

1. PERALATAN KIMIA KLINIK DAN TOKSIKOLOGI KLINIK

1.1 TES KIMIA KLINIK

§ 862.1030	Alanine amino transferase (ALT/SGPT) test system	
§ 862.1040	Aldolase test system	
§ 862.1060	Delta-aminolevulinic acid test system	
§ 862.1065	Ammonia test system	
§ 862.1075	Androstenedione test system	
§ 862.1080	Androsterone test system	
§ 862.1095	Ascorbic acid test system	
§ 862.1115	Urinary bilirubin and its conjugates (nonquantitative) test system	
§ 862.1130	Blood volume test system	
§ 862.1135	C-peptides of proinsulin test system	
§ 862.1165	Catecholamines (total) test system.	
§ 862.1175	Cholesterol (total) test system	
§ 862.1180	Chymotrypsin test system	
§ 862.1185	Compound S (11-deoxycortisol) test system	
§ 862.1190	Copper test system	
§ 862.1195	Corticoids test system	
§ 862.1200	Corticosterone test system	
§ 862.1210	Creatine test system	
§ 862.1240	Cystine test system	
§ 862.1245	Dehydroepiandrosterone (free and sulfate) test system	
§ 862.1250	Desoxycorticosterone test system	
§ 862.1255	2,3-Diphosphoglyceric acid test system	
§ 862.1260	Estradiol test system	
§ 862.1265	Estriol test system	
§ 862.1270	Estrogens (total, in pregnancy) test system.	
§ 862.1275	Estrogens (total, nonpregnancy) test system	
§ 862.1280	Estrone test system	
§ 862.1285	Etiocolanalone test system.	
§ 862.1290	Fatty acids test system	
§ 862.1300	Follicle-stimulating hormone test system.	
§ 862.1305	Formiminoglutamic acid (FIGLU) test system	
§ 862.1310	Galactose test system	
§ 862.1320	Gastric acidity test system	
§ 862.1325	Gastrin test system	
§ 862.1330	Globulin test system	
§ 862.1335	Glucagon test system.	
§ 862.1360	Gamma-glutamyl transpeptidase and isoenzymes test system	
§ 862.1365	Glutathione test system	
§ 862.1370	Human growth hormone test system	
§ 862.1375	Histidine test system	
§ 862.1380	Hydroxybutyric dehydrogenase test system.	
§ 862.1385	17-Hydroxycorticosteroids (17-ketogenic steroids) test system	
§ 862.1390	5-Hydroxyindole acetic acid/serotonin test system	
§ 862.1395	17-Hydroxyprogesterone test system.	
§ 862.1400	Hydroxyproline test system	
§ 862.1405	Immunoreactive insulin test system.	
§ 862.1410	Iron (non-heme) test system	
§ 862.1415	Iron-binding capacity test system	
§ 862.1420	Isocitric dehydrogenase test system	

§ 862.1430	17-Ketosteroids test system	I
§ 862.1435	Ketones (nonquantitative) test system	I
§ 862.1450	Lactic acid test system	I
§ 862.1460	Leucine aminopeptidase test system.	I
§ 862.1465	Lipase test system	I
§ 862.1470	Lipid (total) test system	I
§ 862.1475	Lipoprotein test system	I
§ 862.1485	Luteinizing hormone test system	I
§ 862.1490	Lysozyme (muramidase) test system	I
§ 862.1495	Magnesium test system	I
§ 862.1500	Malic dehydrogenase test system	I
§ 862.1505	Mucopolysaccharides (nonquantitative) test system	I
§ 862.1510	Nitrite (nonquantitative) test system	I
§ 862.1520	5'-Nucleotidase test system	I
§ 862.1530	Plasma oncometry test system	I
§ 862.1535	Ornithine carbamyl transferase test system	I
§ 862.1540	Osmolality test system	I
§ 862.1542	Oxalate test system	I
§ 862.1550	Urinary pH (nonquantitative) test system	I
§ 862.1560	Urinary phenylketones (nonquantitative) test system.	I
§ 862.1565	6-Phosphogluconate dehydrogenase test system.	I
§ 862.1570	Phosphohexose isomerase test system.	I
§ 862.1575	Phospholipid test system.	I
§ 862.1580	Phosphorus (inorganic) test system	I
§ 862.1590	Porphobilinogen test system	I
§ 862.1595	Porphyryns test system	I
§ 862.1605	Pregnanediol test system	I
§ 862.1610	Pregnanetriol test system.	I
§ 862.1615	Pregnenolone test system	I
§ 862.1620	Progesterone test system	I
§ 862.1625	Prolactin (lactogen) test system	I
§ 862.1630	Protein (fractionation) test system	I
§ 862.1640	Protein-bound iodine test system	I
§ 862.1645	Urinary protein or albumin (nonquantitative) test system	I
§ 862.1650	Pyruvate kinase test system	I
§ 862.1655	Pyruvic acid test system	I
§ 862.1660	Quality control material (assayed and unassayed).	I
§ 862.1670	Sorbitol dehydrogenase test system	I
§ 862.1680	Testosterone test system	I
§ 862.1705	Triglyceride test system	I
§ 862.1720	Triose phosphate isomerase test system	I
§ 862.1725	Trypsin test system	I
§ 862.1730	Free tyrosine test system.	I
§ 862.1775	Uric acid test system.	I
§ 862.1780	Urinary calculi (stones) test system	I
§ 862.1785	Urinary urobilinogen (nonquantitative) test system	I
§ 862.1790	Uroporphyrin test system	I
§ 862.1795	Vanilmandelic acid test system	I
§ 862.1805	Vitamin A test system	I
§ 862.1815	Vitamin E test system	I
§ 862.1820	Xylose test system.	I
§ 862.1020	Acid phosphatase (total or prostatic) test system	II

§ 862.1025	Adrenocorticotrophic hormone (ACTH) test system	II
§ 862.1035	Albumin test system.	II
§ 862.1045	Aldosterone test system	II
§ 862.1050	Alkaline phosphatase or isoenzymes test system	II
§ 862.1055	Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry	II
§ 862.1070	Amylase test system	II
§ 862.1085	Angiotensin I and renin test system	II
§ 862.1090	Angiotensin converting enzyme (A.C.E.) test system	II
§ 862.1100	Aspartate amino transferase (AST/SGOT) test system	II
§ 862.1110	Bilirubin (total or direct) test system	II
§ 862.1113	Bilirubin (total and unbound) in the neonate test system	II
§ 862.1117	B-type natriuretic peptide test system	II
§ 862.1118	Biotinidase test system	II
§ 862.1120	Blood gases (PO2) and blood pH test system	II
§ 862.1140	Calcitonin test system	II
§ 862.1145	Calcium test system	II
§ 862.1150	Calibrator.	II
§ 862.1155	Human chorionic gonadotropin (HCG) test system	II
§ 862.1160	Bicarbonate/carbon dioxide test system	II
§ 862.1170	Chloride test system	II
§ 862.1177	Cholyglycine test system	II
§ 862.1187	Conjugated sulfolithocholic acid (SLCG) test system	II
§ 862.1205	Cortisol (hydrocortisone and hydroxycorticosterone) test system	II
§ 862.1215	Creatine phosphokinase/creatine kinase or isoenzymes test system.	II
§ 862.1225	Creatinine test system	II
§ 862.1230	Cyclic AMP test system	II
§ 862.1235	Cyclosporine test system	II
§ 862.1295	Folic acid test system	II
§ 862.1315	Galactose-1-phosphate uridyl transferase test system	II
§ 862.1340	Urinary glucose (nonquantitative) test system	II
§ 862.1345	Glucose test system	II
§ 862.1377	Urinary homocystine (nonquantitative) test system	II
§ 862.1440	Lactate dehydrogenase test system	II
§ 862.1445	Lactate dehydrogenase isoenzymes test system	II
§ 862.1455	Lecithin/sphingomyelin ratio in amniotic fluid test system	II
§ 862.1509	Methylmalonic acid (nonquantitative) test system	II
§ 862.1515	Nitrogen (amino-nitrogen) test system	II
§ 862.1545	Parathyroid hormone test system	II
§ 862.1555	Phenylalanine test system	II
§ 862.1585	Human placental lactogen test system	II
§ 862.1600	Potassium test system	II
§ 862.1635	Total protein test system	II
§ 862.1665	Sodium test system	II
§ 862.1675	Blood specimen collection device	II
§ 862.1678	Tacrolimus test system	II
§ 862.1685	Thyroxine-binding globulin test system	II
§ 862.1690	Thyroid stimulating hormone test system	II
§ 862.1695	Free thyroxine test system	II
§ 862.1700	Total thyroxine test system.	II
§ 862.1710	Total triiodothyronine test system.	II
§ 862.1715	Triiodothyronine uptake test system	II
§ 862.1770	Urea nitrogen test system	II

§ 862.1810	Vitamin B ₁₂ test system.	
§ 862.1825	Vitamin D test system	

1.2 PERALATAN LABORATORIUM KLINIK

§ 862.2050	General purpose laboratory equipment labeled or promoted for a specific medical use	
§ 862.2100	Calculator/data processing module for clinical use	
§ 862.2140	Centrifugal chemistry analyzer for clinical use	
§ 862.2150	Continuous flow sequential multiple chemistry analyzer for clinical use	
§ 862.2160	Discrete photometric chemistry analyzer for clinical use	
§ 862.2170	Micro chemistry analyzer for clinical use	
§ 862.2230	Chromatographic separation material for clinical use	
§ 862.2250	Gas liquid chromatography system for clinical use.	
§ 862.2260	High pressure liquid chromatography system for clinical use	
§ 862.2270	Thin-layer chromatography system for clinical use.	
§ 862.2300	Colorimeter, photometer, or spectrophotometer for clinical use	
§ 862.2310	Clinical sample concentrator.	
§ 862.2320	Beta or gamma counter for clinical use.	
§ 862.2400	Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.	
§ 862.2485	Electrophoresis apparatus for clinical use	
§ 862.2500	Enzyme analyzer for clinical use.	
§ 862.2540	Flame emission photometer for clinical use	
§ 862.2560	Fluorometer for clinical use	
§ 862.2680	Microtitrator for clinical use	
§ 862.2700	Nephelometer for clinical use.	
§ 862.2720	Plasma oncometer for clinical use	
§ 862.2730	Osmometer for clinical use	
§ 862.2750	Pipetting and diluting system for clinical use.	
§ 862.2800	Refractometer for clinical use	
§ 862.2850	Atomic absorption spectrophotometer for clinical use	
§ 862.2860	Mass spectrometer for clinical use.	
§ 862.2900	Automated urinalysis system	
§ 862.2920	Plasma viscometer for clinical use.	
§ 862.2570	Instrumentation for clinical multiplex test systems	

1.3 TES TOKSIKOLOGI KLINIK

§ 862.3050	Breath-alcohol test system	
§ 862.3110	Antimony test system	
§ 862.3120	Arsenic test system	
§ 862.3220	Carbon monoxide test system	
§ 862.3240	Cholinesterase test system	
§ 862.3280	Clinical toxicology control material.	
§ 862.3600	Mercury test system	
§ 862.3750	Quinine test system	
§ 862.3850	Sulfonamide test system	
§ 862.3030	Acetaminophen test system	
§ 862.3035	Amikacin test system	
§ 862.3040	Alcohol test system	
§ 862.3080	Breath nitric oxide test system	
§ 862.3100	Amphetamine test system	

§ 862.3150	Barbiturate test system	
§ 862.3170	Benzodiazepine test system	
§ 862.3200	Clinical toxicology calibrator	
§ 862.3250	Cocaine and cocaine metabolite test system	
§ 862.3270	Codeine test system	
§ 862.3300	Digitoxin test system	
§ 862.3320	Digoxin test system	
§ 862.3350	Diphenylhydantoin test system	
§ 862.3360	Drug metabolizing enzyme genotyping system	
§ 862.3380	Ethosuximide test system	
§ 862.3450	Gentamicin test system	
§ 862.3520	Kanamycin test system	
§ 862.3550	Lead test system	
§ 862.3555	Lidocaine test system	
§ 862.3560	Lithium test system	
§ 862.3580	Lysergic acid diethylamide (LSD) test system.	
§ 862.3610	Methamphetamine test system	
§ 862.3620	Methadone test system	
§ 862.3630	Methaqualone test system	
§ 862.3640	Morphine test system	
§ 862.3645	Neuroleptic drugs radioreceptor assay test system.	
§ 862.3650	Opiate test system	
§ 862.3660	Phenobarbital test system	
§ 862.3670	Phenothiazine test system	
§ 862.3680	Primidone test system	
§ 862.3700	Propoxyphene test system	
§ 862.3830	Salicylate test system	
§ 862.3840	Sirolimus test system	
§ 862.3870	Cannabinoid test system	
§ 862.3880	Theophylline test system	
§ 862.3900	Tobramycin test system	
§ 862.3910	Tricyclic antidepressant drugs test system	
§ 862.3950	Vancomycin test system	

2. PERALATAN HEMATOLOGI DAN PATOLOGI

2.1 PEWARNAAN BIOLOGIKAL

§ 864.1850	Dye and chemical solution stains	I
§ 864.1860	Immunohistochemistry reagents and kits.	II

2.2 PRODUK KULTUR SEL DAN JARINGAN

§ 864.2220	Synthetic cell and tissue culture media and components	I
§ 864.2240	Cell and tissue culture supplies and equipment	I
§ 864.2260	Chromosome culture kit.	I
§ 864.2280	Cultured animal and human cells	I
§ 864.2360	Mycoplasma detection media and components	I
§ 864.2800	Animal and human sera.	I
§ 864.2875	Balanced salt solutions or formulations	I

