

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA CIRCULAR 7

11 6 AUG 2021

SUBJECT: Reference List of Class A Medical Devices

I. BACKGROUND AND RATIONALE

On 26 January 2018, DOH Administrative Order (AO) No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements" was issued requiring for the notification of all medical devices under class A (low risk medical device) and registration for Class B (low-moderate risk), Class C (moderate-high risk) and Class D (high risk) medical devices.

Subsections V(1) and V(2) of AO No. 2018-0002 stipulate that a guidance document containing the list of medical devices per classification shall be issued by the Food and Drug Administration (FDA) - Center for Device Regulation, Radiation Health, and Research (CDRRHR). Initial list of medical devices with risk classification was issued through FDA Circular No. 2020-001 entitled "Initial Implementation of Administrative Order No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements" as amended by FDA Circular No. 2020-001-A re: Amendment to Annex A of FDA Circular No. 2020-001.

Due to the wide array of available medical devices in the market, identifying the risk classification of these health products could be an arduous task for the industry particularly those establishments that are just starting with the medical device business.

To guide the medical device industry on identifying the medical devices that are classified as low risk and in line with the implementation of the above-mentioned provisions of AO No. 2018-0002, this Circular providing the list of Class A medical devices is hereby issued.

II. OBJECTIVE

This issuance aims to guide the manufacturers, importers, distributors and all other concerned stakeholders regarding the list of medical devices classified as Class A and to help the industry to determine the appropriate authorization specifically Certificate of Medical Device Notification (CMDN) to secure for their medical device products that fall under Class A classification.





III. GUIDELINES

- 1. All medical device manufacturers, importers, exporters, and distributors shall apply for a CMDN prior to manufacture, distribution, importation, exportation, sale, offer for sale, and where applicable, promotion, advertising of Class A medical devices listed in Annex A.
- 2. As provided for in AO 2018-0002, if the product is not included in the list, the company shall classify the device based on the intended use and on the classification rules of the ASEAN Medical Device Directive (AMDD). The CDRRHR shall verify the classification made by the applicant and shall reclassify the device if another classification is deemed to be more appropriate.
- 3. The classification of medical devices listed in Annex A is subject to change if there will be additional indicated use, claim and duration of use of the product. New classification of the medical device shall follow the classification rules of the AMDD.

IV. PENALTY CLAUSE

Any establishment found to be in violation of the provisions of this issuance shall be subjected to sanctions and penalties as prescribed under Republic Act No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009" and its Implementing Rules and Regulations.

V. REPEALING CLAUSE

Provisions of FDA Circular No. 2020-001-A that are inconsistent with this issuance are hereby modified, withdrawn, repealed, and/or revoked accordingly. Furthermore, FDA Memo No. 2018-011 entitled "Regulation of Toothbrush, Sanitary Napkins and Baby Diapers" is amended to reclassify electric toothbrush as a consumer product until further notice or until agreed upon by the ASEAN Medical Device Committee to classify the said product as a medical device.

VI. SEPARABILITY CLAUSE

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions of this Circular shall not be affected.

VII. EFFECTIVITY

This Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified copies to the University of the Philippines Law Center.

ROLANDO ENRIQUE D. DOMINGO, MD

Director General

ANNEX A

LIST OF CLASS A MEDICAL DEVICES

A. A	NESTHESIOLOGY DEVICES
	Administration Set (All Types) / Delivery System, Without Needle, Fluid/Medicine/
1	Parenteral Nutrition, Not for connection to an active medical device; intended for
	channeling or storing body liquids or tissues, liquids or gases
2	Airway, Nasopharyngeal, short term (>30mins - up to 30 days)
3	Airway, Oropharyngeal, Anesthesiology, short-term (>30 mins up to 30 days)
4	Algesimeter, Manual
5	Apparatus, Gas-Scavenging
6	Bottle, Blow
7	Cardiopulmonary Resuscitation Aid Kit, Manual
8	Cart, Emergency, Cardiopulmonary (Excluding equipment)
9	Chair, Posture, For Cardiac and Pulmonary Treatment
10	Clip, Nose
11	Connector, Airway (Extension)
12	Cylinder, Compressed Gas, and Valve
13	Cylinder, Gas (Empty)
14	Device, Fixation, Tracheal Tube
15	Device, Rebreathing
16	Device, Heimlich Maneuver Assist
17	Drain, Tee (Water trap)
18	Dropper, Ether
19	Flowmeter, Nonback-Pressure Compensated, Bourdon Gauge
20	Flowmeter, Tube, Thorpe, Back-Pressure Compensated
21	Forceps, Tube Introduction
22	Gas, Collecting Vessel
	Hood, Oxygen, Infant
24	Hook, Ether
25	Laryngoscope Kit
26	Laryngoscope, Non-Rigid
····	Laryngoscope, Rigid
28	Mask, Oxygen (Not connected in an active medical device)
	Mask, Oxygen, Low Concentration, Venturi (Not connected in an active medical
	device)
30	Mask, Oxygen, Non-Rebreathing (Not connected in an active medical device)
31	Meter, Airway Pressure (Inspiratory Force) - Analog
32	Meter, Peak Flow, Spirometry - Analog
33	Mixer, Breathing Gases, Anesthesia Inhalation
34	Nasal Endotracheal Tube Holder Kit
35	Protector, Dental
36	Resuscitator, Manual Non Self-Inflating (Attached in an oxygen tank)
37	Spacer, Direct Patient Interface
38	Spreader, Cuff

39	Stethoscope Head
40	Strap, Head, Gas Mask
41	Stylet, Tracheal Tube
42	Support, Breathing Tube
43	Support, Patient Position
44	Transducer, Gas Flow
45	Transducer, Gas Pressure
46	Transducer, Gas Pressure, Differential
47	Tubing, Pressure and Accessories (External medical device for channeling gases or body fluids)
48	Valve, Non-Rebreathing
49	Valve, Switching (Ploss)
50	Ventilator, Emergency, Manual (Resuscitator)
51	Yoke Assembly, Medical Gas

В. С	B. CARDIOVASCULAR DEVICES	
1	Adaptor, Lead Switching, Electrocardiograph	
2	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass	
3	Antimicrobial Blood Pressure Cuff	
4	Auxiliary Power Supply (Ac or Dc) For External Transcutaneous Cardiac Pacemaker	
5	Auxiliary Power Supply (Ac or Dc) For Low-Energy Dc- Defibrillator	
6	Charger, Pacemaker	
7	Compressor, Cardiac, External	
8	Display, Cathode-Ray Tube, Medical	
9	Electrode, Electrocardiograph	
10	Electrode, Electrocardiograph, Multi-Function	
11	Instruments, Surgical, Cardiovascular	
12	Legging, Compression, Non-Inflatable	
13	Monitor, Line Isolation	
14	Recorder, Magnetic Tape, Medical	
15	Recorder, Paper Chart	
16	Reprocessed/Reusable Blood Pressure Cuff	
17	Stethoscope, Manual	
18	Stripper, Artery, Intraluminal, Reusable	
19	Stripper, Vein, External, Reusable	
20	Syringe, Balloon Inflation (Inflation device)	
21	System, Signal Isolation	

