injecting needle	1
F.5410	Orthodontic appliance and accessories	1
F.5525	Preformed tooth positioner	1
F.6010	Abrasive device and accessories	1
F.6030	Oral cavity abrasive polishing agent	1
F.6050	Saliva absorber	1
F.6100	Anesthetic warmer	1
F.6140	Articulation paper	1
F.6200	Base plate shellac	1
F.6250	Dental chair and accessories	1
F.6290	Prophylaxis cup	1
F.6300	Rubber dam and accessories	1
F.6475	Heat source for bleaching teeth	1
F.6570	Impression tube	1
F.6640	Dental operative unit and accessories	1
F.6710	Boiling water sterilizer	1
F.6870	Disposable fluoride tray	1
F.6880	Preformed impression tray	1
F.6890	Intraoral dental wax	1

七、	EAR,NOSE,AND THORAT DEVICES		
Classification Number	Classification Name		Class
G.1100	Earphone cushion for audiometric testing		1
G.1600	Olfactory test device		1
G.1925	Toynbee diagnostic tube		1
G.3300	Hearing aid		1
G.3540	Prosthesis modification instrument for ossicular replacement surgery		1
G.3900	Nasal dilator		1
G.4100	Epistaxis balloon		1
G.4140	Ear, nose, and throat bur		1
G.4175	Nasopharyngeal catheter		1
G.4350	Ear, nose, and throat fiberoptic light source and carrier		1
G.4420	Ear, nose, and throat manual surgical instrument		1
G.4750	Laryngostroboscope		1
G.4770	Otoscope		1
G.4780	Intranasal splint		1
G.4800	Bone Particle collector		1
G.5220	Ear, nose, and throat drug administration device		1
G.5300	Ear, nose, and throat examination and treatment unit		1
G.5550	Powered nasal irrigator		1
G.5800	External nasal splint		1
G.5840	Antistammering device		1
八、	GASTROENTROLOGY-UROLOGY DEVICES		
Classification Number	Classification Name		Class
H.1075	Gastroenterology-urology biopsy instrument		1
H.4530	Gastroenterolgy-urology fiberoptic retractor		1
H.4560	Ribdam		1
H.4590	Interlocking urethral sound		1
H.4730	Manual gastroenterolgoy-urology surgical instrument and accessories		1
H.4890	Urological table and accessories		1
H.5030	Continent ileostomy catheter		1
H.5090	Suprapubic urological catheter and accessories		1

H.5130	Urological catheter and accessories	1
H.5160	Urological clamp for males	1
H.5210	Enema kit	1
H.5450	Rectal dilator	1
H.5520	Urethral dilator	1
H.5900	Ostomy pouch and accessories	1
H.5970	Hernia support	1
H.5980	Gastrointestinal tube and accessories	1
九、	GENERAL AND PLASTIC SURGERY DEVICES	
Classification Number	Classification Name	Class
I.1800	Speculum and accessories	1
I.3250	External facial fracture fixation appliance	1
I.3750	External prosthesis adhesive	1
I.3800	External aesthetic restoration prosthesis	1
I.3900	Inflatable extremity splint	1
I.3910	Noninflatable extremity splint	1
I.3925	Plastic surgery kit and accessories	1
I.4014	Nonresorbable gauze/sponge for external use	1
I.4018	Hydrophilic wound dressing	1
I.4020	Occlusive wound/burn dressing	1
I.4025	Silicone sheeting	1
I.4022	Hydrogel wound dressing and burn dressing	1
I.4040	Surgical apparel(Surgical gowns and surgical masks)	1
I.4100	Organ bag	1
I.4160	Surgical camera and accessories	1
I.4200	Introduction/drainage catheter and Accessories	1
I.4320	Removable skin clip	1
I.4370	Surgical drape and drape accessories	1
I.4380	Drape adhesive	1
I.4440	Eye pad	1
I.4450	Nonabsorbable gauze for internal use	1
I.4470	Surgeon's gloving cream	1
I.4660	Skin marker	1
I.4680	Nonpowered,single patient,portable suction apparatus	1
I.4700	Surgical microscope and accessories	1
I.4730	Surgical skin degreaser or adhesive tape solvent	1
I.4760	Removable skin staple	1