2.3 PERALATAN DAN AKSESORI PATOLOGI

§ 864.3010	Tissue processing equipment	I
§ 864.3250	Specimen transport and storage container	I
§ 864.3260	OTC test sample collection systems for drugs of abuse testing	I
§ 864.3300	Cytocentrifuge	I
§ 864.3400	Device for sealing microsections	I
§ 864.3600	Microscopes and accessories	I
§ 864.3800	Automated slide stainer	I
§ 864.3875	Automated tissue processor	I

2.4 PEREAKSI PENYEDIAAN SPECIMEN

§ 864.4010	General purpose reagent	I
§ 864.4400	Enzyme preparations	I
§ 864.4020	Analyte specific reagents	II

2.5 PERALATAN HEMATOLOGI OTOMATIS DAN SEMI OTOMATIS

§ 864.5240	Automated blood cell diluting apparatus	I
§ 864.5350	Microsedimentation centrifuge	I
§ 864.5800	Automated sedimentation rate device	I
§ 864.5850	Automated slide spinner	I
§ 864.5200	Automated cell counter	II
§ 864.5220	Automated differential cell counter	II
§ 864.5260	Automated cell-locating device	II
§ 864.5300	Red cell indices device	II
§ 864.5400	Coagulation instrument.	II
§ 864.5425	Multipurpose system for in vitro coagulation studies.	II
§ 864.5600	Automated hematocrit instrument.	II
§ 864.5620	Automated hemoglobin system	II
§ 864.5680	Automated heparin analyzer	II

§ 864.5700	Automated platelet aggregation system	
§ 864.5950	Blood volume measuring device	

2.6 PERALATAN HEMATOLOGI MANUAL

§ 864.6150	Capillary blood collection tube	
§ 864.6160	Manual blood cell counting device	
§ 864.6600	Osmotic fragility test	
§ 864.6700	Erythrocyte sedimentation rate test.	
§ 864.6100	Bleeding time device	
§ 864.6400	Hematocrit measuring device	
§ 864.6550	Occult blood test	
§ 864.6650	Platelet adhesion test.	
§ 864.6675	Platelet aggregometer	

2.7 PAKET HEMATOLOGI

§ 864.7040	Adenosine triphosphate release assay	
§ 864.7660	Leukocyte alkaline phosphatase test	
§ 864.7675	Leukocyte peroxidase test	
§ 864.7900	Thromboplastin generation test.	
§ 864.7060	Antithrombin III assay	
§ 864.7100	Red blood cell enzyme assay	
§ 864.7140	Activated whole blood clotting time tests	
§ 864.7250	Erythropoietin assay.	
§ 864.7275	Euglobulin lysis time tests	
§ 864.7280	Factor V Leiden DNA mutation detection systems.	
§ 864.7290	Factor deficiency test.	
§ 864.7300	Fibrin monomer paracoagulation test	
§ 864.7320	Fibrinogen/fibrin degradation products assay	
§ 864.7340	Fibrinogen determination system	
§ 864.7360	Erythrocytic glucose-6-phosphate dehydrogenase assay.	
§ 864.7375	Glutathione reductase assay.	
§ 864.7400	Hemoglobin A ₂ assay.	
§ 864.7415	Abnormal hemoglobin assay	
§ 864.7425	Carboxyhemoglobin assay.	
§ 864.7440	Electrophoretic hemoglobin analysis system	
§ 864.7455	Fetal hemoglobin assay	
§ 864.7470	Glycosylated hemoglobin assay	
§ 864.7490	Sulfhemoglobin assay.	
§ 864.7500	Whole blood hemoglobin assays	
§ 864.7525	Heparin assay.	
§ 864.7695	Platelet factor 4 radioimmunoassay	
§ 864.7720	Prothrombin consumption test	
§ 864.7735	Prothrombin-proconvertin test and thrombotest	
§ 864.7750	Prothrombin time test	
§ 864.7825	Sickle cell test.	
§ 864.7875	Thrombin time test	
§ 864.7925	Partial thromboplastin time tests	

2.8 PEREAKSI HEMATOLOGI

§ 864.8200	Blood cell diluent.	I
§ 864.8500	Lymphocyte separation medium	I
§ 864.8540	Red cell lysing reagent	I
§ 864.8950	Russell viper venom reagent.	I
§ 864.8100	Bothrops atrox reagent	II
§ 864.8150	Calibrator for cell indices	II
§ 864.8165	Calibrator for hemoglobin or hematocrit measurement	II
§ 864.8175	Calibrator for platelet counting	II
§ 864.8185	Calibrator for red cell and white cell counting	II
§ 864.8625	Hematology quality control mixture	II

2.9 PRODUK YANG DIGUNAKAN DALAM PEMBUATAN SEDIAAN DARAH DAN SEDIAAN BERASAL DARI DARAH

§ 864.9050	Blood bank supplies	I
§ 864.9125	Vacuum-assisted blood collection system	I
§ 864.9185	Blood grouping view box	I
§ 864.9195	Blood mixing devices and blood weighing devices	I
§ 864.9225	Cell-freezing apparatus and reagents for in vitro diagnostic use	I
§ 864.9275	Blood bank centrifuge for in vitro diagnostic use.	I
§ 864.9320	Copper sulfate solution for specific gravity determinations.	I
§ 864.9750	Heat-sealing device	I
§ 864.9100	Empty container for the collection and processing of blood and blood components	II
§ 864.9145	Processing system for frozen blood	II
§ 864.9160	Blood group substances of nonhuman origin for in vitro diagnostic use.	II
§ 864.9175	Automated blood grouping and antibody test system	II
§ 864.9205	Blood and plasma warming device	II
§ 864.9285	Automated cell-washing centrifuge for immuno-hematology	II
§ 864.9300	Automated Coombs test systems	II
§ 864.9400	Stabilized enzyme solution	II
§ 864.9550	Lectins and protectins	II
§ 864.9575	Environmental chamber for storage of platelet concentrate	II
§ 864.9600	Potentiating media for in vitro diagnostic use.	II
§ 864.9650	Quality control kit for blood banking reagents	II
§ 864.9700	Blood storage refrigerator and blood storage freezer	II
§ 864.9875	Transfer set.	II
§ 864.9245	Automated blood cell separator	II

3 . PERALATAN IMUNOLOGI DAN MIKROBIOLOGI

3.1 PERALATAN DIAGNOSTIK

§ 866.1620	Antimicrobial susceptibility test disc	
§ 866.1640	Antimicrobial susceptibility test powder	
§ 866.1645	Fully automated short-term incubation cycle antimicrobial susceptibility system	
§ 866.1700	Culture medium for antimicrobial susceptibility tests	

3.2 PERALATAN MIKROBIOLOGI

§ 866.2050	Staphylococcal typing bacteriophage	
§ 866.2120	Anaerobic chamber	
§ 866.2160	Coagulase plasma.	
§ 866.2170	Automated colony counter	
§ 866.2180	Manual colony counter	
§ 866.2300	Multipurpose culture medium	
§ 866.2320	Differential culture medium	
§ 866.2330	Enriched culture medium	
§ 866.2350	Microbiological assay culture medium	
§ 866.2360	Selective culture medium	
§ 866.2390	Transport culture medium	
§ 866.2440	Automated medium dispensing and stacking device	
§ 866.2450	Supplement for culture media	
§ 866.2480	Quality control kit for culture media	
§ 866.2500	Microtiter diluting and dispensing device	
§ 866.2540	Microbiological incubator	
§ 866.2560	Microbial growth monitor	
§ 866.2580	Gas-generating device	
§ 866.2600	Wood's fluorescent lamp	
§ 866.2660	Microorganism differentiation and identification device	
§ 866.2850	Automated zone reader	
§ 866.2900	Microbiological specimen collection and transport device	
§ 866.2410	Culture medium for pathogenic Neisseria spp	
§ 866.2420	Oxidase screening test for gonorrhoea	

3.3 PEREAKSI SEROLOGI

§ 866.3010	Acinetobacter calcoaceticus serological reagents	
§ 866.3020	Adenovirus serological reagents	
§ 866.3035	Arizona spp. serological reagents	
§ 866.3040	Aspergillus spp. serological reagents	
§ 866.3065	Bordetella spp. serological reagents	
§ 866.3110	Campylobacter fetus serological reagents	
§ 866.3120	Chlamydia serological reagents	
§ 866.3125	Citrobacter spp. serological reagents	

§ 866.3140	Corynebacterium spp. serological reagents	I
§ 866.3145	Coxsackievirus serological reagents	I
§ 866.3200	Echinococcus spp. serological reagents	I
§ 866.3205	Echovirus serological reagents	I
§ 866.3235	Epstein-Barr virus serological reagents	I
§ 866.3240	Equine encephalomyelitis virus serological reagents	I
§ 866.3250	Erysipelothrix rhusiopathiae serological reagents	I
§ 866.3255	Escherichia coli serological reagents	I
§ 866.3270	Flavobacterium spp. serological reagents	I
§ 866.3330	Influenza virus serological reagents	I
§ 866.3340	Klebsiella spp. serological reagents.	I
§ 866.3355	Listeria spp. serological reagents.	I
§ 866.3360	Lymphocytic choriomeningitis virus serological reagents.	I
§ 866.3370	Mycobacterium tuberculosis immunofluorescent reagents	I
§ 866.3375	Mycoplasma spp. serological reagents	I
§ 866.3380	Mumps virus serological reagents	I
§ 866.3400	Parainfluenza virus serological reagents	I
§ 866.3405	Poliovirus serological reagents	I
§ 866.3410	Proteus spp. (Weil-Felix) serological reagents	I
§ 866.3470	Reovirus serological reagents	I
§ 866.3480	Respiratory syncytial virus serological reagents	I
§ 866.3490	Rhinovirus serological reagents	I
§ 866.3500	Rickettsia serological reagents	I
§ 866.3520	Rubeola (measles) virus serological reagents	I
§ 866.3600	Schistosoma spp. serological reagents	I
§ 866.3630	Serratia spp. serological reagents	I
§ 866.3680	Sporothrix schenckii serological reagents	I
§ 866.3700	Staphylococcus aureus serological reagents	I
§ 866.3720	Streptococcus spp. exoenzyme reagents	I
§ 866.3740	Streptococcus spp. serological reagents	I
§ 866.3850	Trichinella spiralis serological reagents	I
§ 866.3870	Trypanosoma spp. serological reagents	I
§ 866.3050	Beta-glucan serological assays	II
§ 866.3060	Blastomyces dermatitidis serological reagents	II
§ 866.3085	Brucella spp. serological reagents	II
§ 866.3135	Coccidioides immitis serological reagents	II
§ 866.3165	Cryptococcus neoformans serological reagents	II
§ 866.3175	Cytomegalovirus serological reagents	II
§ 866.3210	Endotoxin assay	II
§ 866.3220	Entamoeba histolytica serological reagents	II
§ 866.3280	Francisella tularensis serological reagents	II
§ 866.3290	Gonococcal antibody test (GAT)	II
§ 866.3300	Haemophilus spp. serological reagents	II
§ 866.3305	Herpes simplex virus serological reagents	II
§ 866.3310	Hepatitis A virus (HAV) serological assays	II
§ 866.3320	Histoplasma capsulatum serological reagents.	II
§ 866.3332	Reagents for detection of specific novel influenza A viruses	II
§ 866.3350	Leptospira spp. serological reagents	II
§ 866.3390	Neisseria spp. direct serological test reagents	II
§ 866.3402	Plasmodium Species Antigen Detection Assays	II
§ 866.3415	Pseudomonas spp. serological reagents	II
§ 866.3460	Rabiesvirus immunofluorescent reagents	II

§ 866.3510	Rubella virus serological reagents	II
§ 866.3550	Salmonella spp. serological reagents	II
§ 866.3660	Shigella spp. serological reagents	II
§ 866.3780	Toxoplasma gondii serological reagents	II
§ 866.3820	Treponema pallidum nontreponemal test reagents	II
§ 866.3830	Treponema pallidum treponemal test reagents	II
§ 866.3900	Varicella-zoster virus serological reagents	II
§ 866.3930	Vibrio cholerae serological reagents	II
§ 866.3940	West Nile virus serological reagents	II
§ 866.3950	In vitro human immunodeficiency virus (HIV) drug resistance genotype assay.	II

3.4 PERLENGKAPAN DAN PEREAKSI LABORATORIUM IMUNOLOGI

§ 866.4100	Complement reagent	I
§ 866.4500	Immunoelectrophoresis equipment.	I
§ 866.4520	Immunofluorometer equipment	I
§ 866.4540	Immunonephelometer equipment	I
§ 866.4600	Ouchterlony agar plate	I
§ 866.4800	Radial immunodiffusion plate	I
§ 866.4830	Rocket immunoelectrophoresis equipment.	I
§ 866.4900	Support gel	I
§ 866.4070	RNA Preanalytical Systems	II
§ 866.4700	Automated fluorescence in situ hybridization (FISH) enumeration systems	II