C. I	C. DENTAL DEVICES	
1	Absorber, Saliva, Paper	
2	Accessories, Implant, Dental, Endosseous	
3	Accessories, Retractor, Dental	
4	Adhesive, Denture, Acacia and Karaya With Sodium Borate	

5	Adhesive, Denture, Acacia and Karaya With Sodium Borate > 12% By Weight
	Adhesive, Denture, Carboxymethylcellulose Sodium (32%) And Ethylene-Oxide
6	Homopolymer
7	Adhesive, Denture, Carboxymethylcellulose Sodium (40- 100%)
8	Adhesive, Denture, Carboxymethylcellulose Sodium (49%) And Ethylene-Oxide
	Homopolymer
9	Adhesive, Denture, Carboxymethylcellulose Sodium and Cationic Polyacrylamide
10	Polymer
10	Adhesive, Denture, Karaya
11	Adhesive, Denture, Karaya and Ethylene-Oxide Homopolymer
12	Adhesive, Denture, Karaya With Sodium Borate
13	Adhesive, Denture, Polyacrylamide Polymer (Modified cationic)
14	Adhesive, Denture, Polyvinyl Methyl Ether Maleic Acid Calcium-Sodium Double Salt
15	Agent, Polishing, Abrasive, Oral Cavity
16	Aligner, Beam, X-Ray
17	Aligner, Bracket, Orthodontic
18	Amalgamator, Dental, Ac-Powered
19	Anchor, Preformed
20	Applicator, Rapid Wax, Dental
21	Applicator, Resin
22	Articulators
23	Attachment, Precision, All
24	Bar, Preformed
25	Base Paste
26	Broach, Endodontic, Reusable
27	Bur, Dental, Reusable
28	Bur, Diamond Coated, Reusable
29	Burnisher, Operative
30	Carboxymethylcellulose Sodium or Polyvinyl Methyl Ether Maleic Acid Calcium-Sodium
31	Caries Detector, Laser Light, Transmission
32	Carver, Wax, Dental
33	Carver, wax, Bental Cephalometer
34	Chair, Dental, Without Operative Unit
35	Chisel, Bone, Surgical
36	Chisel, Osteotome, Surgical
37	Clamp, Rubber Dam
38	Clamp, Wire, Orthodontic
39	Clasp, Preformed
40	Clasp, Wire
41	Coating, Denture Hydrophilic, Resin
42	Condenser, Amalgam and Foil, Operative
43	Controller, Foot, Handpiece and Cord
44	Cord, Retraction
45	Cotton, Roll

46	Cup, Prophylaxis
47	Curette, Endodontic, Reusable
48	Curette, Operative, Reusable
49	Curette, Periodontic, Reusable
50	Curette, Surgical, Dental, Reusable
51	Cushion, Denture, Over The Counter
52	Cushion, Pad, Denture, Wax Impregnated Cotton, Over The Counter
53	Dam, Rubber
54	Dental Fixture Mount Kit
55	Dental Implant Surgical Tray (Kit)
56	Dental Lapping Tool Kit
57	Device, Anti-Snoring
58	Device, Caries Detection
59	Device, Jaw Repositioning
60	Diamond Disc
61	Diagnostic Light, Soft Tissue Detector (Near infrared spectrum)
62	Driver, Band, Orthodontic
63	Driver, Wire, And Bone Drill, Manual
64	Elevator, Surgical, Dental
65	Eraser, Dental Stain
66	Expiratory Resistance Valve, Intranasal, For Obstructive Sleep Apnea
67	Explorer, Operative
68	Facebow
69	File, Bone, Surgical, Reusable
70	File, Margin Finishing, Operative, Reusable
71	File, Periodontic, Reusable
72	File, Pulp Canal, Endodontic, Reusable
73	Forceps, Articulation Paper
74	Forceps, Dressing, Dental
75	Forceps, Rongeur, Surgical
76	Forceps, Rubber Dam Clamp
77	Forceps, Tooth Extractor, Surgical
78	Frame, Rubber Dam
79	Gauge, Depth, Instrument, Dental
80	Gel, Electrode, For Pulp Tester
81	General Purpose Dental Tray (Kit)
82	Gingival Retraction Kit
83	Guard, Disk
84	Handle, Instrument, Dental
85	Hemostat, Surgical, Reusable
86	Hoe, Periodontic
87	Holder, Film, X-Ray
88	Ink, Arch Tracing
89	Instrument, Contouring, Matrix, Operative

90	Instrument, Cutting, Operative
91	Instrument, Diamond, Dental
92	Instrument, Diamond, Dental, Reusable
93	Instrument, Filling, Plastic, Dental, Reusable
94	Instrument, Hand, Calculus Removal
95	Instrument, Ligature Tucking, Orthodontic, Reusable
96	Instruments, Dental Hand
97	Intraoral Pressure Gradient Device
98	Knife, Margin Finishing, Operative, Reusable
99	Knife, Periodontic, Reusable
100	Light, Fiber Optic, Dental
101	Light, Operating, Dental
102	Light, Surgical Headlight
103	Marker, Periodontic
104	Material, Impression
105	Material, Impression Tray, Resin
106	Measurer, Gingival Fluid
107	Mirror, Mouth
108	Mouthguard, Migraine/Tension Headache
109	Mouthguard, Over-The-Counter
110	Mouthguard, Prescription
111	Mouthpiece, Saliva Ejector
112	Oral Irrigation Kit
113	Oral Wound Dressing (Mechanical barrier, no secondary intent)
114	Over The Counter Denture Repair Kit
115	Pad, Denture, Over The Counter
116	Pantograph
117	Paper, Articulation
118	Pillow, Cervical (For mild sleep apnea)
119	Plate, Base, Shellac
120	Plier, Orthodontic
121	Pliers, Operative
122	Plugger, Root Canal, Endodontic
123	Point, Abrasive
124	Polyvinyl Methyl Ether Maleic Anhydride &/Or Acid Copolymer & Carboxymethylce
125	Positioner, Tooth, Preformed
126	Preparer, Root Canal Endodontic
127	Probe, Periodontic
128	Protector, Silicate
129	Punch, Biopsy, Surgical Reusable
130	Pusher, Band, Orthodontic
131	Reamer, Pulp Canal, Endodontic, Reusable
132	Reliner, Denture, Over The Counter
133	Remover, Crown

134	Resin, Denture, Relining, Repairing, Rebasing
135	Restorative Instrument and Component Tray (Kit), Reusable
136	Retainer, Matrix
137	Retractor, All Types
138	Saliva, Artificial (Treatment of dryness)
139	Scaler, Periodontic
140	Scanner, Color
141	Scissors, Collar and Crown
142	Scissors, Surgical Tissue, Dental
143	Scraper, Tongue
144	Setter, Band, Orthodontic
145	Solution, Removal, Carries
146	Spreader, Pulp Canal Filling Material, Endodontic, Reusable
147	Strip, Polishing Agent
148	Syringe, Cartridge
149	Syringe, Irrigating (Dental)
150	Syringe, Periodontic, Endodontic, Irrigating
151	Syringe, Restorative and Impression Material
152	System, Optical Impression, Computer Assisted Design and Manufacturing
	(Cad/Cam) Of Dental Restorations
153	Teeth, Preformed Gold Denture (Short-term)
154	Tip, Rubber, Oral Hygiene
155	Tray, Fluoride, Disposable
156	Tray, Impression, Preformed
157	Tube Impression and Matrix
158	Warmer, Anesthetic Tube
159	Wax, Dental, Intraoral
160	Wheel, Polishing Agent

