



**FDA CIRCULAR**

No. \_\_\_\_\_

**TO: ALL MEDICAL DEVICE MANUFACTURERS, TRADERS, DISTRIBUTORS AND OTHER CONCERNED PARTIES**

**SUBJECT: 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 apply 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 RA 9711 and its IRR.

## **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.

## **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.

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DRAFT FOR COMMENT



ANNEX A  
LIST OF CLASS A MEDICAL DEVICES

A. ANESTHESIOLOGY DEVICES	
1	Airway, Nasopharyngeal, short term (>30mins - up to 30 days)
2	Airway, Oropharyngeal, Anesthesiology, short-term (>30 mins. - up to 30 days)
3	Algesimeter, Manual
4	Apparatus, Gas-Scavenging
5	Bottle, Blow
6	Cardiopulmonary Resuscitation Aid Kit, Manual
7	Cart, Emergency, Cardiopulmonary (Excluding equipment)
8	Chair, Posture, For Cardiac and Pulmonary Treatment
9	Clip, Nose
10	Connector, Airway (Extension)
11	Cylinder, Compressed Gas, and Valve
12	Cylinder, Gas (Empty)
13	Device, Fixation, Tracheal Tube
14	Device, Rebreathing
15	Device, Heimlich Maneuver Assist
16	Drain, Tee (Water trap)
17	Dropper, Ether
18	Flowmeter, Nonback-Pressure Compensated, Bourdon Gauge
19	Flowmeter, Tube, Thorpe, Back-Pressure Compensated
20	Forceps, Tube Introduction
21	Gas, Collecting Vessel
22	Hood, Oxygen, Infant
23	Hook, Ether
24	Laryngoscope Kit
25	Laryngoscope, Non-Rigid
26	Laryngoscope, Rigid
27	Mask, Oxygen (Not connected in an active medical device)
28	Mask, Oxygen, Low Concentration, Venturi (Not connected in an active medical device)
29	Mask, Oxygen, Non-Rebreathing (Not connected in an active medical device)
30	Meter, Airway Pressure (Inspiratory Force) - Analog
31	Meter, Peak Flow, Spirometry - Analog
32	Mixer, Breathing Gases, Anesthesia Inhalation
33	Nasal Endotracheal Tube Holder Kit
34	Protector, Dental
35	Resuscitator, Manual Non Self-Inflating (Attached in an oxygen tank)
36	Spacer, Direct Patient Interface
37	Spreader, Cuff
38	Stethoscope Head



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

### **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	Batteries, Rechargeable, for Class 2 Devices
7	Batteries, Rechargeable, for Class 3 Devices
8	Charger, Pacemaker
9	Compressor, Cardiac, External
10	Display, Cathode-Ray Tube, Medical
11	Electrode, Electrocardiograph
12	Electrode, Electrocardiograph, Multi-Function
13	Instruments, Surgical, Cardiovascular
14	Legging, Compression, Non-Inflatable
15	Monitor, Line Isolation
16	Recorder, Magnetic Tape, Medical
17	Recorder, Paper Chart
18	Reprocessed/Reusable Blood Pressure Cuff
19	Stethoscope, Manual
20	Stripper, Artery, Intraluminal, Reusable
21	Stripper, Vein, External, Reusable
22	Syringe, Balloon Inflation (Inflation device)
23	System, Signal Isolation

### **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
6	Adhesive, Denture, Carboxymethylcellulose Sodium (32%) And Ethylene-Oxide 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 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	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	Diagnostic Light, Soft Tissue Detector (Near infrared spectrum)
61	Driver, Band, Orthodontic
62	Driver, Wire, And Bone Drill, Manual
63	Elevator, Surgical, Dental
64	Eraser, Dental Stain
65	Expiratory Resistance Valve, Intranasal, For Obstructive Sleep Apnea
66	Explorer, Operative
67	Facebow
68	File, Bone, Surgical, Reusable
69	File, Margin Finishing, Operative, Reusable
70	File, Periodontic, Reusable
71	File, Pulp Canal, Endodontic, Reusable
72	Forceps, Articulation Paper
73	Forceps, Dressing, Dental
74	Forceps, Rongeur, Surgical
75	Forceps, Rubber Dam Clamp
76	Forceps, Tooth Extractor, Surgical
77	Frame, Rubber Dam
78	Gauge, Depth, Instrument, Dental
79	Gel, Electrode, For Pulp Tester
80	General Purpose Dental Tray (Kit)
81	Gingival Retraction Kit
82	Guard, Disk
83	Handle, Instrument, Dental
84	Hemostat, Surgical, Reusable
85	Hoe, Periodontic
86	Holder, Film, X-Ray
87	Ink, Arch Tracing
88	Instrument, Contouring, Matrix, Operative
89	Instrument, Cutting, Operative