3.5 TES IMUNOLOGIKAL

§ 866.5060	Prealbumin immunological test system	I
§ 866.5065	Human allotypic marker immunological test system	I
§ 866.5160	Beta-globulin immunological test system.	I
§ 866.5170	Breast milk immunological test system	I
§ 866.5200	Carbonic anhydrase B and C immunological test system	I
§ 866.5220	Cohn fraction II immunological test system	I
§ 866.5230	Colostrum immunological test system	I
§ 866.5330	Factor XIII, A, S, immunological test system	I
§ 866.5360	Cohn fraction IV immunological test system	I
§ 866.5370	Cohn fraction V immunological test system	I
§ 866.5400	Alpha-globulin immunological test system	I
§ 866.5420	Alpha-1-glycoproteins immunological test system	I
§ 866.5425	Alpha-2-glycoproteins immunological test system	I
§ 866.5430	Beta-2-glycoprotein I immunological test system	I
§ 866.5440	Beta-2-glycoprotein III immunological test system	I
§ 866.5520	Immunoglobulin G (Fab fragment specific) immunological test system.	I
§ 866.5530	Immunoglobulin G (Fc fragment specific) immunological test system	I
§ 866.5540	Immunoglobulin G (Fd fragment specific) immunological test system	I
§ 866.5560	Lactic dehydrogenase immunological test system	I
§ 866.5570	Lactoferrin immunological test system	I
§ 866.5590	Lipoprotein X immunological test system	I
§ 866.5700	Whole human plasma or serum immunological test system	I
§ 866.5715	Plasminogen immunological test system	I
§ 866.5735	Prothrombin immunological test system	I
§ 866.5765	Retinol-binding protein immunological test system	I

§ 866.5800	Seminal fluid (sperm) immunological test system	I
§ 866.5860	Total spinal fluid immunological test system	I
§ 866.5890	Inter-alpha trypsin inhibitor immunological test system	I
§ 866.5180	Fecal calprotectin immunological test system	II
§ 866.5040	Albumin immunological test system	II
§ 866.5080	Alpha-1-antichymotrypsin immunological test system	II
§ 866.5090	Antimitochondrial antibody immunological test system	II
§ 866.5110	Antiparietal antibody immunological test system	II
§ 866.5120	Antismooth muscle antibody immunological test system	II
§ 866.5130	Alpha-1-antitrypsin immunological test system	II
§ 866.5150	Bence-Jones proteins immunological test system	II
§ 866.5210	Ceruloplasmin immunological test system	II
§ 866.5240	Complement components immunological test system	II
§ 866.5250	Complement C ₁ inhibitor (inactivator) immunological test system	II
§ 866.5260	Complement C _{3b} inactivator immunological test system.	II
§ 866.5270	C-reactive protein immunological test system	II
§ 866.5320	Properdin factor B immunological test system	II
§ 866.5340	Ferritin immunological test system	II
§ 866.5350	Fibrinopeptide A immunological test system	II
§ 866.5380	Free secretory component immunological test system	II
§ 866.5460	Haptoglobin immunological test system	II
§ 866.5470	Hemoglobin immunological test system	II
§ 866.5490	Hemopexin immunological test system	II
§ 866.5500	Hypersensitivity pneumonitis immunological test system	II
§ 866.5510	Immunoglobulins A, G, M, D, and E immunological test system	II
§ 866.5550	Immunoglobulin (light chain specific) immunological test system	II
§ 866.5580	Alpha-1-lipoprotein immunological test system	II
§ 866.5600	Low-density lipoprotein immunological test system	II
§ 866.5620	Alpha-2-macroglobulin immunological test system	II
§ 866.5630	Beta-2-microglobulin immunological test system	II
§ 866.5640	Infectious mononucleosis immunological test system	II
§ 866.5680	Myoglobin immunological test system	II
§ 866.5750	Radioallergosorbent (RAST) immunological test system	II
§ 866.5775	Rheumatoid factor immunological test system	II
§ 866.5785	Anti-Saccharomyces cerevisiae (S. cerevisiae) antibody (ASCA) test systems	II
§ 866.5820	Systemic lupus erythematosus immunological test system	II
§ 866.5870	Thyroid autoantibody immunological test system	II
§ 866.5880	Transferrin immunological test system	II
§ 866.5900	Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system.	II
§ 866.5910	Quality control material for cystic fibrosis nucleic acid assays.	II
§ 866.5100	Antinuclear antibody immunological test system	III
§ 866.5660	Multiple autoantibodies immunological test system	III

3.6 TES IMUNOLOGIKAL ANTIGEN TUMOR

§ 866.6010	Tumor-associated antigen immunological test system	II
§ 866.6020	Immunomagnetic circulating cancer cell selection and enumeration system	II
§ 866.6030	AFP-L3% immunological test system	II
§ 866.6040	Gene expression profiling test system for breast cancer prognosis.	II

4. PERALATAN ANESTESI

4.1. PERALATAN ANESTESI DIAGNOSTIK

§ 868.1030	Manual algometer	I
§ 868.1100	Arterial blood sampling kit	I
§ 868.1575	Gas collection vessel.	I
§ 868.1870	Gas volume calibrator.	I
§ 868.1910	Esophageal stethoscope.	I
§ 868.1930	Stethoscope head.	I
§ 868.1965	Switching valve (ploss).	I
§ 868.1975	Water vapor analyzer.	I
§ 868.1040	Powered algometer.	II
§ 868.1075	Argon gas analyzer.	II
§ 868.1150	Indwelling blood carbon dioxide partial pressure (PCO ₂) analyzer.	II
§ 868.1170	Indwelling blood hydrogen ion concentration (pH) analyzer.	II
§ 868.1200	Indwelling blood oxygen partial pressure (PO ₂) analyzer.	II
§ 868.1400	Carbon dioxide gas analyzer.	II
§ 868.1430	Carbon monoxide gas analyzer.	II
§ 868.1500	Enflurane gas analyzer.	II
§ 868.1620	Halothane gas analyzer.	II
§ 868.1640	Helium gas analyzer.	II
§ 868.1670	Neon gas analyzer.	II
§ 868.1690	Nitrogen gas analyzer.	II
§ 868.1700	Nitrous oxide gas analyzer.	II
§ 868.1720	Oxygen gas analyzer.	II
§ 868.1730	Oxygen uptake computer.	II
§ 868.1750	Pressure plethysmograph.	II
§ 868.1760	Volume plethysmograph.	II
§ 868.1780	Inspiratory airway pressure meter.	II
§ 868.1800	Rhinoanemometer.	II
§ 868.1840	Diagnostic spirometer.	II
§ 868.1850	Monitoring spirometer.	II
§ 868.1860	Peak-flow meter for spirometry.	II
§ 868.1880	Pulmonary-function data calculator.	II
§ 868.1890	Predictive pulmonary-function value calculator.	II
§ 868.1900	Diagnostic pulmonary-function interpretation calculator.	II
§ 868.1920	Esophageal stethoscope with electrical conductors.	II
§ 868.1120	Indwelling blood oxyhemoglobin concentration analyzer	III

4.2. PERALATAN ANESTESI PEMANTAUAN

§ 868.2300	Bourdon gauge flowmeter.	I
§ 868.2320	Uncompensated thorpe tube flowmeter.	I
§ 868.2340	Compensated thorpe tube flowmeter.	I

§ 868.2350	Gas calibration flowmeter.	I
§ 868.2610	Gas pressure gauge.	I
§ 868.2620	Gas pressure calibrator.	I
§ 868.2700	Pressure regulator.	I
§ 868.2875	Differential pressure transducer.	I
§ 868.2885	Gas flow transducer.	I
§ 868.2900	Gas pressure transducer.	I
§ 868.2025	Ultrasonic air embolism monitor.	II
§ 868.2375	Breathing frequency monitor.	II
§ 868.2377	Apnea monitor.	II
§ 868.2380	Nitric oxide analyzer.	II
§ 868.2385	Nitrogen dioxide analyzer.	II
§ 868.2480	Cutaneous carbon dioxide (PcCO2) monitor.	II
§ 868.2500	Cutaneous oxygen (PcO2) monitor.	II
§ 868.2550	Pneumotachometer.	II
§ 868.2600	Airway pressure monitor.	II
§ 868.2775	Electrical peripheral nerve stimulator.	II
§ 868.2450	Lung water monitor.	III

4.3. PERALATAN ANASTESI TERAUPETIK

§ 868.5100	Nasopharyngeal airway.	I
§ 868.5110	Oropharyngeal airway.	I
§ 868.5220	Blow bottle.	I
§ 868.5240	Anesthesia breathing circuit.	I
§ 868.5280	Breathing tube support.	I
§ 868.5300	Carbon dioxide absorbent.	I
§ 868.5310	Carbon dioxide absorber.	I
§ 868.5320	Reservoir bag.	I
§ 868.5340	Nasal oxygen cannula.	I
§ 868.5350	Nasal oxygen catheter.	I
§ 868.5365	Posture chair for cardiac or pulmonary treatment.	I
§ 868.5375	Heat and moisture condenser (artificial nose).	I
§ 868.5420	Ether hook.	I
§ 868.5460	Therapeutic humidifier for home use.	I
§ 868.5530	Flexible laryngoscope.	I
§ 868.5540	Rigid laryngoscope.	I
§ 868.5550	Anesthetic gas mask.	I
§ 868.5560	Gas mask head strap.	I
§ 868.5570	Nonrebreathing mask	I
§ 868.5580	Oxygen mask.	I
§ 868.5590	Scavenging mask.	I
§ 868.5600	Venturi mask.	I
§ 868.5620	Breathing mouthpiece.	I
§ 868.5640	Medicinal nonventilatory nebulizer (atomizer).	I
§ 868.5675	Rebreathing device.	I
§ 868.5700	Nonpowered oxygen tent.	I
§ 868.5760	Cuff spreader.	I
§ 868.5770	Tracheal tube fixation device.	I
§ 868.5780	Tube introduction forceps.	I
§ 868.5790	Tracheal tube stylet.	I
§ 868.5795	Tracheal tube cleaning brush.	I

§ 868.5810	Airway connector.	I
§ 868.5820	Dental protector.	I
§ 868.5860	Pressure tubing and accessories.	I
§ 868.5975	Ventilator tubing.	I
§ 868.5995	Tee drain (water trap)	I
§ 868.5090	Emergency airway needle.	II
§ 868.5115	Device to relieve acute upper airway obstruction.	II
§ 868.5120	Anesthesia conduction catheter.	II
§ 868.5130	Anesthesia conduction filter.	II
§ 868.5140	Anesthesia conduction kit.	II
§ 868.5150	Anesthesia conduction needle.	II
§ 868.5160	Gas machine for anesthesia or analgesia.	II
§ 868.5165	Nitric oxide administration apparatus.	II
§ 868.5170	Laryngotracheal topical anesthesia applicator.	II
§ 868.5180	Rocking bed.	II
§ 868.5250	Breathing circuit circulator.	II
§ 868.5260	Breathing circuit bacterial filter.	II
§ 868.5270	Breathing system heater.	II
§ 868.5330	Breathing gas mixer.	II
§ 868.5430	Gas-scavenging apparatus.	II
§ 868.5440	Portable oxygen generator.	II
§ 868.5450	Respiratory gas humidifier.	II
§ 868.5470	Hyperbaric chamber.	II
§ 868.5630	Nebulizer.	II
§ 868.5650	Esophageal obturator.	II
§ 868.5655	Portable liquid oxygen unit.	II
§ 868.5665	Powered percussor.	II
§ 868.5690	Incentive spirometer.	II
§ 868.5710	Electrically powered oxygen tent.	II
§ 868.5720	Bronchial tube.	II
§ 868.5730	Tracheal tube.	II
§ 868.5740	Tracheal/bronchial differential ventilation tube.	II
§ 868.5750	Inflatable tracheal tube cuff.	II
§ 868.5800	Tracheostomy tube and tube cuff.	II
§ 868.5830	Autotransfusion apparatus.	II
§ 868.5870	Nonrebreathing valve.	II
§ 868.5880	Anesthetic vaporizer.	II
§ 868.5895	Continuous ventilator.	II
§ 868.5905	Noncontinuous ventilator (IPPB).	II
§ 868.5915	Manual emergency ventilator.	II
§ 868.5925	Powered emergency ventilator.	II
§ 868.5935	External negative pressure ventilator.	II
§ 868.5955	Intermittent mandatory ventilation attachment.	II
§ 868.5965	Positive end expiratory pressure breathing attachment.	II
§ 868.5400	Electroanesthesia apparatus.	III
§ 868.5610	Membrane lung for long-term pulmonary support.	III

4.4. PERALATAN ANESTESI LAINNYA

§ 868.6100	Anesthetic cabinet, table, or tray.	I
§ 868.6175	Cardiopulmonary emergency cart.	I
§ 868.6225	Nose clip.	I

§ 868.6400	Calibration gas.	I
§ 868.6700	Anesthesia stool	I
§ 868.6810	Tracheobronchial suction catheter.	I
§ 868.6820	Patient position support.	I
§ 868.6885	Medical gas yoke assembly.	I
§ 868.6250	Portable air compressor.	II