D.	EAR, NOSE, AND THROAT DEVICES
1	Adenotome
. 2	Aid, Visual, For Nausea
3	Applicator, Ent
4	Applicator, Ent Drug
5	Balloon, Epistaxis
6	Bistoury, Tracheal
7	Block, Cutting, Ent, Non-Sterile
8	Block, Cutting, Ent, Sterile
9	Blower, Powder, Ent
10	Bone Particle Collector
11	Bougie, Esophageal, Ent
12	Bougie, Eustachian
13	Bronchoscope Accessory
14	Brush, Biopsy, Bronchoscope (Non-rigid)

15	Bur, Ear, Nose and Throat
16	Catheter, Nasopharyngeal
17	Chisel, Middle-Ear
18	Clamp, Ossicle Holding, Reusable
19	Claw, Foreign Body, Bronchoscope (Non-rigid)
20	Crimper, Wire, Ent, Non-Sterile
21	Crimper, Wire, Ent, Sterile
22	Curette, Adenoid
23	Curette, Biopsy, Bronchoscope (Rigid)
24	Curette, Ear
25	Curette, Ethmoid
26	Curette, Nasal
27	Curette, Salpingeal
28	Curette, Biopsy, Bronchoscope (Non-rigid)
29	Depressor, Metal Tongue, Surgical
30	Device, Antichoke, Tongs
31	Die, Wire Bending, Ent, Non-Sterile
32	Die, Wire Bending, Ent, Sterile
33	Dilator, Nasal
34	Dilator, Tracheal
35	Dissector, Tonsil
36	Dropper, Ent
37	Ear Wax Remover (Non-Active)
38	Ear Wick
39	Ear, Nose, And Throat Surgical Tray (Kit), Reusable
40	Elevator, Ent
41	Excavator, Ear
42	Forceps, Ent
43	Forceps, Wire Closure, Ent, Non-Sterile
44	Gag, Mouth
45	Gauge, Mastoid
46	Gauge, Measuring
47	Gouge, Nasal, Ent
48	Guillotine, Tonsil
49	Hook, Microsurgical Ear
50	Hook, Tonsil Suturing
51	Hook, Tracheal
52	Inhaler, Nasal / Nasal Spray (Without Claims)
53	Inserter, Myringotomy Tube
54	Inserter, Sacculotomy Tack
55	Instrument, Ent Manual Surgical
56	Instrument, Prosthesis Modification for Ossicular Replacement Surgery, Non-Sterile
57	Instrument, Prosthesis Modification for Ossicular Replacement Surgery, Sterile
58	Irrigator, Sinus
59	Jig, Piston Cutting, Ent, Non-Sterile

60	Kit, Earmold, Impression
61	Kit, Test, Olfactory
62	Knife, Ear
63	Knife, Ent
64	Knife, Laryngeal
65	Knife, Myringotomy
66	Knife, Nasal
67	Knife, Tonsil
68	Loop, Wire
69	Microrule, Ent
70	Mirror, Ent
71	Mobilizer, Ent
72	Myringotomy Procedure Kit, (Components are reusable)
73	Needle, Tonsil Suturing
74	Nipper, Malleus
75	Otoscope
76	Perforator, Antrum
77	Perforator, Ear-Lobe
78	Pick, Microsurgical Ear
79	Pierced Ear/Entry Cleaning Tray
80	Press, Vein
81	Probe, Ent
82	Protector, Hearing (Circumaural)
83	Protector, Hearing (Insert)
84	Pump, Nebulizer, Manual
85	Punch, Adenoid
86	Punch, Antrum
87	Punch, Attic
88	Punch, Ent
89	Punch, Ethmoid
90	Punch, Gelfoam, Sterile
91	Punch, Nasal
92	Punch, Tonsil
93	Punch, Gelfoam, Non-Sterile
94	Rasp, Ear
95	Rasp, Frontal-Sinus
96	Rasp, Nasal
97	Retractor, Ent
98	Rod, Measuring Ear
99	Rongeur, Mastoid
100	Rongeur, Nasal
101	Saw, Laryngeal
102	Saw, Nasal
103	Scissors, Ear

104	Scissors, Nasal
105	Scissors, Wire Cutting, Ent, Non-Sterile
106	Scissors, Wire Cutting, Ent, Sterile
107	Screw, Oral
108	Screw, Tonsil
109	Searcher, Mastoid
110	Set, Filliform, Eustachian
111	Set, Laryngeal Injection, Reusable
112	Snare, Ear
113	Snare, Nasal
114	Snare, Tonsil
115	Source, Carrier, Fiber Optic Light
116	Splint, Intranasal Septal
117	Splint, Nasal
118	Spoon, Ear
119	Support, Head, Surgical, Ent
120	Syringe, Ent
121	Tonsillectome
122	Tracheotome
123	Transilluminator, Fiber Optic
124	Tray, Surgical, Ent
125	Trephine, Sinus
126	Tube, Ear Suction
127	Tube, Tonsil Suction, Reusable
128	Vise, Ossicular Finger, Non-Sterile
129	Vise, Ossicular Finger, Sterile
130	Tube, Toynbee Diagnostic

E. G	E. GASTROENTEROLOGY-UROLOGY DEVICES	
1	Accessories, Photographic, For Endoscope (Exclude light sources)	
2	Adapter, Y (Except if intended to transport blood)	
3	Appliance, Colostomy, Disposable	
4	Applicator for Rectal Suppository	
5	Attachment, Binocular, For Endoscope	
6	Attachment, Eyepiece, For Insertion of Prescription Lens	
7	Attachment, Teaching, For Endoscope	
8	Bag, Bile Collecting	
9	Bag, Drainage, With Adhesive, Ostomy	
10	Bag, Hemostatic	
11	Bag, Stoma	
12	Bag, Urinary, Ileostomy	
13	Bag, Urine Collecting, Ureterostomy	
14	Bag, Urine Collection, Leg, For External Use, Non-Sterile	
15	Bag, Urine Collection, Leg, For External Use, Sterile	