90	Instrument, Diamond, Dental
91	Instrument, Diamond, Dental, Reusable
92	Instrument, Filling, Plastic, Dental, Reusable
93	Instrument, Hand, Calculus Removal
94	Instrument, Ligature Tucking, Orthodontic, Reusable
95	Instruments, Dental Hand
96	Intraoral Pressure Gradient Device
97	Knife, Margin Finishing, Operative, Reusable
98	Knife, Periodontic, Reusable
99	Light, Fiber Optic, Dental
100	Light, Operating, Dental
101	Light, Surgical Headlight
102	Marker, Periodontic
103	Material, Impression
104	Material, Impression Tray, Resin
105	Measurer, Gingival Fluid
106	Mirror, Mouth
107	Mouthguard, Migraine/Tension Headache
108	Mouthguard, Over-The-Counter
109	Mouthguard, Prescription
110	Mouthpiece, Saliva Ejector
111	Oral Irrigation Kit
112	Oral Wound Dressing (Mechanical barrier, no secondary intent)
113	Over The Counter Denture Repair Kit
114	Pad, Denture, Over The Counter
115	Pantograph
116	Paper, Articulation
117	Patient Personal Hygiene Kit (Electric toothbrush)
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 Wick
38	Ear, Nose, And Throat Surgical Tray (Kit), Reusable
39	Elevator, Ent
40	Excavator, Ear
41	Forceps, Ent
42	Forceps, Wire Closure, Ent, Non-Sterile
43	Gag, Mouth
44	Gauge, Mastoid
45	Gauge, Measuring
46	Gouge, Nasal, Ent
47	Guillotine, Tonsil
48	Hook, Microsurgical Ear
49	Hook, Tonsil Suturing
50	Hook, Tracheal
51	Inhaler, Nasal
52	Insertor, Myringotomy Tube
53	Insertor, Sacculotomy Tack
54	Instrument, Ent Manual Surgical
55	Instrument, Prosthesis Modification for Ossicular Replacement Surgery, Non-Sterile
56	Instrument, Prosthesis Modification for Ossicular Replacement Surgery, Sterile
57	Irrigator, Sinus
58	Jig, Piston Cutting, Ent, Non-Sterile
59	Kit, Earmold, Impression
60	Kit, Test, Olfactory



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



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

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



62	Laryngoscope, Endoscope
63	Light Source System, Diagnostic Endoscopic
64	Light Source, Endoscope, Xenon Arc
65	Light Source, Fiberoptic, Routine
66	Light Source, Incandescent, Diagnostic
67	Light Source, Photographic, Fiberoptic
68	Light, Catheter, Fiberoptic, Glass, Ureteral
69	Media, Culture, Ex Vivo, Tissue and Cell (If components are classified as CLASS A)
70	Oral Removable Retainer for Weight Loss (If not customized)
71	Orchidometer
72	Plate, Patient (Grounding pad, return plate)
73	Plier, Crimp
74	Plier, Tube
75	Pouch, Colostomy
76	Probe and Director, Gastro-Urology
77	Probe, Rectal, Non-Powered
78	Protector, Ostomy
79	Recorder, External, Pressure, Amplifier & Transducer (Analog)
80	Retractor, Fiberoptic, Reusable
81	Retractor, Non-Self-Retaining, Reusable
82	Retractor, Self-Retaining, Reusable
83	Ribdam
84	Ring, Crimp
85	Ring, Joint
86	Ring, Laparotomy
87	Scoop
88	Selector, Size, Ostomy
89	Set, Dialyzer Holder
90	Sheath, Corrugated Rubber, For Non-Indwelling Catheter, Non-Sterile
91	Sheath, Corrugated Rubber, For Non-Indwelling Catheter, Sterile
92	Snare, Flexible, Reusable
93	Snare, Non-Electrical, Reusable
94	Sound, Metal, Interconnected, Reusable
95	Speculum, Rectal
96	Sphincteroscope
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	Stylet for Catheter, Gastro-Urology
103	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	Truss, Umbilical
114	Urethrometer
115	Urethrotome, Reusable
116	Urinary Drainage Collection Kit, For Indwelling Catheter
117	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	Battery, Replacement, Rechargeable
15	Beads, Hydrophilic, For Wound Exudate Absorption
16	Biopsy Device, Percutaneous, Reusable
17	Bit, Surgical, Reusable
18	Blade, Saw, General & Plastic Surgery, Surgical, Reusable
19	Blade, Saw, Surgical, Cardiovascular, Reusable
20	Board, Arm (With cover), Sterile
21	Board, Arm (With cover), Non-Sterile
22	Body Fluid Barrier Kit (Surgical apparel)
23	Brush, Biopsy, General & Plastic Surgery, 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	Chisel (Osteotome), Reusable
40	Chisel, Mastoid, Reusable
41	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, Ceiling Mounted
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	Scraper, 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
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. GENERAL HOSPITAL AND PERSONAL USE DEVICES**