I.4800	Manual surgical instrument for general use	1
I.4820	Surgical instrument motors and accessories/attachments	1
I.4930	Suture retention device	1
I.4950	Manual operating table and accessories and manual operating chair and accessories	1
I.4960	Operating tables and accessories and operating chairs and accessories	1
I.5350	Needle-type epilator	1
I.5360	Tweezer-type epilator	1
I.5900	Nonpneumatic tourniquet	1
I.5910	Pneumatic tourniquet	1
十、	GENERAL HOSPITAL AND PERSONAL USE DEVICES	
Classification Number	Classification Name	Class
J.2200	Liquid crystal forehead temperature strip	1
J.2900	Clinical color change thermometer	1
J.5075	Elastic bandage	1
J.5090	Liquid bandage	1
J.5110	Hydraulic adjustable hospital bed	1
J.5120	Manual adjustable hospital bed	1
J.5150	Nonpowered flotation therapy mattress	1
J.5160	Therapeutic medical binder	1
J.5180	Burn sheet	1
J.5210	Intravascular catheter securement Device	1
J.5240	Medical adhesive tape and adhesive bandage	1
J.5270	Neonatal eye pad	1
J.5300	Medical absorbent fiber	1
J.5420	Pressure infusor for an I.V. bag	1
J.5510	Non-AC-powered patient lift	1
J.5550	Alternating pressure air flotation Mattress	1
J.5560	Temperature regulated water Mattress	1
J.5680	Pediatric position holder	1
J.5740	Suction snakebite kit	1
J.5780	Medical support stocking	1
J.5820	Therapeutic scrotal support	1
J.5950	Umbilical occlusion device	1
J.6025	Absorbent tipped applicator	1
J.6150	Ultrasonic cleaner for medical Instruments	1
J.6230	Tongue depressor	1

J.6280	Medical insole	1
J.6375	Patient lubricant	1
J.6430	Liquid medication dispenser	1
J.6450	Skin pressure protectors	1
J.6775	Powered patient transfer device	1
J.6785	Manual patient transfer device	1
J.6820	Medical disposable scissors	1
J.6890	General purpose disinfectants	1
J.6900	Hand-carried stretcher	1
J.6910	Wheeled stretcher	1
J.6960	Irrigating syringe	1
J.6970	Liquid crystal vein locator	1
J.6980	Vein stabilizer	1
J.6990	Infusion stand	1
十一、	NEUROLOGICAL DEVICES	
Classification Number	Classification Name	Class
K.1200	Two-point discriminator	1
K.1500	Esthesiometer	1
K.1525	Tuning fork	1
K.4030	Skull plate anvil	1
K.4060	Ventricular cannula	1
K.4125	Neurosurgical chair	1
K.4190	Clip forming/cutting instrument	1
K.4200	Clip removal instrument	1
K.4325	Cranial drill handpiece(brace)	1
K.4500	Cranioplasty material forming instrument	1
K.4525	Microsurgical instrument	1
K.4535	Nonpowered neurosurgical instrument	1
K.4545	Shunt system implantation instrument	1
K.4600	Leukotome	1
K.4650	Neurosurgical suture needle	1
K.4750	Skull punch	1
K.4900	Skullplate screwdriver	1
十二、	OBSTETRICAL AND GYNECOLOGICAL DEVICES	

Classification Number	Classification Name	Class
L.1640	Culdoscope and accessories	1
L.1690	Hysteroscope and accessories	1
L.1700	Hysteroscopic insufflator	1
L.1720	Gynecologic laparoscope and accessories	1
L.1730	Laparoscopic insufflator	1
L.2900	Fetal stethoscope	1
L.4520	Obstetric-gynecologic general manual instrument	1
L.4530	Obstetric-gynecologic specialized manual instrument	1
L.5900	Therapeutic vaginal douche apparatus	1
L.5920	Vaginal insufflator	1
L.6190	Assisted reproductive microscopes and microscope accessories	1
十三、	OPHTHALMIC DEVICES	
Classification Number	Classification Name	Class
M.1040	Ocular esthesiometer	1
M.1070	Anomaloscope	1
M.1090	Haidlinger brush	1
M.1140	Ophthalmic chair	1
M.1160	Color vision plate illuminator	1
M.1200	Optokinetic drum	1
M.1250	Euthyscope	1
M.1290	Fixation device	1
M.1320	Fornixscope	1
M.1350	Keratoscope	1
M.1375	Bagolini lens	1
M.1380	Diagnostic condensing lens	1
M.1390	Flexible diagnostic Fresnel lens	1
M.1395	Diagnostic Hruby fundus lens	1
M.1400	Maddox lens	1
M.1405	Ophthalmic trial lens set	1
M.1410	Ophthalmic trial lens clip	1
M.1435	Maxwell spot	1
M.1460	Stereopsis measuring instrument	1
M.1605	Perimeter	1
M.1650	Ophthalmic bar prism	1
M.1655	Ophthalmic Fresnel prism	1
M.1660	Gonioscopic prism	1