16	Bag, Urine Collection, Newborn
17	Bougie, Esophageal, And Gastrointestinal, Gastro- Urology
18	Bougie, Urological
19	Bulb, Inflation, For Endoscope
20	Cannula and Trocar, Suprapubic, Non-Disposable
21	Carrier, Sponge, Endoscopic
22	Cement, Stoma Appliance, Ostomy (Stoma adhesive protective powder/wafer)
23	Chair, Dialysis, Without Scales
24	Clamp, Cannula
25	Clamp, Dialysis Arm
26	Clamp, Line
27	Clamp, Non-Electrical
28	Clamp, Penile
29	Collector, Ostomy
30	Collector, Urine, (And accessories) For Indwelling Catheter
31	Collector, Urine, Pediatric, For Indwelling Catheter
32	Collector, Urine, Powered, Non Indwelling Catheter
33	Connector, Ureteral Catheter
34	Cover, Biopsy Forceps, Reusable
35	Crusher, Spur, Colostomy
36	Cushion, Hemorrhoid
37	Device, Erectile Dysfunction
38	Device, Incontinence, Urosheath Type, Non-Sterile
39	Device, Incontinence, Urosheath Type, Sterile
40	Device, Locking, for Intestinal Clamp
41	Device, Measuring, for Panendoscope
42	Device, Paste-On for Incontinence, Non-Sterile
43	Device, Paste-On for Incontinence, Sterile
44	Dislodger, Stone, Basket, Ureteral, Metal, Reusable
45	Dislodger, Stone, Flexible, Ureteral, Reusable
46	Endoscopic Bite Block
47	Endoscopic, Cytology Brush (Through body orifice)
48	Endoscopic Harvesting Instrument, Reusable
49	Forceps, Disconnect
50	Garment, Protective, For Incontinence (Adult diaper)
51	Gun, Tie, Dialysis
52	Holder, Needle, Gastroenterologic
53	Holder, Ureteral Catheter
54	Hook, Gastro-Urology
55	Instrument, Catheter, Punch
56	Instrument, Special Lens, For Endoscope
57	Jelly, Contact, For Transurethral Surgical Instrument
58	Jelly, Lubricating, For Transurethral Surgical Instrument
59	Knot pusher, Endoscope Accessory (Reusable)

60	Lamp, Endoscope, Incandescent
61	Laryngoscope, Endoscope
62	Light Source System, Diagnostic Endoscopic
63	Light Source, Endoscope, Xenon Arc
64	Light Source, Fiberoptic, Routine
65	Light Source, Incandescent, Diagnostic
66	Light Source, Photographic, Fiberoptic
67	Light, Catheter, Fiberoptic, Glass, Ureteral
68	Media, Culture, Ex Vivo, Tissue and Cell (If components are classified as CLASS A)
69	Oral Removable Retainer for Weight Loss (If not customized)
70	Orchidometer
71	Plate, Patient (Grounding pad, return plate)
72	Plier, Crimp
73	Plier, Tube
74	Pouch, Colostomy
75	Probe and Director, Gastro-Urology
76	Probe, Rectal, Non-Powered
77	Protector, Ostomy
78	Recorder, External, Pressure, Amplifier & Transducer (Analog)
79	Retractor, Fiberoptic, Reusable
80	Retractor, Non-Self-Retaining, Reusable
81	Retractor, Self-Retaining, Reusable
82	Ribdam
83	Ring, Crimp
84	Ring, Joint
85	Ring, Laparotomy
86	Scoop
87	Selector, Size, Ostomy
88	Set, Dialyzer Holder
89	Sheath, Corrugated Rubber, For Non-Indwelling Catheter, Non-Sterile
90	Sheath, Corrugated Rubber, For Non-Indwelling Catheter, Sterile
91	Skin Barrier For Ostomy Use
92	Snare, Flexible, Reusable
93	Snare, Non-Electrical, Reusable
94	Sound, Metal, Interconnected, Reusable
95	Speculum, Rectal
96	Sphyncteroscope
97	Spreader, Bladder Neck
98	Stirrups
99	Strip, Dialysate Ph Indicator
100	Strip, Dialysate, Ph, Bicarbonate, Glucose, Acid, Indicator
101	Strip, Test, Reagent, Residuals for Dialysate, Disinfectant
-	
102 103	Stylet for Catheter, Gastro-Urology Stylet, Ureteral

104	Support, Hernia
105	Surgical Instruments, G-U, Manual (And accessories), Reusable
106	System, Hemodialysis, Remote Accessories
107	System, Urine Drainage, Closed, For Non-Indwelling Catheter, Non-Sterile, Reprocessed/Reusable
108	System, Urine Drainage, Closed, For Non-Indwelling Catheter, Sterile
109	Table, Cysto, Non-Electrical
110	Table, Cystometric, Electric
111	Table, Cystometric, Non-Electric And Accessories
112	Tie, Dialysis
113	Trocar System, Reusable
114	Truss, Umbilical
115	Underpads, Absorbable Padding
116	Urethrometer
117	Urethrotome, Reusable
118	Urinary Drainage Collection Kit, For Indwelling Catheter
119	Wristlet, Patient Return

F.	GENERAL AND PLASTIC SURGERY DEVICES
1	Accessories, Catheter
2	Accessories, Operating-Room, Table (Kit)
3	Accessory, Surgical Apparel
4	Adaptor, Catheter
5	Air Filter Portable Apparatus
6	Apparatus, Suction, Single Patient Use, Portable, Non Powered
7	Apparatus, Suturing, Stomach and Intestinal, Reusable
8	Appliance, Facial Fracture, External
9	Applier, Hemostatic Clip, Reusable
10	Applier, Staple, Surgical, Reusable
11	Applier, Surgical, Clip, Reusable
12	Aspiration Tray (Kit), With Manual Surgical Instruments, Reusable
13	Bag, Intestine
14	Beads, Hydrophilic, For Wound Exudate Absorption
15	Biopsy Device, Percutaneous, Reusable
16	Bit, Surgical, Reusable
17	Blade, Saw, General & Plastic Surgery, Surgical, Reusable
18	Blade, Saw, Surgical, Cardiovascular, Reusable
19	Board, Arm (With cover), Sterile
20	Board, Arm (With cover), Non-Sterile
21	Body Fluid Barrier Kit (Surgical apparel)
22	Brush, Biopsy, General & Plastic Surgery, Reusable
23	Burr, Orthopedic, Reusable

24	Camera, Still, Endoscopic (To record operative procedure)
25	Camera, Still, Microsurgical (To record operative procedure)
26	Camera, Still, Surgical (To record operative procedure)
27	Camera, Surgical and Accessories
28	Camera, Television, Microsurgical, With Audio
29	Camera, Television, Microsurgical, Without Audio
30	Camera, Television, Surgical, With Audio
31	Camera, Television, Surgical, Without Audio
32	Cannula, Ear
33	Cap, Surgical
34	Carrier, Ligature
35	Catheter, Eustachian, General & Plastic Surgery
36	Catheter, Irrigation, to be inserted in the body orifice
37	Chair, Surgical, Ac-Powered
38	Chair, Surgical, Non-Electrical
39	Chiari, Surgical, Non-Electrical Chisel (Osteotome), Reusable
40	Chisel, Mastoid, Reusable
41	Chisel, Nasal, Reusable Chisel, Nasal, Reusable
42	Chisel, Surgical, Manual, Reusable
43	Clamp, Reusable
44	Clamp, Surgical, General & Plastic Surgery, Reusable
45	Closure, Wound, Adhesive
46	Connector, Catheter (Except if use transport blood)
47	Contractor, Surgical
48	Cover, Barrier, Protective
49	Cover, Shoe, Operating-Room
50	Cutter, Surgical, Reusable
51	Dilator, Catheter
52	Dissector, Surgical, General & Plastic Surgery, Reusable
53	Drape, Adhesive, Aerosol
54	Drape, Microscope, Ophthalmic
55	Drape, Patient, Ophthalmic
56	Drape, Pure Latex Sheet, With Self-Retaining Finger Cot
57	Drape, Surgical
58	Drape, Surgical, Ent
59	Drape, Urological, Disposable
60	Dress, Surgical
61	Dressing Change Tray
62	Driver, Surgical, Pin (Air-powered)
63	Elastomer, Silicone, For Scar Management
64	Electrode, Gel, Electrosurgical
65	Elevator, Reusable
66	Elevator, Surgical, General & Plastic Surgery, Reusable
67	Examination Gloves, Non Sterile