5. PERALATAN KARDIOLOGI

5.1 Peralatan Kardiologi Diagnostik

§ 870.1025 - Arrhythmia detector and alarm (including ST-segment measurement and alarm).	II
§ 870.1100 - Blood pressure alarm.	II
§ 870.1110 - Blood pressure computer.	II
§ 870.1120 - Blood pressure cuff.	II
§ 870.1130 - Noninvasive blood pressure measurement system.	II
§ 870.1140 - Venous blood pressure manometer.	II
§ 870.1200 - Diagnostic intravascular catheter.	II
§ 870.1210 - Continuous flush catheter.	II
§ 870.1220 - Electrode recording catheter or electrode recording probe.	II
§ 870.1230 - Fiberoptic oximeter catheter.	II
§ 870.1240 - Flow-directed catheter.	II
§ 870.1250 - Percutaneous catheter.	II
§ 870.1270 - Intracavitary phonocatheter system.	II
§ 870.1280 - Steerable catheter.	II
§ 870.1290 - Steerable catheter control system.	II
§ 870.1300 - Catheter cannula.	II
§ 870.1310 - Vessel dilator for percutaneous catheterization.	II
§ 870.1330 - Catheter guide wire.	II
§ 870.1340 - Catheter introducer.	II
§ 870.1350 - Catheter balloon repair kit.	III
§ 870.1360 - Trace microsphere.	III
§ 870.1370 - Catheter tip occluder.	II
§ 870.1380 - Catheter stylet.	II
§ 870.1390 - Trocar.	II
§ 870.1425 - Programmable diagnostic computer.	II
§ 870.1435 - Single-function, preprogrammed diagnostic computer.	II
§ 870.1450 - Densitometer.	II
§ 870.1650 - Angiographic injector and syringe.	II
§ 870.1660 - Indicator injector.	II
§ 870.1670 - Syringe actuator for an injector.	II
§ 870.1750 - External programmable pacemaker pulse generator.	II
§ 870.1800 - Withdrawal-infusion pump.	II
§ 870.1875 - Stethoscope.	I/II
§ 870.1915 - Thermodilution probe.	II

5.2 Peralatan Kardiologi Pemantauan

§ 870.2050 - Biopotential amplifier and signal conditioner.	II
§ 870.2060 - Transducer signal amplifier and conditioner.	II
§ 870.2100 - Cardiovascular blood flowmeter.	II
§ 870.2120 - Extravascular blood flow probe.	II
§ 870.2300 - Cardiac monitor (including cardiometer and rate alarm).	II
§ 870.2310 - Apex cardiograph (vibrocardiograph).	II
§ 870.2320 - Ballistocardiograph.	II
§ 870.2330 - Echocardiograph.	II
§ 870.2340 - Electrocardiograph.	II
§ 870.2350 - Electrocardiograph lead switching adaptor.	II
§ 870.2360 - Electrocardiograph electrode.	II
§ 870.2370 - Electrocardiograph surface electrode tester.	II
§ 870.2390 - Phonocardiograph.	I
§ 870.2400 - Vectorcardiograph.	II
§ 870.2450 - Medical cathode-ray tube display.	II
§ 870.2600 - Signal isolation system.	I
§ 870.2620 - Line isolation monitor.	I

§ 870.2640 - Portable leakage current alarm.	I
§ 870.2675 - Oscillometer.	II
§ 870.2700 - Oximeter.	II
§ 870.2710 - Ear oximeter.	II
§ 870.2750 - Impedance phlebograph.	II
§ 870.2770 - Impedance plethysmograph.	II
§ 870.2780 - Hydraulic, pneumatic, or photoelectric plethysmographs.	II
§ 870.2800 - Medical magnetic tape recorder.	II
§ 870.2810 - Paper chart recorder.	I
§ 870.2840 - Apex cardiographic transducer.	II
§ 870.2850 - Extravascular blood pressure transducer.	II
§ 870.2855 - Implantable Intra-aneurysm Pressure Measurement System.	II
§ 870.2860 - Heart sound transducer.	II
§ 870.2870 - Catheter tip pressure transducer.	II
§ 870.2880 - Ultrasonic transducer.	II
§ 870.2890 - Vessel occlusion transducer.	II
§ 870.2900 - Patient transducer and electrode cable (including connector).	II
§ 870.2910 - Radiofrequency physiological signal transmitter and receiver.	II
§ 870.2920 - Telephone electrocardiograph transmitter and receiver.	II

5.3 Peralatan Kardiologi Prostetik

§ 870.3250 - Vascular clip.	II
§ 870.3260 - Vena cava clip.	II
§ 870.3300 - Vascular embolization device.	II
§ 870.3375 - Cardiovascular intravascular filter.	II
§ 870.3450 - Vascular graft prosthesis.	II
§ 870.3470 - Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene.	II
§ 870.3535 - Intra-aortic balloon and control system	III
§ 870.3545 - Ventricular bypass (assist) device.	III
§ 870.3600 - External pacemaker pulse generator.	III
§ 870.3610 - Implantable pacemaker pulse generator.	III
§ 870.3620 - Pacemaker lead adaptor.	II
§ 870.3630 - Pacemaker generator function analyzer.	II
§ 870.3640 - Indirect pacemaker generator function analyzer.	II
§ 870.3650 - Pacemaker polymeric mesh bag.	I
§ 870.3670 - Pacemaker charger.	I
§ 870.3680 - Cardiovascular permanent or temporary pacemaker electrode.	II/III
§ 870.3690 - Pacemaker test magnet.	I
§ 870.3700 - Pacemaker programmers.	III
§ 870.3710 - Pacemaker repair or replacement material.	III
§ 870.3720 - Pacemaker electrode function tester.	II
§ 870.3730 - Pacemaker service tools.	I
§ 870.3800 - Annuloplasty ring.	II
§ 870.3850 - Carotid sinus nerve stimulator.	III
§ 870.3925 - Replacement heart valve.	III
§ 870.3935 - Prosthetic heart valve holder.	I
§ 870.3945 - Prosthetic heart valve sizer.	I

5.4 Peralatan Kardiologi Bedah

§ 870.4075 - Endomyocardial biopsy device.	II
§ 870.4200 - Cardiopulmonary bypass accessory equipment.	II
§ 870.4205 - Cardiopulmonary bypass bubble detector.	II
§ 870.4210 - Cardiopulmonary bypass vascular catheter, cannula, or tubing.	II
§ 870.4220 - Cardiopulmonary bypass heart-lung machine console.	II
§ 870.4230 - Cardiopulmonary bypass defoamer.	II
§ 870.4240 - Cardiopulmonary bypass heat exchanger.	II
§ 870.4250 - Cardiopulmonary bypass temperature controller.	II
§ 870.4260 - Cardiopulmonary bypass arterial line blood filter.	II
§ 870.4270 - Cardiopulmonary bypass cardiotomy suction line blood filter.	II
§ 870.4280 - Cardiopulmonary prebypass filter.	II
§ 870.4290 - Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting.	II
§ 870.4300 - Cardiopulmonary bypass gas control unit.	II
§ 870.4310 - Cardiopulmonary bypass coronary pressure gauge.	II
§ 870.4320 - Cardiopulmonary bypass pulsatile flow generator.	III
§ 870.4330 - Cardiopulmonary bypass on-line blood gas monitor.	II
§ 870.4340 - Cardiopulmonary bypass level sensing monitor and/or control.	II

§ 870.4350 - Cardiopulmonary bypass oxygenator.	II
§ 870.4360 - Nonroller-type cardiopulmonary bypass blood pump.	III
§ 870.4370 - Roller-type cardiopulmonary bypass blood pump.	II
§ 870.4380 - Cardiopulmonary bypass pump speed control.	II
§ 870.4390 - Cardiopulmonary bypass pump tubing.	II
§ 870.4400 - Cardiopulmonary bypass blood reservoir.	II
§ 870.4410 - Cardiopulmonary bypass in-line blood gas sensor.	II
§ 870.4420 - Cardiopulmonary bypass cardiotomy return sucker.	II
§ 870.4430 - Cardiopulmonary bypass intracardiac suction control.	II
§ 870.4450 - Vascular clamp.	II
§ 870.4475 - Surgical vessel dilator.	II
§ 870.4500 - Cardiovascular surgical instruments.	I
§ 870.4875 - Intraluminal artery stripper.	II
§ 870.4885 - External vein stripper.	II

5.5 Peralatan Kardiologi Terapetik

§ 870.5050 - Patient care suction apparatus.	II
§ 870.5150 - Embolectomy catheter.	II
§ 870.5175 - Septostomy catheter.	II
§ 870.5200 - External cardiac compressor.	III
§ 870.5225 - External counter-pulsating device.	III
§ 870.5300 - DC-defibrillator (including paddles).	II/III
§ 870.5310 - Automated external defibrillator.	III
§ 870.5325 - Defibrillator tester.	II
§ 870.5550 - External transcutaneous cardiac pacemaker (noninvasive).	II
§ 870.5800 - Compressible limb sleeve.	II
§ 870.5900 - Thermal regulating system.	II
§ 870.5925 - Automatic rotating tourniquet.	II

6. PERALATAN GIGI

6.1 Peralatan Gigi Diagnostik

§ 872.1500 - Gingival fluid measurer.	I
§ 872.1720 - Pulp tester.	II
§ 872.1730 - Electrode gel for pulp testers.	I
§ 872.1740 - Caries detection device.	II
§ 872.1745 - Laser fluorescence caries detection device.	II
§ 872.1800 - Extraoral source x-ray system.	II
§ 872.1810 - Intraoral source x-ray system.	II
§ 872.1820 - Dental x-ray exposure alignment device.	I
§ 872.1830 - Cephalometer.	II
§ 872.1840 - Dental x-ray position indicating device.	I
§ 872.1850 - Lead-lined position indicator.	I
§ 872.1870 - Sulfide detection device.	II
§ 872.1905 - Dental x-ray film holder.	I
§ 872.2050 - Dental sonography device.	I/II
§ 872.2060 - Jaw tracking device.	I/II

Subpart C [Reserved]

6.2 Peralatan Gigi Prostetik

§ 872.3050 - Amalgam alloy.	II
§ 872.3060 - Noble metal alloy.	II
§ 872.3080 - Mercury and alloy dispenser.	I
§ 872.3100 - Dental amalgamator.	I
§ 872.3110 - Dental amalgam capsule.	I
§ 872.3130 - Preformed anchor.	I
§ 872.3140 - Resin applicator.	I
§ 872.3150 - Articulator.	I
§ 872.3165 - Precision attachment.	I
§ 872.3200 - Resin tooth bonding agent.	II
§ 872.3220 - Facebow.	I
§ 872.3240 - Dental bur.	I
§ 872.3250 - Calcium hydroxide cavity liner.	II
§ 872.3260 - Cavity varnish.	II
§ 872.3275 - Dental cement.	I/II
§ 872.3285 - Preformed clasp.	I
§ 872.3300 - Hydrophilic resin coating for dentures.	II
§ 872.3310 - Coating material for resin fillings.	II
§ 872.3330 - Preformed crown.	I
§ 872.3350 - Gold or stainless steel cusp.	I
§ 872.3360 - Preformed cusp.	I
§ 872.3400 - Karaya and sodium borate with or without acacia denture adhesive.	I/III
§ 872.3410 - Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive.	I
§ 872.3420 - Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.	III
§ 872.3450 - Ethylene oxide homopolymer and/or karaya denture adhesive.	I
§ 872.3480 - Polyacrylamide polymer (modified cationic) denture adhesive.	III
§ 872.3490 - Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.	I
§ 872.3500 - Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive.	III
§ 872.3520 - OTC denture cleanser.	I
§ 872.3530 - Mechanical denture cleaner.	I
§ 872.3540 - OTC denture cushion or pad.	I/II

§ 872.3560 - OTC denture reliner.	II
§ 872.3570 - OTC denture repair kit.	II
§ 872.3580 - Preformed gold denture tooth.	I
§ 872.3590 - Preformed plastic denture tooth.	II
§ 872.3600 - Partially fabricated denture kit.	II
§ 872.3630 - Endosseous dental implant abutment.	II
§ 872.3640 - Endosseous dental implant.	II/III
§ 872.3645 - Subperiosteal implant material.	II
§ 872.3660 - Impression material.	II
§ 872.3661 - Optical Impression Systems for CAD/CAM.	II
§ 872.3670 - Resin impression tray material.	I
§ 872.3680 - Polytetrafluoroethylene (PTFE) vitreous carbon materials.	II
§ 872.3690 - Tooth shade resin material.	II
§ 872.3700 - Dental mercury.	I
§ 872.3710 - Base metal alloy.	II
§ 872.3730 - Pantograph.	I
§ 872.3740 - Retentive and splinting pin.	I
§ 872.3750 - Bracket adhesive resin and tooth conditioner.	II
§ 872.3760 - Denture relining, repairing, or rebasing resin.	II
§ 872.3765 - Pit and fissure sealant and conditioner.	II
§ 872.3770 - Temporary crown and bridge resin.	II
§ 872.3810 - Root canal post.	I
§ 872.3820 - Root canal filling resin.	II/III
§ 872.3830 - Endodontic paper point.	I
§ 872.3840 - Endodontic silver point.	I
§ 872.3850 - Gutta percha.	I
§ 872.3890 - Endodontic stabilizing splint.	II
§ 872.3900 - Posterior artificial tooth with a metal insert.	I
§ 872.3910 - Backing and facing for an artificial tooth.	I
§ 872.3920 - Porcelain tooth.	II
§ 872.3930 - Bone grafting material.	II/III
§ 872.3940 - Total temporomandibular joint prosthesis.	III
§ 872.3950 - Glenoid fossa prosthesis.	III
§ 872.3960 - Mandibular condyle prosthesis.	III
§ 872.3970 - Interarticular disc prosthesis (interpositional implant).	III
§ 872.3980 - Endosseous dental implant accessories.	I