M.1665	Ophthalmic rotary prism	1
M.1680	Ophthalmic projector	1
M.1690	Pupillograph	1
M.1700	Pupillometer	1
M.1750	Skiascopic rack	1
M.1790	Nearpoint ruler	1
M.1800	Schirmer strip	1
M.1810	Tangent screen (campimeter)	1
M.1870	Stereoscope	1
M.1905	Nystagmus tape	1
M.1910	Spectacle dissociation test system	1
M.1940	Tonometer sterilizer	1
M.1945	Transilluminator	1
M.3200	Artificial eye	1
M.4070	Powered corneal burr	1
M.4250	Ophthalmic electrolysis unit	1
M.4300	Intraocular lens guide	1
M.4335	Operating headlamp	1
M.4350	Manual ophthalmic surgical instrument	1
M.4360	Ocular surgery irrigation device	1
M.4370	Keratome	1
M.4570	Ophthalmic surgical marker	1
M.4750	Ophthalmic eye shield	1
M.4770	Ophthalmic operating spectacles (loupes)	1
M.5600	Ptosis crutch	1
M.5844	Corrective spectacle lens	1
十四、	ORTHOPEDIC DEVICES	
Classification Number	Classification Name	Class
N.1100	Arthroscope	1
N.3000	Bone cap	1
N.4200	Cement dispenser	1
N.4210	Cement mixer for clinical use	1
N.4220	Cement monomer vapor evacuator	1
N.4230	Cement ventilation tube	1
N.4540	Orthopedic manual surgical instrument	1
N.5850	Nonpowered orthopedic traction apparatus and accessories	1
N.5890	Noninvasive traction component	1



N.5940	Cast component	1
N.5960	Cast removal instrument	1
N.5980	Manual cast application and removal instrument	1
十五、	PHYSICAL MEDICINE DEVICES	
Classification Number	Classification Name	Class
O.0003	Topical refrigerant (vapocoolant)	1
O.0006	Continuous Passive Motion Device	1
O.1175	Electrode cable	1
O.3025	Prosthetic and orthotic accessory	1
O.3075	Cane	1
O.3100	Mechanical chair	1
O.3150	Crutch	1
O.3175	Flotation cushion	1
O.3410	External limb orthotic component	1
O.3420	External limb prosthetic component	1
O.3475	Limb orthosis	1
O.3490	Truncal orthosis	1
O.3500	External assembled lower limb prosthesis	1
O.3520	Plinth	1
O.3640	Arm sling	1
O.3665	Congenital hip dislocation abduction splint	1
O.3675	Denis Brown splint	1
O.3750	Mechanical table	1
O.3760	Powered table	1
O.3825	Mechanical walker	1
O.3850	Mechanical wheelchair	1
O.3930	Mobile wheelchair elevator	1
O.5125	Nonpowered sitz bath	1
O.5150	Powered patient transport	1
O.5160	Air-fluidized bed	1
O.5170	Powered flotation therapy bed	1
O.5180	Manual patient rotation bed	1
O.5225	Powered patient rotation bed	1
O.5700	Cold pack	1
O.5710	Hot or cold disposable pack	1
O.5720	Water circulating hot or cold pack	1

O.5730	Moist heat pack	1
O.5765	Pressure-applying device	1
O.5925	Traction accessory	1
十六、	RADIOLOGY DEVICES	
Classification Number	Classification Name	Class
P.1350	Nuclear scanning bed	1
P.1400	Nuclear sealed calibration source	1
P.1410	Nuclear electrocardiograph synchronizer	1
P.1640	Radiographic film marking system	1
P.1760	Diagnostic x-ray tube housing assembly	1
P.1830	Radiologic patient cradle	1
P.1840	Radiographic film	1
P.1910	Radiographic grid	1
P.1920	Radiographic head holder	1
P.1960	Radiographic intensifying screen	1
P.1970	Radiographic ECG/respirator synchronizer	1
P.2010	Medical image storage device	1
P.2020	Medical image communication device	1
P.5740	Radionuclide teletherapy source	1
P.5780	Light beam patient position indicator	1
P.6500	Personnel protective shield	1
十七、	OTHER CATERORIES SPECIFIED BY THE CENTRAL COMPETENT HEALTH AUTHORITY	
Classification Number	Classification Name	Class
B.0002	Blood component extractor	1