68	Expander, Surgical, Skin Graft (Instrument)
69	Extractor, Vein
70	File, Surgical, General & Plastic Surgery
71	Film, Camera, Surgical
72	First Aid Kit Without Drug (components are in CLASS A)
73	Forceps, Reusable
74	Forceps, General & Plastic Surgery, Reusable
75	Forceps, Wire Holding
76	Frame, Camera, Surgical
77	Gauze/Sponge, Nonresorbable For External Use
78	General Surgery Tray (Kit), Includes Reusable Instruments
79	Gouge, Surgical, General & Plastic Surgery
80	Gown, Isolation, Surgical
81	Gown, Patient
82	Gown, Surgical
83	Guard, Instrument
84	Guard, Skin Graft
85	Guide, Surgical, Instrument, Reusable
86	Hammer, Surgical, Reusable
87	Handle, Scalpel
88	Head, Surgical, Hammer
89	Helmet, Surgical
90	Hemostat (For physical compression)
91	Holder, Camera, Surgical
92	Holder, Ear Speculum
93	Holder, Speculum, Ent
94	Hood, Surgical
95	Hook, Bone
96	Hook, Surgical, General & Plastic Surgery, Reusable
97	Illuminator, Fiberoptic, Surgical Field
98	Illuminator, Non-Remote
99	Illuminator, Remote
100	Instrument, Manual, Surgical, General Use
101	Kit, First Aid, Talking (Nonresorbable sponge w/o drugs/biologics)
102	Kit, Plastic Surgery and Accessories (All components are in CLASS A)
103	Knife, Amputation
104	Knife, Surgical, Reusable
105	Label or Tag, Sterile
106	Lamp, Fluorescein, Ac-Powered
107	Lamp, Operating-Room
108	Lamp, Surgical
109	Lamp, Surgical, Incandescent
110	Lens, Camera, Surgical
111	Light, Surgical, Accessories

112	Light, Surgical, Carrier
113	
	Light, Surgical, Councerton
114	Light, Surgical, Connector
115	Light, Surgical, Endoscopic
116	Light, Surgical, Fiberoptic
117	Light, Surgical, Floor Standing
118	Light, Surgical, Instrument
119	Loupe, Diagnostic/Surgical
120	Mallet
121	Mallet, Surgical, General & Plastic Surgery
122	Marker, Skin
123	Mask, Surgical
124	Material, External Aesthetic Restoration, No Adhesive
125	Material, External Aesthetic Restoration, Used with Adhesive
126	Microscope, Operating & Accessories, Ac-Powered, Ophthalmic
127	Microscope, Operating, Non-Electric, Ophthalmic
128	Microscope, Surgical
129	Microscope, Surgical, General & Plastic Surgery
130	Non-Surgical Isolation Gown
131	Orthopedic Tray
132	Osteotome, Reusable
133	Osteotome, Manual, Reusable
134	Pad, Eye
135	Pad, Kelly
136	Pliers, Surgical
137	Prosthesis, Adhesive, External
138	Prosthesis, Breast, External, No Adhesive
139	Prosthesis, Breast, External, Used with Adhesive
140	Prosthesis, Nail
141	Rasp
142	Rasp, Surgical, General & Plastic Surgery
143	Razor, Surgical
144	Retractor, Reusable
145	Scissors, General, Surgical
146	Scrapper, Skin Specimen
147	Single Use Instrument Tray Kit
148	Skin Prep Tray (Kit), (Without alcohol pad)
149	Snare, Surgical
150	Solvent, Adhesive Tape
151	Spatula, Orthopedic
152	Spatula, Surgical, General & Plastic Surgery
153	Specula Accessories
154	Speculum, Ent
155	Speculum, Illuminated
	r

156	Speculum, Non-Illuminated
157	Splint, Extremity, Inflatable, External
158	Splint, Extremity, Non-Inflatable, External, Non-Sterile
159	Splint, Extremity, Noninflatable, External, Sterile
160	Strip, Adhesive, Closure, Skin
161	Stripper, Vein, Reusable
162	Stylet, Surgical, General & Plastic Surgery
163	Suit, Surgical
164	Surgical Mask with Antimicrobial/Antiviral Agent
165	Surgical Table Cushion
166	Suture Removal Kit
167	System, Skin Closure
168	Table and Attachments, Operating-Room
169	Table, Examination, Medical, Powered
170	Table, Operating-Room, Ac-Powered
171	Table, Operating-Room, Electrical
172	Table, Operating-Room, Manual
173	Table, Operating-Room, Mechanical
174	Table, Operating-Room, Non-Electrical
175	Table, Operating-Room, Pneumatic
176	Table, Surgical with Orthopedic Accessories, Ac- Powered
177	Table, Surgical with Orthopedic Accessories, Manual
178	Tape, Camera, Surgical
179	Tape, Measuring, Rulers and Calipers
180	Tape, Orthopedic
181	Tourniquet Kit
182	Tourniquet, Gastro-Urology
183	Tourniquet, Nonpneumatic
184	Tray, Surgical
185	Tray, Surgical, Instrument
186	Trousers, Anti-Shock
187	Vise, Bench, Surgical

G. (G. GENERAL HOSPITAL AND PERSONAL USE DEVICES	
1	Abdominal Pad	
2	Applicator, Absorbent Tipped, Non-Sterile	
3	Applicator, Absorbent Tipped, Sterile	
4	Bag, Ice (For medical purpose)	
5	Bandage, Elastic	
6	Bandage, Liquid	
7	Bandage, Liquid, Skin Protectant	
8	Bariatric Bed	
9	Bassinet, Hospital	
10	Bed, Ac-Powered Adjustable Hospital	

11	Bed, Hydraulic, Adjustable Hospital
12	Bed, Manual
13	Bed, Pediatric Open Hospital
14	Bed, Therapeutic, Ac-Powered, Adjustable Home-Use
15	Bedding, Disposable, Medical
16	Binder, Abdominal, For medical purpose
17	Binder, Elastic
18	Binder, Medical, Therapeutic
19	Binder, Perineal
20	Board, Bed
21	Board, Cardiopulmonary
22	Bottle, Hot/Cold Water
23	Cap (For disinfection, seal, taper or dead end)
24	Chair and Table, Medical
25	Chair, Blood Donor
26	Chair, Examination and Treatment
27	Chair, Geriatric
28	Clip Applier, Reusable
29	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
30	Container, Liquid Medication, Graduated
31	Corset Cast
32	
33	Counter, Sponge, Surgical Cover, Cast
34	Cover, Mattress (Medical purposes)
35	Cream, Skin Barrier
36	Depressor, Tongue, Non-Surgical
37	Detectors and Removers, Lice, (Including combs)
38	Device, Intravascular Catheter Securement
39	Device, Occlusion, Umbilical
40	Device, Transfer, Patient, Manual
41	Device, Vein Location, Liquid Crystal
42	Device, Vein Education, Enquire Crystal Device, Vein Stabilization
43	Dispenser, Liquid Medication
44	Dressing, Compression
45	Ear Irrigation Kit, non-powered
46	Electrode, In Vivo Calcium Ion Selective
47	Fiber, Medical, Absorbent
48	Finger Cot
49	Glove, Patient Examination, Powder-Free
50	Gown, Examination
51	Infant Positioner, Rx, Use In Highly Monitored Setting
52	Infusor, Pressure, For I.V. Bags
53	Insoles, Medical
54	Kit, Decontamination
J T	Ni, Decontainination