6.3 Peralatan Gigi Bedah

§ 872.4120 - Bone cutting instrument and accessories.	II
§ 872.4130 - Intraoral dental drill.	I
§ 872.4200 - Dental handpiece and accessories.	I
§ 872.4465 - Gas-powered jet injector.	II
§ 872.4475 - Spring-powered jet injector.	II
§ 872.4535 - Dental diamond instrument.	I
§ 872.4565 - Dental hand instrument.	I
§ 872.4600 - Intraoral ligature and wire lock.	II
§ 872.4620 - Fiber optic dental light.	I
§ 872.4630 - Dental operating light.	I
§ 872.4730 - Dental injecting needle.	I
§ 872.4760 - Bone plate.	II
§ 872.4840 - Rotary scaler.	II
§ 872.4850 - Ultrasonic scaler.	II
§ 872.4880 - Intraosseous fixation screw or wire.	II
§ 872.4920 - Dental electrosurgical unit and accessories.	II

6.4 Peralatan Gigi Terapeutik

§ 872.5410 - Orthodontic appliance and accessories.	I
§ 872.5470 - Orthodontic plastic bracket.	II
§ 872.5500 - Extraoral orthodontic headgear.	II
§ 872.5525 - Preformed tooth positioner.	I
§ 872.5550 - Teething ring.	I/II
§ 872.5570 - Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.	II
§ 872.5580 - Oral rinse to reduce the adhesion of dental plaque.	II

6.5 Peralatan Gigi Lainnya

§ 872.6010 - Abrasive device and accessories.	I
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§ 872.6030 - Oral cavity abrasive polishing agent.	I
§ 872.6050 - Saliva absorber.	I
§ 872.6070 - Ultraviolet activator for polymerization.	II
§ 872.6080 - Airbrush.	II
§ 872.6100 - Anesthetic warmer.	I
§ 872.6140 - Articulation paper.	I
§ 872.6200 - Base plate shellac.	I
§ 872.6250 - Dental chair and accessories.	I
§ 872.6290 - Prophylaxis cup.	I
§ 872.6300 - Rubber dam and accessories.	I
§ 872.6350 - Ultraviolet detector.	II
§ 872.6390 - Dental floss.	I
§ 872.6475 - Heat source for bleaching teeth.	I
§ 872.6510 - Oral irrigation unit.	I
§ 872.6570 - Impression tube.	I
§ 872.6640 - Dental operative unit and accessories.	I
§ 872.6650 - Massaging pick or tip for oral hygiene.	I
§ 872.6660 - Porcelain powder for clinical use.	II
§ 872.6670 - Silicate protector.	I
§ 872.6710 - Boiling water sterilizer.	I
§ 872.6730 - Endodontic dry heat sterilizer.	III
§ 872.6770 - Cartridge syringe.	II
§ 872.6855 - Manual toothbrush.	I
§ 872.6865 - Powered toothbrush.	I
§ 872.6870 - Disposable fluoride tray.	I
§ 872.6880 - Preformed impression tray.	I
§ 872.6890 - Intraoral dental wax.	I

7. PERALATAN TELINGA, HIDUNG DAN TENGGOROKAN (THT)

7.1 PERALATAN THT DIAGNOSTIK	
§ 874.1050 - Audiometer.	II
§ 874.1060 - Acoustic chamber for audiometric testing.	I
§ 874.1070 - Short increment sensitivity index (SISI) adapter.	I
§ 874.1080 - Audiometer calibration set.	I
§ 874.1090 - Auditory impedance tester.	II
§ 874.1100 - Earphone cushion for audiometric testing.	I
§ 874.1120 - Electronic noise generator for audiometric testing.	II
§ 874.1325 - Electroglottograph.	II
§ 874.1500 - Gustometer.	I
§ 874.1600 - Olfactory test device.	II
§ 874.1800 - Air or water caloric stimulator.	I
§ 874.1820 - Surgical nerve stimulator/locator.	II
§ 874.1925 - Toynbee diagnostic tube.	I
Subpart C [Reserved]	
7.2 PERALATAN THT PROSTETIK	
§ 874.3300 - Hearing Aid.	I/II
§ 874.3310 - Hearing aid calibrator and analysis system.	II
§ 874.3320 - Group hearing aid or group auditory trainer.	II
§ 874.3330 - Master hearing aid.	II
§ 874.3375 - Battery-powered artificial larynx.	I
§ 874.3400 - Tinnitus masker.	II
§ 874.3430 - Middle ear mold.	II
§ 874.3450 - Partial ossicular replacement prosthesis.	II
§ 874.3495 - Total ossicular replacement prosthesis.	II
§ 874.3540 - Prosthesis modification instrument for ossicular replacement surgery.	I
§ 874.3620 - Ear, nose, and throat synthetic polymer material.	II
§ 874.3695 - Mandibular implant facial prosthesis.	II
§ 874.3730 - Laryngeal prosthesis (Taub design).	II
§ 874.3760 - Sacculotomy tack (Cody tack)	II
§ 874.3820 - Endolymphatic shunt.	II
§ 874.3850 - Endolymphatic shunt tube with valve.	II
§ 874.3880 - Tympanostomy tube.	II
§ 874.3900 - Nasal dilator.	I
§ 874.3930 - Tympanostomy tube with semipermeable membrane.	II
§ 874.3950 - Transcutaneous air conduction hearing aid system.	II
7.3 PERALATAN THT BEDAH	
§ 874.4100 - Epistaxis balloon.	I
§ 874.4140 - Ear, nose, and throat bur.	I
§ 874.4175 - Nasopharyngeal catheter.	I
§ 874.4250 - Ear, nose, and throat electric or pneumatic surgical drill.	II
§ 874.4350 - Ear, nose, and throat fiberoptic light source and carrier.	I
§ 874.4420 - Ear, nose, and throat manual surgical instrument.	I
§ 874.4490 - Argon laser for otology, rhinology, and laryngology.	II
§ 874.4500 - Ear, nose, and throat microsurgical carbon dioxide laser.	II
§ 874.4680 - Bronchoscope (flexible or rigid) and accessories.	II
§ 874.4710 - Esophagoscope (flexible or rigid) and accessories.	II
§ 874.4720 - Mediastinoscope and accessories.	II
§ 874.4750 - Laryngostroboscope.	I
§ 874.4760 - Nasopharyngoscope (flexible or rigid) and accessories.	II
§ 874.4770 - Otoscope.	I
§ 874.4780 - Intranasal splint.	I

§ 874.4800 - Bone particle collector.	I
7.4 PERALATAN THT TERAPETIK	
§ 874.5220 - Ear, nose, and throat drug administration device.	I
§ 874.5300 - Ear, nose, and throat examination and treatment unit.	I
§ 874.5350 - Suction antichoke device.	III
§ 874.5370 - Tongs antichoke device.	III
§ 874.5550 - Powered nasal irrigator.	I
§ 874.5800 - External nasal splint.	I
§ 874.5840 - Antistammering device.	I

8. PERALATAN GASTROENTEROLOGI DAN UROLOGI (GU)

8.1 Peralatan GU Diagnostik	
§ 876.1075 - Gastroenterology-Urology Biopsy Instrument	I/II
§ 876.1300 - Ingestible telemetric gastrointestinal capsule imaging System	II
§ 876.1400 - Stomach pH Electrode	I
§ 876.1500 - Endoscope and Accessories	I/II
§ 876.1620 - Urodynamics measurement system	II
§ 876.1725 - Gastrointestinal motility monitoring system	II
§ 876.1735 - Electrogastrography system	II
§ 876.1800 - Urine flow or volume measuring system	II
	II
8.2 Peralatan GU Pematauan	
§ 876.2040 - Enuresis alarm.	II
8.3 Peralatan GU Prostetik	
§ 876.3350 - Penile inflatable implant.	III
§ 876.3630 - Penile rigidity implant.	II
§ 876.3750 - Testicular prosthesis.	III
8.4 Peralatan GU Bedah	
§ 876.4020 - Fiberoptic light ureteral catheter.	II
§ 876.4270 - Colostomy rod.	II
§ 876.4300 - Endoscopic electrosurgical unit and accessories.	II
§ 876.4370 - Gastroenterology-urology evacuator.	I/II
§ 876.4400 - Hemorrhoidal ligator.	II
§ 876.4480 - Electrohydraulic lithotripter.	II
§ 876.4500 - Mechanical lithotripter.	II
§ 876.4530 - Gastroenterology-urology fiberoptic retractor.	I
§ 876.4560 - Ribdam.	I
§ 876.4590 - Interlocking urethral sound.	I
§ 876.4620 - Ureteral stent.	II
§ 876.4650 - Water jet renal stone dislodger system.	II
§ 876.4680 - Ureteral stone dislodger.	II
§ 876.4730 - Manual gastroenterology-urology surgical instrument and accessories.	I
§ 876.4770 - Urethrotome.	II
§ 876.4890 - Urological table and accessories.	I/II
8.5 Peralatan GU Terapeutik	
§ 876.5010 - Biliary catheter and accessories.	II
§ 876.5020 - External penile rigidity devices.	II
§ 876.5030 - Continent ileostomy catheter.	I
§ 876.5090 - Suprapubic urological catheter and accessories.	I/II
§ 876.5130 - Urological catheter and accessories.	I/II
§ 876.5160 - Urological clamp for males.	I
§ 876.5210 - Enema kit.	I
§ 876.5220 - Colonic irrigation system.	II/III
§ 876.5250 - Urine collector and accessories.	I/II
§ 876.5270 - Implanted electrical urinary continence device.	III
§ 876.5280 - Implanted mechanical/hydraulic urinary continence device.	III
§ 876.5310 - Nonimplanted, peripheral electrical continence device.	II
§ 876.5320 - Nonimplanted electrical continence device.	II
§ 876.5365 - Esophageal dilator.	II
§ 876.5450 - Rectal dilator.	I
§ 876.5470 - Ureteral dilator.	II
§ 876.5520 - Urethral dilator.	I/II

§ 876.5540 - Blood access device and accessories.	I/II/III
§ 876.5600 - Sorbent regenerated dialysate delivery system for hemodialysis.	II
§ 876.5630 - Peritoneal dialysis system and accessories.	II
§ 876.5665 - Water purification system for hemodialysis.	II
§ 876.5820 - Hemodialysis system and accessories.	I/II
§ 876.5830 - Hemodialyzer with disposable insert (Kiil type).	II
§ 876.5860 - High permeability hemodialysis system.	II
§ 876.5870 - Sorbent hemoperfusion system.	III
§ 876.5880 - Isolated kidney perfusion and transport system and accessories.	II
§ 876.5885 - Tissue culture media for human ex vivo tissue and cell culture processing applications	II
§ 876.5895 - Ostomy irrigator.	II
§ 876.5900 - Ostomy pouch and accessories.	I
§ 876.5920 - Protective garment for incontinence.	I
§ 876.5955 - Peritoneo-venous shunt.	II
§ 876.5970 - Hernia support.	I
§ 876.5980 - Gastrointestinal tube and accessories.	I/II
§ 876.5990 - Extracorporeal shock wave lithotripter.	II

9. PERALATAN RUMAH SAKIT UMUM DAN PERORANGAN

Subpart C--General Hospital and Personal Use Monitoring Devices	
§ 880.2200 - Liquid crystal forehead temperature strip.	2
§ 880.2400 - Bed-patient monitor.	1
§ 880.2420 - Electronic monitor for gravity flow infusion systems.	2
§ 880.2460 - Electrically powered spinal fluid pressure monitor.	2
§ 880.2500 - Spinal fluid manometer.	2
§ 880.2700 - Stand-on patient scale.	1
§ 880.2720 - Patient scale.	1
§ 880.2740 - Surgical sponge scale.	1
§ 880.2800 - Sterilization process indicator.	2
§ 880.2900 - Clinical color change thermometer.	1
§ 880.2910 - Clinical electronic thermometer.	2
§ 880.2920 - Clinical mercury thermometer.	2
§ 880.2930 - Apgar timer.	1
Subparts D-E [Reserved]	
Subpart F--General Hospital and Personal Use Therapeutic Devices	
§ 880.5025 - I.V. container.	2
§ 880.5045 - Medical recirculating air cleaner.	2
§ 880.5075 - Elastic bandage.	1
§ 880.5090 - Liquid bandage.	1
§ 880.5100 - AC-powered adjustable hospital bed.	2
§ 880.5110 - Hydraulic adjustable hospital bed.	1
§ 880.5120 - Manual adjustable hospital bed.	1
§ 880.5130 - Infant radiant warmer.	2
§ 880.5140 - Pediatric hospital bed.	2
§ 880.5150 - Nonpowered flotation therapy mattress.	1
§ 880.5160 - Therapeutic medical binder.	1
§ 880.5180 - Burn sheet.	1
§ 880.5200 - Intravascular catheter.	2
§ 880.5210 - Intravascular catheter securement device.	1
§ 880.5240 - Medical adhesive tape and adhesive bandage.	1
§ 880.5270 - Neonatal eye pad.	1
§ 880.5300 - Medical absorbent fiber.	1
§ 880.5400 - Neonatal incubator.	2
§ 880.5410 - Neonatal transport incubator.	2
§ 880.5420 - Pressure infusor for an I.V. bag.	1
§ 880.5430 - Nonelectrically powered fluid injector.	2
§ 880.5440 - Intravascular administration set.	2
§ 880.5450 - Patient care reverse isolation chamber.	2
§ 880.5475 - Jet lavage.	2
§ 880.5500 - AC-powered patient lift.	2
§ 880.5510 - Non-AC-powered patient lift.	1
§ 880.5550 - Alternating pressure air flotation mattress.	2
§ 880.5560 - Temperature regulated water mattress.	1
§ 880.5570 - Hypodermic single lumen needle.	2
§ 880.5580 - Acupuncture needle.	2
§ 880.5630 - Nipple shield.	1
§ 880.5640 - Lamb feeding nipple.	1
§ 880.5680 - Pediatric position holder.	1
§ 880.5700 - Neonatal phototherapy unit.	2
§ 880.5725 - Infusion pump.	2
§ 880.5740 - Suction snakebite kit.	1