1	Applicator, Absorbent Tipped, Non-Sterile
2	Applicator, Absorbent Tipped, Sterile
3	Bag, Ice (For medical purpose)
4	Bandage, Elastic
5	Bandage, Liquid
6	Bandage, Liquid, Skin Protectant
7	Bariatric Bed
8	Bassinet, Hospital
9	Bed, Ac-Powered Adjustable Hospital
10	Bed, Hydraulic, Adjustable Hospital
11	Bed, Manual
12	Bed, Pediatric Open Hospital
13	Bed, Therapeutic, Ac-Powered, Adjustable Home-Use
14	Bedding, Disposable, Medical



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



59	Lubricant, Vaginal, Patient
60	Luer Lock
61	Manometer, Spinal-Fluid
62	Mattress, Flotation Therapy, Non-Powered
63	Medical Device Data System
64	Medical Gloves With Chemotherapy Labeling Claims - Test For Use With Chemotherapy Drugs
65	Medication Management System, Remote
66	N95 Respirator with Antimicrobial/Antiviral Agent For Use By The General Public In Public Health Medical Emergencies
67	Needle, Hypodermic, Single Lumen, Reusable
68	Oral Lubricant
69	Pad, Neonatal Eye
70	Patient Bed with Canopy/Restraints
71	Patient Examination Glove
72	Patient Examination Glove, Specialty
73	Polymer Patient Examination Glove
74	Port, Protector/Cushion
75	Powdered Latex Patient Examination Glove
76	Powdered Nitrile Patient Examination Glove
77	Powdered Polychloroprene Patient Examination Glove
78	Powdered Vinyl Patient Examination Glove
79	Powder-Free Guayle Rubber Examination Glove
80	Powder-Free Polychloroprene Patient Examination Glove
81	Protector, Skin Pressure
82	Protector, Wound, Plastic
83	Radiation Attenuating Medical Glove
84	Respirator, N95, For Use in Health Care Facilities
85	Restraint, Patient, Conductive
86	Restraint, Protective
87	Ring Cutter
88	Scale, Patient, for medical purpose
89	Scale, Sponge, Surgical, Electrically-Powered
90	Scale, Stand-On, Patient, for medical examination
91	Scale, Surgical Sponge
92	Scissors, Medical, Reusable
93	Sheet, Burn
94	Solution, Cold Sterilizing
95	Stand, Infusion
96	Stocking, Medical Support (For general medical purposes)
97	Stocking, Medical Support (To prevent pooling of blood in legs)
98	Stretcher, Hand-Carried
99	Stretcher, Patient Restraint
100	Stretcher, Wheeled
101	Support, Scrotal, Therapeutic



102	Syringe, Antistick
103	Syringe, Cartridge
104	Syringe, Irrigating (Non dental)
105	Syringe, Piston
106	Syringe, Piston, Reusable
107	Tape and Bandage, Adhesive
108	Tape and Bandage, Adhesive (With disinfectant)
109	Timer, Apgar
110	Topical Approximation System
111	Trap, Sterile Specimen
112	Tube, Aspirating, Flexible, Connecting
113	Tubing, Fluid Delivery
114	Tubing, Noninvasive
115	Urinal
116	Vinyl Patient Examination Glove
117	Washer of Body Waste Receptacles