55	Kit, Suction, Snake-Bite
56	Latex Patient Examination Glove
57	Lift, Patient, Ac-Powered
58	Lift, Patient, Non-Ac-Powered
59	Light, Examination, Medical, Battery Powered
60	Lotion, Skin Barrier
61	Lubricant, Patient
62	Lubricant, Vaginal, Patient
63	Luer Lock
64	Manometer, Spinal-Fluid
65	Mattress, Flotation Therapy, Non-Powered
66	Medical Device Data System
67	Medical Gloves With Chemotherapy Labeling Claims - Test For Use With
07	Chemotherapy Drugs
68	Medication Management System, Remote
69	N95 Respirator with Antimicrobial/Antiviral Agent For Use By The General Public In
	Public Health Medical Emergencies
70	Needle, Hypodermic, Single Lumen, Reusable
71	Oral Lubricant
72	Pad, Neonatal Eye
73	Patient Bed with Canopy/Restraints
74	Patient Examination Glove
75	Patient Examination Glove, Specialty
76	Pen Injector
77	Plaster/Plastic Strip
78	Polymer Patient Examination Glove
79	Port, Protector/Cushion
80	Powder-Free Guayle Rubber Examination Glove
81	Powder-Free Polychloroprene Patient Examination Glove
82	Protector, Skin Pressure
83	Protector, Wound, Plastic
84	Radiation Attenuating Medical Glove
85	Reconstruction Kit/Device; Fixation Device, Reusable
86	Respirator, N95, For Use in Health Care Facilities
87	Restraint, Patient, Conductive
88	Restraint, Protective
89	Ring Cutter
90	Scale, Patient, for medical purpose
91	Scale, Sponge, Surgical, Electrically-Powered
92	Scale, Stand-On, Patient, for medical examination
93	Scale, Surgical Sponge
94	Scissors, Medical, Reusable
95	Sheet, Burn
96	Solution, Cold Sterilizing
97	Stand, Infusion

98	Stocking, Medical Support (For general medical purposes)
99	Stocking, Medical Support (To prevent pooling of blood in legs)
100	Stretcher, Hand-Carried
101	Stretcher, Patient Restraint
102	Stretcher, Wheeled
103	Support, Scrotal, Therapeutic
104	Syringe, Antistick
105	Syringe, Cartridge
106	Syringe, Irrigating (Non dental)
107	Syringe, Piston
108	Syringe, Piston, Reusable
109	Syringe Without Needle
110	Tape and Bandage, Adhesive
111	Tape and Bandage, Adhesive (With disinfectant)
112	Timer, Apgar
113	Topical Approximation System
114	Trap, Sterile Specimen
115	Tube, Aspirating, Flexible, Connecting
116	Tubing, Fluid Delivery
117	Tubing, Noninvasive
118	Umbilical Clamp
119	Urinal
120	Vinyl Patient Examination Glove
121	Washer of Body Waste Receptacles

Н. 1	NEUROLOGICAL DEVICES
1	Analyzer, Spectrum, Electroencephalogram Signal
2	Anvil, Skull Plate
3	Ataxiagraph
4	Block, Bite
5	Block, Test, Ultrasonic Scanner Calibration
6.	Chair, Neurosurgical
7	Clip, Scalp, Reusable
8	Device, Acupressure
9	Device, Vibration Threshold Measurement
10	Device, Cpr Assist
11	Discriminator, Two-Point
12	Eating Disorder Conditioning Tool
13	Esthesiometer
14	Fork, Tuning
15	Generator, Electroencephalograph Test Signal
16	Headrest, Neurosurgical
17	Instrument, Clip Forming/Cutting
18	Instrument, Clip Removal, Reusable

19	Instrument, Clip, Forming/Cutting, Reusable
20	Instrument, Cranioplasty Material Forming
21	Instrument, Microsurgical, Reusable
22	Instrument, Surgical, Non-Powered
23	Leukotome
24	Percussor
25	Pinwheel
26	Punch, Skull
27	Rack, Clip
28	Rongeur, Manual (Reusable)
29	Screwdriver, Skull Plate

I. C	DBSTETRICAL AND GYNECOLOGICAL DEVICES
1	Applicator, Vaginal
2	Bell, Circumcision
3	Brush, Endometrial, Reusable
4	Clamp, Uterine, Reusable
5	Cranioclast, Reusable
6	Craniotribe, Reusable
7	Curette, Suction, Endometrial (And accessories), Reusable
8	Curette, Uterine, Reusable
9	Dilator, Cervical, Expandable
10	Dilator, Cervical, Fixed Size
11	Dilator, Cervical, Vibratory
12	Dilator, Vaginal
13	Douche Apparatus, Vaginal, Therapeutic
14	Elevator, Uterine (Reusable)
15	Emergency Obstetrical Kit (Components are classified as CLASS A)
16	Fluid, Cytological Collection
17	Forceps, Biopsy, Gynecological, Reusable
18	Forceps, Obstetrical
. 19	Forceps, Surgical, Gynecological
20	Hook, Destructive, Obstetrical
21	Hook, Fibroid, Gynecological
22	Hysteroscope (And accessories) - for visual examination using visible or near infrared spectrum
23	Hysteroscope Accessories
24	Instrument, Destructive, Fetal, Obstetric
25	Instrument, Manual, General Obstetric-Gynecologic
26	Instrument, Manual, Specialized Obstetric-Gynecologic
27	Kit, Pelvic Exam (Components are Reusable)
28	Knife, Cervical Cone, Reusable
29	Labor and Delivery Kit (Components are reusable)
30	Lubricant, Personal

31	Microscope And Microscope Accessories, Reproduction, Assisted
32	Packer, Uterine
33	Pap Smear Kit
34	Pelvimeter, External
35	Pelvimeter, Internal
36	Remover, Intrauterine Device, Contraceptive, Hook-Type
37	Retractor, Vaginal
38	Scissors, Episiotomy
39	Scissors, Umbilical
40	Seminal Fluid Collection Kit
41	Sheet, Recording, Breast Examination
42	Shield, Circumcision, Reusable
43	Sound, Uterine
44	Source, Chemiluminescent Light (Near the infrared spectrum)
45	Spatula, Cervical, Cytological
46	Speculum, Vaginal, Metal
47	Speculum, Vaginal, Metal, Fiberoptic
48	Speculum, Nonmetal
49	Speculum, Nonmetal, Fiberoptic
50	Stethoscope, Fetal
51	Table, Obstetric (And Accessories)
52	Table, Obstetrical, AC-Powered (And accessories)
53	Table, Obstetrical, Manual (And accessories)
54	Tenaculum, Uterine, Reusable
55	Tubing and Tubing/Filter Fits
56	Viscometer, Mucus, Cervical