§ 880.5760 - Chemical cold pack snakebite kit.	3
§ 880.5780 - Medical support stocking.	2
§ 880.5820 - Therapeutic scrotal support.	1
§ 880.5860 - Piston syringe.	2
§ 880.5950 - Umbilical occlusion device.	1
§ 880.5960 - Lice removal kit.	1
§ 880.5965 - Subcutaneous, implanted, intravascular infusion port and catheter.	2
§ 880.5970 - Percutaneous, implanted, long-term intravascular catheter.	2
Subpart G--General Hospital and Personal Use Miscellaneous Devices	
§ 880.6025 - Absorbent tipped applicator.	1
§ 880.6050 - Ice bag.	1
§ 880.6060 - Medical disposable bedding.	1
§ 880.6070 - Bed board.	1
§ 880.6080 - Cardiopulmonary resuscitation board.	1
§ 880.6085 - Hot/cold water bottle.	1
§ 880.6100 - Ethylene oxide gas aerator cabinet.	2
§ 880.6140 - Medical chair and table.	1
§ 880.6150 - Ultrasonic cleaner for medical instruments.	1
§ 880.6175 - [Reserved]	
§ 880.6185 - Cast cover.	1
§ 880.6190 - Mattress cover for medical purposes.	1
§ 880.6200 - Ring cutter.	1
§ 880.6230 - Tongue depressor.	1
§ 880.6250 - Patient examination glove.	1
§ 880.6260 - Filtering facepiece respirator for use by the general public in public health medical emergencies.	1
§ 880.6265 - Examination gown.	1
§ 880.6280 - Medical insole	1
§ 880.6300 - Implantable radio frequency transponder system for patient identification and health information	2
§ 880.6320 - AC-powered medical examination light	1
§ 880.6350 - Battery powered medical examination light	1
§ 880.6375 - Patient lubricant	1
§ 880.6430 - Liquid medication dispenser	1
§ 880.6450 - Skin pressure protectors	1
§ 880.6500 - Medical ultraviolet air purifier	2
§ 880.6710 - Medical ultraviolet water purifier	2
§ 880.6770 - Body waste receptacle	1
§ 880.6740 - Vacuum powered body fluid suction apparatus	2
§ 880.6760 - Protective restraint	1
§ 880.6775 - Powered patient transfer device	2
§ 880.6785 - Manual patient transfer device	1
§ 880.6800 - Washers for body waste receptacle	1
§ 880.6820 - Medical disposable scissors	1
§ 880.6850 - Sterilization wrap	2
§ 880.6860 - Ethylen oxide gas sterilization	2
§ 880.6870 - Dry heat sterilization	2
§ 880.6880 - Steam sterilization	2
§ 880.6885 - Liquid chemical sterilants/ high level desinfectan	2
§ 880.6890 - General purpose disinfectants	1
§ 880.6900 - Hand carried stretcher	1
§ 880.6910 - Wheeled stretcher	2
§ 880.6960 - Irrigating syringe	1
§ 880.6970 - Liquid crystal vein locator	1
§ 880.6980 - Vein stabilizer	1
§ 880.6990 - Infusion stand	1
§ 880.6991 - Medical washer	2
§ 880.6992 - Medical washer-disinfecter	2

§ 882.4300 - Manual cranial drills, burrs, trephines, and their accessories.	2
§ 882.4305 - Powered compound cranial drills, burrs, trephines, and their accessories.	2
§ 882.4310 - Powered simple cranial drills, burrs, trephines, and their accessories.	2
§ 882.4325 - Cranial drill handpiece (brace).	1
§ 882.4360 - Electric cranial drill motor.	2
§ 882.4370 - Pneumatic cranial drill motor.	2
§ 882.4400 - Radiofrequency lesion generator.	2
§ 882.4440 - Neurosurgical headrests.	1
§ 882.4460 - Neurosurgical head holder (skull clamp).	2
§ 882.4500 - Cranioplasty material forming instrument.	1
§ 882.4525 - Microsurgical instrument.	1
§ 882.4535 - Nonpowered neurosurgical instrument.	1
§ 882.4545 - Shunt system implantation instrument.	1
§ 882.4560 - Stereotaxic instrument.	2
§ 882.4600 - Leukotome.	1
§ 882.4650 - Neurosurgical suture needle.	1
§ 882.4700 - Neurosurgical paddle.	2
§ 882.4725 - Radiofrequency lesion probe.	2
§ 882.4750 - Skull punch.	1
§ 882.4800 - Self-retaining retractor for neurosurgery.	2
§ 882.4840 - Manual rongeur.	2
§ 882.4845 - Powered rongeur.	2
§ 882.4900 - Skullplate screwdriver.	1
Subpart F--Neurological Therapeutic Devices	
§ 882.5030 - Methyl methacrylate for aneurysmorrhaphy.	2
§ 882.5050 - Biofeedback device.	2
§ 882.5070 - Bite block.	2
§ 882.5150 - Intravascular occluding catheter.	3
§ 882.5175 - Carotid artery clamp.	2
§ 882.5200 - Aneurysm clip.	2
§ 882.5225 - Implanted malleable clip.	2
§ 882.5235 - Aversive conditioning device.	2
§ 882.5250 - Burr hole cover.	2
§ 882.5275 - Nerve cuff.	2
§ 882.5300 - Methyl methacrylate for cranioplasty.	2
§ 882.5320 - Preformed alterable cranioplasty plate.	2
§ 882.5330 - Preformed nonalterable cranioplasty plate.	2
§ 882.5360 - Cranioplasty plate fastener.	2
§ 882.5500 - Lesion temperature monitor.	2
§ 882.5550 - Central nervous system fluid shunt and components.	2
§ 882.5800 - Cranial electrotherapy stimulator.	3
§ 882.5810 - External functional neuromuscular stimulator.	2
§ 882.5820 - Implanted cerebellar stimulator.	3
§ 882.5830 - Implanted diaphragmatic/phrenic nerve stimulator.	3
§ 882.5840 - Implanted intracerebral/subcortical stimulator for pain relief.	3
§ 882.5850 - Implanted spinal cord stimulator for bladder evacuation.	3
§ 882.5860 - Implanted neuromuscular stimulator.	3
§ 882.5870 - Implanted peripheral nerve stimulator for pain relief.	2
§ 882.5880 - Implanted spinal cord stimulator for pain relief.	2
§ 882.5890 - Transcutaneous electrical nerve stimulator for pain relief.	2
§ 882.5900 - Preformed craniosynostosis strip.	2
§ 882.5910 - Dura substitute.	2
§ 882.5940 - Electroconvulsive therapy device.	3
§ 882.5950 - Neurovascular embolization device.	2
§ 882.5960 - Skull tongs for traction.	2
§ 882.5970 - Cranial orthosis.	2
§ 882.5975 - Human dura mater.	2

11. OBSTETRICAL AND GYNECOLOGICAL DEVICES

Subpart B--Obstetrical and Gynecological Diagnostic Devices	
§ 884.1040 - Viscometer for cervical mucus.	1
§ 884.1050 - Endocervical aspirator.	2
§ 884.1060 - Endometrial aspirator.	2
§ 884.1100 - Endometrial brush.	2
§ 884.1175 - Endometrial suction curette and accessories.	2
§ 884.1185 - Endometrial washer.	2
§ 884.1300 - Uterotubal carbon dioxide insufflator and accessories.	2
§ 884.1425 - Perineometer.	2
§ 884.1550 - Amniotic fluid sampler (amniocentesis tray).	1
§ 884.1560 - Fetal blood sampler.	2
§ 884.1600 - Transabdominal amnioscope (fetoscope) and accessories.	3
§ 884.1630 - Colposcope.	2
§ 884.1640 - Culdoscope and accessories.	2/1
§ 884.1660 - Transcervical endoscope (amnioscope) and accessories.	2
§ 884.1690 - Hysteroscope and accessories.	2/1
§ 884.1700 - Hysteroscopic insufflator.	2/1
§ 884.1720 - Gynecologic laparoscope and accessories.	2/1
§ 884.1730 - Laparoscopic insufflator.	
Subpart C--Obstetrical and Gynecological Monitoring Devices	
§ 884.2050 - Obstetric data analyzer.	3
§ 884.2225 - Obstetric-gynecologic ultrasonic imager.	2
§ 884.2600 - Fetal cardiac monitor.	2
§ 884.2620 - Fetal electroencephalographic monitor.	3
§ 884.2640 - Fetal phonocardiographic monitor and accessories.	2
§ 884.2660 - Fetal ultrasonic monitor and accessories.	2
§ 884.2675 - Fetal scalp circular (spiral) electrode and applicator.	2
§ 884.2685 - Fetal scalp clip electrode and applicator.	3
§ 884.2700 - Intrauterine pressure monitor and accessories.	2
§ 884.2720 - External uterine contraction monitor and accessories.	2
§ 884.2730 - Home uterine activity monitor.	2
§ 884.2740 - Perinatal monitoring system and accessories.	1
§ 884.2800 - Computerized Labor Monitoring System.	2
§ 884.2900 - Fetal stethoscope.	1/3
§ 884.2960 - Obstetric ultrasonic transducer and accessories.	2
§ 884.2980 - Telethermographic system.	1/3
§ 884.2982 - Liquid crystal thermographic system.	1/3
§ 884.2990 - Breast lesion documentation system.	2
Subpart D--Obstetrical and Gynecological Prosthetic Devices	
§ 884.3200 - Cervical drain.	2
§ 884.3575 - Vaginal pessary.	2
§ 884.3650 - Fallopian tube prosthesis.	2
§ 884.3900 - Vaginal stent.	2
Subpart E--Obstetrical and Gynecological Surgical Devices	
§ 884.4100 - Endoscopic electrocautery and accessories.	2
§ 884.4120 - Gynecologic electrocautery and accessories.	2
§ 884.4150 - Bipolar endoscopic coagulator-cutter and accessories.	2

§ 884.4160 - Unipolar endoscopic coagulator-cutter and accessories.	2
§ 884.4250 - Expandable cervical dilator.	3
§ 884.4260 - Hygroscopic Laminaria cervical dilator.	2
§ 884.4270 - Vibratory cervical dilators.	3
§ 884.4340 - Fetal vacuum extractor.	2
§ 884.4400 - Obstetric forceps.	2
§ 884.4500 - Obstetric fetal destructive instrument.	2
§ 884.4520 - Obstetric-gynecologic general manual instrument.	1
§ 884.4530 - Obstetric-gynecologic specialized manual instrument.	2/1
§ 884.4550 - Gynecologic surgical laser.	2
§ 884.4900 - Obstetric table and accessories.	2
Subpart F--Obstetrical and Gynecological Therapeutic Devices	
§ 884.5050 - Metreurynter-balloon abortion system.	3
§ 884.5070 - Vacuum abortion system.	2
§ 884.5100 - Obstetric anesthesia set.	2
§ 884.5150 - Nonpowered breast pump.	1
§ 884.5160 - Powered breast pump.	2
§ 884.5225 - Abdominal decompression chamber.	3
§ 884.5250 - Cervical cap.	2
§ 884.5300 - Condom.	2
§ 884.5310 - Condom with spermicidal lubricant.	2
§ 884.5320 - Glans sheath.	3
§ 884.5330 - Female condom.	3
§ 884.5350 - Contraceptive diaphragm and accessories.	2
§ 884.5360 - Contraceptive intrauterine device (IUD) and introducer.	3
§ 884.5380 - Contraceptive tubal occlusion device (TOD) and introducer.	3
§ 884.5390 - Perineal heater.	2
§ 884.5400 - Menstrual cup.	2
§ 884.5425 - Scented or scented deodorized menstrual pad.	2
§ 884.5435 - Unscented menstrual pad.	1
§ 884.5460 - Scented or scented deodorized menstrual tampon.	2
§ 884.5470 - Unscented menstrual tampon.	2
§ 884.5900 - Therapeutic vaginal douche apparatus.	2/1
§ 884.5920 - Vaginal insufflator.	1
§ 884.5940 - Powered vaginal muscle stimulator for therapeutic use.	3
§ 884.5960 - Genital vibrator for therapeutic use.	2
§ 884.5970 - Clitoral engorgement device.	2
Subpart G--Assisted Reproduction Devices	
§ 884.6100 - Assisted reproduction needles.	2
§ 884.6110 - Assisted reproduction catheters.	2
§ 884.6120 - Assisted reproduction accessories.	2
§ 884.6130 - Assisted reproduction microtools.	2
§ 884.6140 - Assisted reproduction micropipette fabrication instruments.	2
§ 884.6150 - Assisted reproduction micromanipulators and microinjectors.	2
§ 884.6160 - Assisted reproduction labware.	2
§ 884.6170 - Assisted reproduction water and water purification systems.	2
§ 884.6180 - Reproductive media and supplements.	2
§ 884.6190 - Assisted reproductive microscopes and microscope accessories.	1
§ 884.6200 - Assisted reproduction laser system.	2