J. OPHTHALMIC DEVICES	
1	Adaptometer (Biophotometer)
2	Adaptometer (Biophotometer), Software-Based Data Acquisition And Stimulus Generation
3	Aid, Vision Image Intensification
4	Aid, Vision, Electronic, Ac-Powered
5	Aid, Vision, Electronic, Battery-Powered
6	Aid, Vision, Optical, Ac-Powered
7	Aid, Vision, Optical, Battery-Powered
8	Anomaloscope
9	Applicator, Ocular Pressure
10	Biomicroscope, Slit-Lamp, Ac-Powered
11	Brush, Haidinger, (Including macular integrity)
12	Burr, Corneal, Manual
13	Caliper, Ophthalmic
14	Campimeter, Stereo, Battery-Powered

15	Chair, Ophthalmic, Ac-Powered
16	Chair, Ophthalmic, Manual
17	Chart, Visual Acuity
18	Clamp, Eyelid, Ophthalmic
19	Clamp, Muscle, Ophthalmic
20	Clip, Iris Retractor
21	Clip, Lens, Trial, Ophthalmic
22	Compressor, Orbital
23	Crutch, Ptosis
24	Depressor, Orbital
25	Device, Fixation, Ac-Powered, Ophthalmic
26	Distometer
27	Drum, Opticokinetic
28	Erisophake, Reusable
29	Euthyscope, AC-Powered
30	Euthyscope, Battery-Powered
31	Exophthalmometer
32	Expressor
33	Fixation, Vision Training, Binocular
34	Flasher, Afterimage, Ophthalmic
35	Forceps, Ophthalmic, Reusable
36	Fornixscope
37	Frame, Trial, Ophthalmic Grid, Amsler
38	<u> </u>
39	Haploscope Haploscope A a Powered
40	Headlamp, Operating, Ac-Powered
41	Headlamp, Operating, Battery-Operated
42	Headlight, Fiber Optic Focusing
43	Hook, Ophthalmic, Reusable
44	Illuminator, Color Vision Plate
45	Inserter/Remover Contact Lens
46	Instrument, Measuring, Stereopsis
47	Introducer, Sphere
48	Keratoscope, Ac-Powered
49	Keratoscope, Battery-Powered
50	Knife, Ophthalmic, Reusable
51	Lens, Bagolini
52	Lens, Condensing, Diagnostic
53	Lens, Fresnel, Flexible, Diagnostic
54	Lens, Fundus, Hruby, Diagnostic
55	Lens, Maddox
56	Lens, Spectacle (Prescription), For Reading Discomfort
57	Lens, Spectacle, Non-Custom (Prescription)
58	Lens, Prescription, Color Deficiency

59	Light, Headband, Surgical
60	Locator, Magnetic
61	Loupe, Binocular, Low Power
62	Magnet, Permanent
63	Magnifier, Hand-Held, Low-Vision
64	Maxwell Spot, Ac-Powered
65	Mirror, Headband, Ophthalmic
66	Needle, Phacoemulsification, Reusable
67	Ophthalmoscopes, Replacement Batteries, Hand-Held
68	Perimeter, Ac-Powered
69	Perimeter, Automatic, Ac-Powered
70	Perimeter, Manual
71	Photokeratoscope
72	Photokeratoscope, Battery Powered
73	Prism, Bar, Ophthalmic
74	Prism, Fresnel, Ophthalmic
75	Prism, Gonioscopic
76	Prism, Rotary, Ophthalmic
77	Probe, Lachrymal, Reusable
78	Probe, Trabeculotomy, Reusable
79	Projector, Ophthalmic
80	Punch, Corneo-Scleral, Reusable
81	Pupillograph
82	Pupillometer, Ac-Powered
83	Pupillometer, Manual
84	Rack, Skiascopic
85	Reader, Bar, Ophthalmic
86	Reader, Prism, Ophthalmic
87	Refractor, Manual, Non-Powered, Including Phoropter
88	Retinoscope, Battery-Powered
89	Ring, Ophthalmic (Flieringa)
90	Rongeur, Lachrymal Sac, Reusable
91	Ruler, Nearpoint (Punctometer)
92	Scissors, Ophthalmic, Reusable
93	Screen, Tangent, Ac-Powered (Campimeter)
94	Screen, Tangent, Felt (Campimeter)
95	Screen, Tangent, Projection, Ac-Powered
96	Screen, Tangent, Projection, Battery-Powered
97	Screen, Tangent, Target
98	Screen, Tangent, Target, Battery-Powered
99	Selector, Color, Spectacle, Lens, Tint
100	Set, Lens, Trial, Ophthalmic
101	Shield, Eye, Ophthalmic (Including Sunlamp Protective Eyewear And Post-Mydriatic Eyewear)
102	Simulatan (Including crossed cylinder)

103	Snare, Enucleating
104	Spatula, Ophthalmic
105	Spectacle Microscope, Low-Vision
106	Spectacle, Magnifying
107	Spectacle, Operating (Loupe), Ophthalmic
108	Specula, Ophthalmic, Reusable
109	Spoon, Ophthalmic
110	Spud, Ophthalmic
111	Stand, Instrument, Ac-Powered, Ophthalmic
112	Stand, Instrument, Ophthalmic, Battery Powered
113	Stand, Instrument, Ophthalmic, Non-Powered
114	Stereoscope, Ac-Powered
115	Stereoscope, Battery-Powered
116	Sunglasses (With grade)
117	System, Reading, Television, Closed-Circuit
118	Tape, Nystagmus
119	Target, Fusion and Stereoscopic
120	Telescope, Hand-Held, Low-Vision (For medical purpose)
121	Telescope, Spectacle, Low-Vision
122	Test, Spectacle Dissociation, Ac-Powered (Lancaster)
123	Test, Spectacle Dissociation, Battery-Powered (Lancaster)
124	Tester, Color Vision
125	Trabeculotome, Manual
126	Transilluminator, Ac-Powered
127	Transilluminator, Battery-Powered
128	Trephine, Manual, Ophthalmic
129	Weights, Eyelid, External

К. С	K. ORTHOPEDIC DEVICES	
1	Apparatus, Traction, Non-Powered	
2	Applier, Cerclage	
3	Arthrometer, Manual	
4	Belt, Pelvic, Traction	
5	Bender	
6	Bone Mill	
7	Brace, Drill	
8	Broach	
9	Caliper	
10	Component, Cast (Plaster of Paris)	
11	Component, Traction, Non-Invasive	
12	Corkscrew	
13	Countersink	
14	Crimper, Pin	

15	Cutter, Wire
16	Driver, Prosthesis
17	Dynamometer, Nonpowered
18	Evacuator, Vapor, Cement Monomer
19	Extractor, Reusable
20	File
21	Fork
22	Gauge, Depth
23	Goniometer, Ac-Powered
24	Goniometer, Non-powered
25	Guide, Drill, Ligament
26	Halter, Head, Traction
27	Holder, Needle; Orthopedic
28	Impactor
29	Instrument, Bending or Contouring
30	Instrument, Cast Application/Removal, Manual
31	Instrument, Cast Removal, Ac-Powered
32	Instrument, Compression
33	Knife, Orthopedic, Reusable
34	Mixer, Cement, For Clinical Use
35	Orthopaedic Surgical Planning and Instrument Guides, Reusable
36	Orthopedic Manual Surgical Instrument
37	Passer
38	Passer, Wire, Orthopedic, Reusable
39	Positioner, Socket
40	Probe
41	Protractor
42	Punch, Femoral Neck
43	Pusher, Socket
44	Reamer, Reusable
45	Rongeur, Reusable
46	Scissors, Orthopedic, Surgical
47	Screwdriver
48	Screwdriver, Surgical, Reusable
49	Set, Hollow Mill
50	Skid, Bone
51	Splint, Traction
52	Staple Driver
53	Starter, Bone Screw
54	Stripper, Surgical
55	Tamp
56	Tap, Bone, Reusable
57	Template
58	Trephine, Reusable

59	Tube, Cement Ventilation (Reusable)
60	Twister, Wire
61	Unit, Traction, Hip, Non-Powered, Non-Penetrating
62	Wrench

	PHYSICAL MEDICINE DEVICES
1	Accessories, Traction
2	Accessories, Wheelchair
3	Adaptor, Dressing
4	Adaptor, Grooming (Assist device for patient)
5	Adaptor, Holder, Syringe
6	Adaptor, Hygiene (Assist device for patient)
7	Adaptor, Hygiene (Assist device for patient) Adhesive Backed Thermal Skin Patches
8	Aid, Transfer
9	Armboard, Wheelchair
\vdash	
10	Armrest, Wheelchair
11	Assembly, Knee/Shank/Ankle/Foot, External
12	Assembly, Shoulder/Elbow/Forearm/Wrist/Hand, Mechanical
13	Assembly, Thigh/Knee/Shank/Ankle/Foot, External (Mechanical)
14	Assembly, Shoulder/Elbow/Forearm/Wrist/Hand, Powered
15	Attachment, Commode, Wheelchair
16	Attachment, Narrowing, Wheelchair
17	Band or Belt, Pelvic Support
18	Bandage, Cast (Plaster of Paris)
19	Bars, Parallel, Exercise, for medical purpose
20	Bars, Parallel, Powered, for medical purpose
21	Bath, Sitz, Non Powered
22	Bed, Patient Rotation, Manual
23	Bed, Patient Rotation, Powered
24	Belt, Wheelchair
25	Board, Lap, Wheelchair
.26	Board, Scooter, Prone, for Medical purpose
27	Brake, Extension, Wheelchair
28	Cable
29	Cable, Electrode (Patient Cable for ECG, EEG, etc)
30	Cage, Knee
31	Cane
32	Cane, Safety Walk
33	Chair, Adjustable, Mechanical
34	Chair, Positioning, Electric
35	Chair, With Casters
36	Climber, Curb, Wheelchair
37	Component, External, Limb, Ankle/Foot
38	Components, Exercise, For Medical Purpose

39	Components, Wheelchair
40	Corset Cast
41	Cover, Limb
42	Crutch
43	Cuff, Pusher, Wheelchair
44	Cushion, Flotation, For Medical Purpose
45	Cushion, Flotation, Therapeutic
46	Cushion, Wheelchair
47	Device, Anti-Tip, Wheelchair
48	Device, Finger-Sucking
49	Device, Prosthesis Alignment
50	Elevator, Wheelchair, Portable
51	Exerciser, Non-Measuring, For Medical Purpose
50	First Aid Kit With Drug, if primary intent is as medical device and medical device
52	components are CLASS A
53	Foot Examination Tool for Inflammatory Changes
54	Footrest, Wheelchair
55	Hand, External Limb Component, Mechanical
56	Hand, External Limb Component, Powered
57	Handrim, Wheelchair
58	Head Halter, Traction
59	Helmet, Cranial, For Protective Use
60	Hill Holder, Wheelchair
61	Holder, Crutch And Cane, Wheelchair
62	Hook, External Limb Component, Mechanical
63	Hook, External Limb Component, Powered
64	Joint, Ankle, External Brace
65	Joint, Elbow, External Limb Component, Mechanical
66	Joint, Elbow, External Limb Component, Powered
67	Joint, Hip, External Brace
68	Joint, Hip, External Limb Component
69	Joint, Knee, External Brace
70	Joint, Knee, External Limb Component
71	Joint, Shoulder, External Limb Component
72	Manipulator, Plunger-Like Joint
73	Massager, Therapeutic, Manual
74	Monitor, Orthotic/Prosthetic
75	Orthosis, Abdominal
76	Orthosis, Cervical (cervical collar)
77	Orthosis, Cervical-Thoracic, Rigid
78	Orthosis, Corrective Shoe
79	Orthosis, Foot Drop
80	Orthosis, Limb Brace (Spine system - external, non implantable, support)
81	Orthosis, Lumbar
82	Orthosis, Lumbo-Sacral

r

126	Unit, Heating, Powered
127	Unit, Wrist, External Limb Component, Mechanical
128	Unit, Wrist, External Limb Component, Powered
129	Walker, Mechanical
130	Walker, Mechanical, Poly Vinyl Chloride (Pvc)
131	Wheelchair, Mechanical
132	Wheelchair, Powered
133	Wheelchair, Special Grade
134	Wheelchair, Stair Climbing
135	Wheelchair, Standup

M. I	RADIOLOGY DEVICES
1	Accessory - Film Dosimetry System
2	Apron, Leaded
3	Apron, Protective
4	Barrier, Control Panel, X-Ray, Movable
5	Bed, Scanning, Nuclear
6	Camera, X-Ray, Fluorographic, Cine Or Spot
7	Cap, Cooling (Infants)
8	Chair, Pneumoencephalographic
9	Changer, Radiographic Film/Cassette
10	Couch, Radiation Therapy, Powered
11	Cradle, Patient, Radiologic
12	Curtain, Protective, Radiographic
13	Device, Communications, Images, Ophthalmic
14	Device, Digital Image Storage, Radiological
15	Device, Hardcopy, Images, Ophthalmic
16	Device, Spot-Film
17	Dryer, Film, Radiographic
18	Film, Radiographic
19	Grid, Radiographic
20	Holder, Head, Radiographic
21	Holder, Radiographic Cassette, Wall-Mounted
22	Holder, Syringe, Lead
23	Illuminator, Radiographic-Film
24	Illuminator, Radiographic-Film, Explosion-Proof
25	Media, Reusable Image
26	Media, Coupling, Ultrasound (Acoustic or transmission gel)
27	Radiographic Contrast Tray
28	Radiographic Protective Glove
29	Radiology Dental Tray
30	Screen, Intensifying, Radiographic
31	Screen, Leaded, Operator Radiation Protector
32	Shield, Eye, Radiological

33	Shield, Gonadal
34	Shield, Protective, Personnel
35	Shield, Vial
36	System, X-Ray, Film Marking, Radiographic
37	Table, Radiographic, Non-Tilting, Powered
38	Table, Radiographic, Stationary Top
39	Table, Radiographic, Tilting
40	Table, Radiologic
41	Transilluminator (Diaphanoscope), Visible Light, Near Infrared Spectrum