12. PERALATAN MATA

12.1 PERALATAN ORTOPEDI DIAGNOSTIK

NO.CFR	JENIS PRODUK	KELAS
§ 886.1040	Ocular esthesiometer	I
§ 886.1050	Adaptometer (biophotometer)	I
§ 886.1070	Anomaloscope	I
§ 886.1090	Haidinger brush	I
§ 886.1140	Ophthalmic chair	I
§ 886.1150	Visual acuity chart	I
§ 886.1160	Color vision plate illuminator	I
§ 886.1170	Color vision tester	I
§ 886.1190	Distometer	I
§ 886.1200	Optokinetic drum	I
§ 886.1250	Euthyscope	I
§ 886.1270	Exophthalmometer	I
§ 886.1290	Fixation device	I
§ 886.1320	Fornixscope	I
§ 886.1330	Amsler grid	I
§ 886.1340	Haploscope	I
§ 886.1350	Keratoscope	I
§ 886.1375	Bagolini lens	I
§ 886.1380	Diagnostic condensing lens	I
§ 886.1390	Flexible diagnostic Fresnel lens	I
§ 886.1395	Diagnostic Hruby fundus lens	I
§ 886.1400	Maddox lens	I
§ 886.1405	Ophthalmic trial lens set	I
§ 886.1410	Ophthalmic trial lens clip	I
§ 886.1415	Ophthalmic trial lens frame	I
§ 886.1420	<i>Ophthalmic lens gauge</i>	I
§ 886.1425	Lens measuring instrument	I
§ 886.1430	Ophthalmic contact lens radius measuring device	I
§ 886.1435	Maxwell spot	I
§ 886.1450	Corneal radius measuring device	I
§ 886.1460	Stereopsis measuring instrument	I
§ 886.1500	Headband mirror	I
§ 886.1605	Perimeter	I
§ 886.1650	Ophthalmic bar prism	I
§ 886.1655	Ophthalmic Fresnel prism	I
§ 886.1660	Gonioscopic prism	I
§ 886.1665	Ophthalmic rotary prism	I
§ 886.1680	Ophthalmic projector	I
§ 886.1690	Pupillograph	I
§ 886.1700	Pupillometer	I
§ 886.1750	Skiascopic rack	I

§ 886.1760	Ophthalmic refractometer	I
§ 886.1770	Manual refractor	I
§ 886.1790	Nearpoint ruler	I
§ 886.1800	Schirmer strip	I
§ 886.1810	Tangent screen (campimeter)	I
§ 886.1840	Simultan (including crossed cylinder)	I
§ 886.1860	Ophthalmic instrument stand	I
§ 886.1870	Stereoscope	I
§ 886.1880	Fusion and stereoscopic target	I
§ 886.1905	Nystagmus tape	I
§ 886.1910	Spectacle dissociation test system	I
§ 886.1940	Tonometer sterilizer	I
§ 886.1120	Ophthalmic camera	II
§ 886.1220	Corneal electrode	II
§ 886.1300	Afterimage flasher	II
§ 886.1360	Visual field laser instrument	II
§ 886.1385	Polymethylmethacrylate (PMMA) diagnostic contact lens	II
§ 886.1510	Eye movement monitor	II
§ 886.1570	Ophthalmoscope	II
§ 886.1630	AC-powered photostimulator	II
§ 886.1640	Ophthalmic preamplifier	II
§ 886.1670	Ophthalmic isotope uptake probe	II
§ 886.1780	Retinoscope	II
§ 886.1850	AC-powered slitlamp biomicroscope	II
§ 886.1930	Tonometer and accessories	II
§ 886.1945	Transilluminator	II

12.2 PERALATAN MATA PROSTETIK

§ 886.3200	Artificial eye	I
§ 886.3100	Ophthalmic tantalum clip	II
§ 886.3130	Ophthalmic conformer	II
§ 886.3300	Absorbable implant (scleral buckling method)	II
§ 886.3320	Eye sphere implant	II
§ 886.3340	Extraocular orbital implant	II
§ 886.3800	Scleral shell	II
§ 886.3920	Aqueous shunt	II
§ 886.3320	<i>Eye sphere implant</i>	<i>II</i>
§ 886.3400	Keratoprosthesis	II
§ 886.3600	Intraocular lens	III

12.3 PERALATAN MATA BEDAH

§ 886.4070	Powered corneal burr	I
§ 886.4230	Ophthalmic knife test drum	I
§ 886.4300	Intraocular lens guide	I
§ 886.4335	Operating headlamp	I
§ 886.4350	Manual ophthalmic surgical instrument	I
§ 886.4360	Ocular surgery irrigation device	I
§ 886.4370	Keratome	I
§ 886.4445	Permanent magnet	I
§ 886.4570	Ophthalmic surgical marker	I
§ 886.4750	Ophthalmic eye shield	I
§ 886.4770	Ophthalmic operating spectacles (loupes)	I
§ 886.4855	Ophthalmic instrument table	I
§ 886.4100	Radiofrequencyelectrosurgical cautery apparatus	II
§ 886.4115	Thermal cautery unit	II
§ 886.4150	Vitreous aspiration and cutting instrument	II
§ 886.4170	Cryophthalmic unit	II
§ 886.4250	Ophthalmic electrolysis unit	II
§ 886.4390	Ophthalmic laser	II
§ 886.4392	Nd:YAG laser for posterior capsulotomy and peripheral iridotomy	II
§ 886.4400	Electronic metal locator	II

§ 886.4440	AC powered magnet	II
§ 886.4610	Ocular pressure applicator	II
§ 886.4670	Phacofragmentation system	II
§ 886.4690	Ophthalmic photocoagulator	II
§ 886.4790	Ophthalmic sponge	II
§ 886.4270	Intraocular gas	III
§ 886.4275	Intraocular fluid	III
§ 886.4280	Intraocular pressure measuring device	III

12.4 PERALATAN MATA TERAPETIK

§ 886.5120	Low-power binocular loupe	I
§ 886.5420	Contact lens inserter/remover	I
§ 886.5540	Low-vision magnifier	I
§ 886.5600	Ptosis crutch	I
§ 886.5800	Ophthalmic bar reader	I
§ 886.5810	Ophthalmic prism reader	I
§ 886.5820	Closed-circuit television reading system	I
§ 886.5840	Magnifying spectacles	I
§ 886.5842	Spectacle frame	I
§ 886.5844	Prescription spectacle lens	I
§ 886.5850	Sunglasses (nonprescription)	I
§ 886.5870	Low-vision telescope	I
§ 886.5900	Electronic vision aid	I
§ 886.5910	Image intensification vision aid	I
§ 886.5915	Optical vision aid	I
§ 886.5100	Ophthalmic beta radiation source	II
§ 886.5916	Rigid gas permeable contact lens	II
§ 886.5918	<i>Rigid gas permeable contact lens products</i>	<i>II</i>
§ 886.5925	Soft (hydrophilic) contact lens	II
§ 886.5928	Soft (hydrophilic) contact lens care products	II

13. PERALATAN ORTOPEDI

13.1 PERALATAN ORTOPEDI DIAGNOSTIK

NO.CFR	JENIS PRODUK	KELAS
§ 888.1100	Arthroscope	I
§ 888.1500	Goniometer	I
§ 888.1520	Nonpowered Goniometer	I
§ 888.1240	AC-powered dynamometer	II

13.2 PERALATAN ORTOPEDI PROSTETIK

§ 888.3000	Bone cap	I
§ 888.3010	Bone fixation cerclage	II
§ 888.3020	Intramedullary fixation rod	II
§ 888.3025	Passive tendon prosthesis	II
	Polymethylmethacrylate (PMMA) bone cement	II
§ 888.3030	Single/multiple component metallic bone fixation appliances and accessories	II
§ 888.3040	Smooth or threaded metallic bone fixation fastener	II
	Resorbable calcium salt bone void filler device	II
§ 888.3050	Spinal interlaminar fixation orthosis	II
§ 888.3060	Spinal intervertebral body fixation orthosis	II
§ 888.3070	Pedicle screw spinal system	II/III
§ 888.3100	Ankle joint metal/composite semi-constrained cemented prosthesis	II
§ 888.3110	Ankle joint metal/polymer semi-constrained cemented prosthesis	II
§ 888.3150	Elbow joint metal/polymer constrained cemented prosthesis	II
§ 888.3160	Elbow joint metal/polymer semi-constrained cemented prosthesis	II
§ 888.3170	Elbow joint radial (hemi-elbow) polymer prosthesis	II
§ 888.3230	Finger joint polymer constrained prosthesis	II
	Hip joint metal/polymer constrained cemented or uncemented prosthesis	II
§ 888.3340	Hip joint metal/composite semi-constrained cemented prosthesis	II
§ 888.3350	Hip joint metal/polymer semi-constrained cemented prosthesis	II
§ 888.3353	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncement prothesis	II
§ 888.3358	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis	II
§ 888.3360	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis	II
§ 888.3390	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis	II
§ 888.3400	Hip joint femoral (hemi-hip) metallic resurfacing prosthesis	II
§ 888.3490	Knee joint femorotibial metal/composite non-constrained cemented prosthesis	II
§ 888.3530	Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	II
§ 888.3510	Knee joint femorotibial metal/polymer constrained cemented prosthesis	II
§ 888.3520	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis	II
§ 888.3530	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis	II
§ 888.3560	Knee joint patellofemoral polymer/metal/polymer semi-constrained cemented prosthesis	II
	Knee joint patellofemoral polymer/polymer semi-constrained uncemented prosthesis	II

§ 888.3580	Knee joint patellar (hemi-knee) metallic resurfacing un-cemented prosthesis	II
§ 888.3590	Knee joint tibial (hemi-knee) metallic resurfacing un-cemented prosthesis	II
§ 888.3650	Shoulder joint metal/polymer non-constrained cemented prosthesis	II
§ 888.3660	Shoulder joint metal/polymer semi-constrained cemented prosthesis	II
§ 888.3670	Shoulder joint metal/polymer nonconstrained or semiconstrained porous-coated uncemented prosthesis	II
§ 888.3690	Shoulder joint humeral (hemi-shoulder) metallic un-cemented prosthesis	II
§ 888.3720	Toe joint polymer constrained prosthesis	II
§ 888.3730	Toe joint phalangeal (hemi-toe) polymer prosthesis	II
§ 888.3750	Wrist joint carpal lunate polymer prosthesis	II
§ 888.3760	Wrist joint carpal scaphoid polymer prosthesis	II
§ 888.3770	Wrist joint carpal trapezium polymer prosthesis	II
§ 888.3780	Wrist joint polymer constrained prosthesis	II
§ 888.3800	Wrist joint metal/polymer semi constrained cement prosthesis	II
§ 888.3810	Wrist joint ulnar (hemi-wrist) polymer prosthesis	II
§ 888.3015	Bone heterograft	III
§ 888.3027	Polymethylmethacrylate (PMMA) bone cement	III
§ 888.3120	Ankle joint metal/polymer non-constrained cemented prosthesis	III
	Elbow joint metal/metal or metal/polymer constrained cemented prosthesis	III
§ 888.3180	Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	III
§ 888.3200	Finger joint metal/metal constrained uncemented prosthesis	III
§ 888.3210	Finger joint metal/metal constrained cemented prosthesis	III
§ 888.3220	Finger joint metal/polymer constrained cemented prosthesis	III
§ 888.3300	Hip joint metal constrained cemented or uncemented prosthesis	III
§ 888.3310	Hip joint metal/polymer constrained cemented or uncemented prosthesis	III
§ 888.3320	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis	III
§ 888.3330	Hip joint metal/metal semi-constrained, with an uncemented acetabular component,	III
§ 888.3370	Hip joint (hemi-hip) acetabular metal cemented prosthesis	III
§ 888.3380	Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis	III
	Hip joint femoral metal/polymer resurfacing cemented prosthesis	III
§ 888.3480	Knee joint femorotibial metallic constrained cemented prosthesis	III
§ 888.3540	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	III
§ 888.3550	Knee joint patellofemoral polymer/metal/metal constrained cemented prosthesis	III
§ 888.3570	Knee joint of femoral (hemi-knee) metallic uncemented prosthesis	III
§ 888.3580	Knee joint patellar (hemi-knee) metallic resurfacing un-cemented prosthesis	III
§ 888.3640	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	III
§ 888.3650	Shoulder joint metal/ polymer non-constrained cemented prosthesis	III
§ 888.3660	Shoulder joint metal/ polymer semi constrained cemented prosthesis	III
§ 888.3680	Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis	III
§ 888.3790	Wrist joint metal constrained cement prosthesis	III
13.3 PERALATAN ORTOPEDI BEDAH		
§ 888.4150	Calipers for clinical use	I
§ 888.4200	Cement dispenser	I
§ 888.4210	Cement mixer for clinical use	I
§ 888.4220	Cement monomer vapor evacuator	I
§ 888.4230	Cement ventilator tube	I
§ 888.4300	Depth gauge for clinical use	I
§ 888.4540	Orthopedic manual surgical instrument	I
§ 888.4600	Protractor for clinical use	I
§ 888.4800	Template for clinical use	I
§ 888.5850	Nonpowered orthopedic traction apparatus and accessories	I
§ 888.5890	Noninvasive traction component	I
§ 888.5940	Cast component	I
§ 888.5960	Cast removal instrument	I
§ 888.5980	Manual cast application and removal instrument	I
§ 888.4580	Sonic surgical instrument and accessories/attachments	II

14. PERALATAN KESEHATAN FISIK

14.1 PERALATAN KESEHATAN FISIK DIAGNOSTIK

NO.CFR	JENIS PRODUK	KELAS
§ 890.1175	Electrode cable	II
§ 890.1575	Force-measuring platform	I
§ 890.1600	Intermittent pressure measurement system	I
§ 890.1615	Miniature pressure transducer	I
§ 890.1225	Chronaximeter	II
§ 890.1375	Diagnostic electromyograph	II
§ 890.1385	Diagnostic electromyograph needle electrode	II
§ 890.1450	Powered reflex hammer	II
§ 890.1850	Diagnostic muscle stimulator	II
§ 890.1925	Isokinetic testing and evaluation system	II

14.2 PERALATAN KESEHATAN FISIK PROSTETIK

§ 890.3025	Prosthetic and orthotic accessory	I
§ 890.3075	Cane	I
§ 890.3100	Mechanical chair	I
§ 890.3150	Crutch	I
§ 890.3175	Flotation cushion	I
§ 890.3410	External limb orthotic component	I
§ 890.3420	External limb prosthetic component	I
§ 890.3475	Limb orthosis	I
§ 890.3490	Truncal orthosis	I
§ 890.3520	Plinth	I
§ 890.3640	Arm sling	I
§ 890.3665	Congenital hip dislocation abduction splint	I
§ 890.3675	Denis Brown splint	I
§ 890.3700	Nonpowered communication system	I
§ 890.3750	Mechanical table	I
§ 890.3760	Powered table	I
§ 890.3790	Cane, crutch, and walker tips and pads	I
§ 890.3825	Mechanical walker	I
§ 890.3850	Mechanical wheelchair	I
§ 890.3910	Wheelchair accessory	I
§ 890.3920	Wheelchair component	I
§ 890.3940	Wheelchair platform scale	I
§ 890.3110	Electric positioning chair	II
§ 890.3500	External assembled lower limb prosthesis	II
§ 890.3690	Powered wheeled stretcher	II
§ 890.3710	Powered communication system	II

§ 890.3725	Powered environmental control system	II
§ 890.3800	Motorized three-wheeled vehicle	II
§ 890.3860	Powered wheelchair	II
§ 890.3880	Special grade wheelchair	II
§ 890.3900	Standup wheelchair	II
§ 890.3930	Wheelchair elevator	II
§ 890.3610	Rigid pneumatic structure orthosis	III
§ 890.3890	Stair-climbing wheelchair	III

14.3 PERALATAN KESEHATAN FISIK TERAPETIK

§ 890.5050	Daily activity assist device	I
§ 890.5125	Nonpowered sitz bath	I
§ 890.5180	Manual patient rotation bed	I
§ 890.5350	Exercise component	I
§ 890.5370	Non-measuring exercise equipment	I
§ 890.5380	Powered exercise equipment	I
§ 890.5410	Powered finger exerciser	I
§ 890.5660	Therapeutic massager	I
§ 890.5700	Cold pack	I
§ 890.5710	Hot or Cold disposable pack	I
§ 890.5730	Moist heat pack	I
§ 890.5765	Pressure-applying device	I
§ 890.5925	Traction accessory	I
§ 890.5940	Chilling unit	I
§ 890.5950	Powered heating unit	I
§ 890.5975	Therapeutic vibrator	I
§ 890.5100	Immersion hydrobath	II
§ 890.5110	Paraffin bath	II
§ 890.5150	Powered patient transport	II
§ 890.5160	Air-fluidized bed	II
§ 890.5170	Powered flotation therapy bed	II
§ 890.5225	Powered patient rotation bed	II
§ 890.5250	Moist steam cabinet	II
§ 890.5360	Measuring exercise equipment	II
§ 890.5500	Infrared lamp	II
§ 890.5575	Powered external limb overload warning device	II
§ 890.5650	Powered inflatable tube massager	II
§ 890.5720	Water circulating hot or cold pack	II
§ 890.5740	Powered heating pad	II
§ 890.5850	Powered muscle stimulator	II
§ 890.5880	Multi-function physical therapy table	II
§ 890.5900	Power traction equipment	II
§ 890.5275	Microwave diathermy (for use in applying therapeutic deep heat for selected medical conditions)	II
	Microwave diathermy (for all other use)	III
§ 890.5290	Shortwave diathermy (for use in applying therapeutic deep heat for selected medical conditions)	II
	Shortwave diathermy (for all other use)	III
§ 890.5300	Ultrasonic diathermy (for use in applying therapeutic deep heat for selected medical conditions)	II
	Ultrasonic diathermy (for all other use)	III
§ 890.5525	Iontophoresis device (Intended for certain specified uses)	II
	Iontophoresis device (for all other use)	III
§ 890.5860	Ultrasound and muscle stimulator (for use in applying therapeutic deep heat for selected medical conditions)	II
	Ultrasound and muscle stimulator (for all other use)	III

15. PERALATAN RADIOLOGI

15.1 PERALATAN RADIOLOGI DIAGNOSTIK

NO.CFR	JENIS PRODUK	KELAS
§ 892.1100	Scintillation (gamma) camera	I
§ 892.1110	Positron camera	I
§ 892.1130	Nuclear whole body counter	I
§ 892.1300	Nuclear rectilinear scanner	I
§ 892.1320	Nuclear uptake probe	I
§ 892.1330	Nuclear whole body scanner	I
§ 892.1350	Nuclear scanning bed	I
§ 892.1370	Nuclear anthropomorphic phantom	I
§ 892.1380	Nuclear flood source phantom	I
§ 892.1400	Nuclear sealed calibration source	I
§ 892.1410	Nuclear electrocardiograph synchronizer	I
§ 892.1420	Radionuclide test pattern phantom	I
§ 892.1640	Radiographic film marking system	I
§ 892.1700	Diagnostic x-ray high voltage generator	I
§ 892.1760	Diagnostic x-ray tube housing assembly	I
§ 892.1770	Diagnostic x-ray tube mount	I
§ 892.1830	Radiologic patient cradle	I
§ 892.1840	Radiographic film	I
§ 892.1880	Wall-mounted radiographic cassette holder	I
§ 892.1890	Radiographic film illuminator	I
§ 892.1910	Radiographic grid	I
§ 892.1920	Radiographic head holder	I
§ 892.1940	Radiographic quality assurance instrument	I
§ 892.1950	Radiographic anthropomorphic phantom	I
§ 892.1960	Radiographic intensifying screen	I
§ 892.1970	Radiographic ECG/respirator synchronizer	I
§ 892.2010	Medical image storage device	I
§ 892.2020	Medical image communication device	I
§ 892.1000	Magnetic resonance diagnostic device	II
§ 892.1170	Bone densitometer	II
§ 892.1200	Emission computed tomography system	II
§ 892.1220	Fluorescent scanner	II
§ 892.1310	Nuclear tomography system	II
§ 892.1360	Radionuclide dose calibrator	II
§ 892.1390	Radionuclide rebreathing system	II
§ 892.1540	Nonfetal ultrasonic monitor	II
§ 892.1550	Ultrasonic pulsed doppler imaging system	II
§ 892.1560	Ultrasonic pulsed echo imaging system	II
§ 892.1570	Diagnostic ultrasonic transducer	II
§ 892.1600	Angiographic x-ray system	II

§ 892.1610	Diagnostic x-ray beam limiting device	II
§ 892.1620	Cine or spot fluorographic x-ray camera	II
§ 892.1630	Electrostatic x-ray imaging system	II
§ 892.1650	Image-intensified fluoroscopic x ray system	II
§ 892.1660	Non-image-intensified fluoroscopic x ray system	II
§ 892.1670	Spot-film device	II
§ 892.1680	Stationary x-ray system	II
§ 892.1710	Mammographic x-ray system	II
§ 892.1720	Mobile x-ray system	II
§ 892.1730	Photofluorographic x-ray system	II
§ 892.1740	Tomographic x-ray system	II
§ 892.1750	Computed tomography x-ray system	II
§ 892.1820	Peumoencephalographic Chair	II
§ 892.1850	Radiographic film cassette	II
§ 892.1860	Radiographic film/cassette changer	II
§ 892.1870	Radiographic film/cassette changer programmer	II
§ 892.1900	Automatic radiographic film processor	II
§ 892.1980	<i>Radiologic table</i>	II
§ 892.2030	Medical image digitizer	II
§ 892.2040	Medical image hardcopy device	II
§ 892.2050	Picture archiving and communication system	II
§ 892.1990	Transilluminator for breast evaluation	III

15.2 PERALATAN RADIOLOGI TERAPETIK

§ 892.5650	<i>Manual radionuclide applicator system</i>	I
§ 892.5740	<i>Radionuclide teletherapy source</i>	I
§ 892.5780	Light beam patient position indicator	I
§ 892.5050	Medical charge-particle radiation therapy system	II
§ 892.5300	Medical neutron radiation therapy system	II
§ 892.5700	Remote controlled radionuclide applicator system	II
§ 892.5710	Radiation therapy beam-shaping block	II
§ 892.5730	Radionuclide brachytherapy source	II
§ 892.5750	Radionuclide radiation therapy system	II
§ 892.5770	Powered radiation therapy patient support assembly	II
§ 892.5840	Radiation therapy simulation system	II
§ 892.5900	X-ray radiation therapy system	II
§ 892.5930	Therapeutic x-ray tube housing assembly	II

15.3 PERALATAN RADIOLOGI LAINNYA

§ 892.6500	Personnel protective shield	I
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16. PERALATAN BEDAH UMUM DAN BEDAH PLASTIK

16.1 PERALATAN DIAGNOSTIK

NO.CFR	JENIS PRODUK	KLS
§ 878.3250	External facial fracture fixation appliance	I
§ 878.3750	External prosthesis adhesive	I
§ 878.3800	External aesthetic restoration prosthesis	I
§ 878.3900	Inflatable extremity splint	I
§ 878.3910	Noninflatable extremity splint	I
§ 878.3925	Plastic surgery kit and accessories	I
§ 878.3300	Surgical mesh	II
§ 878.3500	Polytetrafluoroethylene with carbon fibers composite implant material	II
§ 878.3550	Chin prosthesis	II
§ 878.3590	Ear prosthesis	II
§ 878.3680	Nose prosthesis	II
§ 878.3530	Silicone inflatable breast prosthesis	III
§ 878.3540	Silicone gel-filled breast prosthesis	III
§ 878.3610	Esophageal prosthesis	II
§ 878.3720	Tracheal prosthesis	II
9.3 PERALATAN BEDAH		
§ 878.4014	Nonresorbable gauze/sponge for external use	I
§ 878.4018	Hydrophilic wound dressing	I
§ 878.4020	Occlusive wound dressing	I
§ 878.4022	Hydrogel wound dressing and burn dressing	I
§ 878.4100	Organ bag	I
§ 878.4160	Surgical camera and accessories	I
§ 878.4200	Introduction/drainage catheter and accessories	I
§ 878.4320	Removable skin clip	I
§ 878.4380	Drape adhesive	I
§ 878.4440	Eye pad	I
§ 878.4450	Nonabsorbable gauze for internal use	I
§ 878.4460	Surgeon glove	I
§ 878.4470	Surgeon gloving cream	I
§ 878.4635	Ultraviolet lamp for tanning	I
§ 878.4660	Skin marker	I
§ 878.4680	Nonpowered, single patient, portable suction apparatus	I
§ 878.4700	Surgical microscope and accessories	I
§ 878.4730	Surgical skin degreaser or adhesive tape solvent	I
§ 878.4760	Removable skin staple	I

§ 878.4800	Manual surgical instrument for general use	I
§ 878.4820	Surgical instrument motors and accessories/attachments	I
§ 878.4930	Suture retention device	I
§ 878.4950		I
	Manual operating table and accessories and manual operating chair and accessories	
§ 878.4960		I
	Operating tables and accessories and operating chairs and accessories	
§ 878.4025	<i>Silicone Sheeting</i>	<i>I</i>
§ 878.4300	Implantable clip	II
§ 878.4040	Surgical apparel	II
§ 878.4350	Cryosurgical unit and accessories	II
§ 878.4370	Surgical drape and drape accessories	II
§ 878.4400	Electrosurgical cutting and coagulation device and accessories	II
§ 878.4410	<i>Low energy ultrasound wound cleaner</i>	<i>II</i>
§ 878.4493	Absorbable poly(glycolide/L.lactide) surgical suture	II
§ 878.4494	<i>Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology</i>	<i>II</i>
§ 878.4630	Ultraviolet lamp for dermatologic disorders	II
§ 878.4750	Implantable staple	II
§ 878.4780	Powered suction pump	II
§ 878.4810		II
	Laser surgical instrument for use in general and plastic surgery and in dermatology	II
§ 878.4830	Absorbable surgical gut suture	II
§ 878.5000	Nonabsorbable poly(ethylene terephthalate) surgical suture	II
§ 878.5010	Nonabsorbable polypropylene surgical suture	II
§ 878.5020	Nonabsorbable polyimide surgical suture	II
§ 878.5030	Natural nonabsorbable silk surgical suture	II
§ 878.5035	<i>Nonabsorbable expanded polytetrafluoroethylene surgical suture</i>	<i>II</i>
§ 878.5040	Suction lipoplasty system	II
§ 878.4480	Absorbable powder for lubricating a surgeon's glove	III
§ 878.4490	Absorbable hemostatic agent and dressing	III
§ 878.4520	Polytetrafluoroethylene injectable	III
9.4 PERALATAN TERAPETIK		
§ 878.5350	Needle-type epilator	I
§ 878.5360	Tweezer-type epilator	I
§ 878.5900	Nonpneumatic tourniquet	I
§ 878.5910	Pneumatic tourniquet	I
§ 878.5070	<i>Air-handling apparatus for a surgical operating room</i>	<i>II</i>
§ 878.5650	Topical oxygen chamber for extremities	III