#### **H. 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. OBSTETRICAL 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
38	Grid, Amsler
39	Haploscope
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	Insert/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, Eucleating
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

#### **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

#### **L. 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	Adhesive Backed Thermal Skin Patches
8	Aid, Transfer
9	Armboard, Wheelchair
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
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	Cover, Limb
41	Crutch
42	Cuff, Pusher, Wheelchair
43	Cushion, Flotation, For Medical Purpose
44	Cushion, Flotation, Therapeutic
45	Cushion, Wheelchair
46	Device, Anti-Tip, Wheelchair



47	Device, Finger-Sucking
48	Device, Prosthesis Alignment
49	Elevator, Wheelchair, Portable
50	Exerciser, Non-Measuring, For Medical Purpose
51	First Aid Kit With Drug, if primary intent is as medical device and medical device components are CLASS A
52	Foot Examination Tool for Inflammatory Changes
53	Footrest, Wheelchair
54	Hand, External Limb Component, Mechanical
55	Hand, External Limb Component, Powered
56	Handrim, Wheelchair
57	Head Halter, Traction
58	Helmet, Cranial, For Protective Use
59	Hill Holder, Wheelchair
60	Holder, Crutch And Cane, Wheelchair
61	Hook, External Limb Component, Mechanical
62	Hook, External Limb Component, Powered
63	Joint, Ankle, External Brace
64	Joint, Elbow, External Limb Component, Mechanical
65	Joint, Elbow, External Limb Component, Powered
66	Joint, Hip, External Brace
67	Joint, Hip, External Limb Component
68	Joint, Knee, External Brace
69	Joint, Knee, External Limb Component
70	Joint, Shoulder, External Limb Component
71	Manipulator, Plunger-Like Joint
72	Massager, Therapeutic, Manual
73	Monitor, Orthotic/Prosthetic
74	Orthosis, Abdominal
75	Orthosis, Cervical (cervical collar)
76	Orthosis, Cervical-Thoracic, Rigid
77	Orthosis, Corrective Shoe
78	Orthosis, Foot Drop
79	Orthosis, Limb Brace (Spine system - external, non implantable, support)
80	Orthosis, Lumbar
81	Orthosis, Lumbo-Sacral
82	Orthosis, Moldable, Supportive, Skin Protective
83	Orthosis, Rib Fracture, Soft
84	Orthosis, Sacroiliac, Soft
85	Orthosis, Thoracic
86	Orthosis, Truncal, For Dysmenorrhea
87	Orthosis, Truncal/Orthosis, Limb
88	Pack, Heat, Moist
89	Pack, Hot or Cold, Disposable



90	Pack Hot or Cold, Reusable
91	Pack, Hot or Cold, Water Circulating
92	Platform, Force-Measuring, For Medical Purpose
93	Plinth, For Medical Purpose
94	Prosthesis, Thigh Socket, External Component
95	Pylon, Post Surgical
96	Refrigerant, Topical (Vapocoolant) (For treatment of minor injuries such as sprain or minor burns)
97	Restraint, Wheelchair, Non-Protective
98	Rotator, Transverse
99	Scale, Platform, Wheelchair
100	Shoe, Cast
101	Sling, Arm
102	Sling, Arm, Overhead Supported
103	Sling, Overhead Suspension, Wheelchair
104	Splint, Abduction, Congenital Hip Dislocation
105	Splint, Clavicle
106	Splint, Denis Brown
107	Splint, Hand, And Components
108	Splint, Temporary Training
109	Stirrup, External Brace Component
110	Stocking, Elastic
111	Stretcher, Wheeled, Powered
112	Stroller, Adaptive
113	Support, Arm
114	Support, Head and Trunk, Wheelchair
115	Table, Mechanical (for patient)
116	Table, Physical Therapy, Multi Function (For patient)
117	Table, Powered (for patient)
118	Tips and Pads, Cane, Crutch And Walker
119	Transport, Patient, Powered
120	Treadmill, Mechanical (Use for Physical Therapy)
121	Treadmill, Powered (Use for Physical Therapy)
122	Twister, Brace Setting
123	Unit, Chilling
124	Unit, Heating, Powered
125	Unit, Wrist, External Limb Component, Mechanical
126	Unit, Wrist, External Limb Component, Powered
127	Walker, Mechanical
128	Walker, Mechanical, Poly Vinyl Chloride (Pvc)
129	Wheelchair, Mechanical
130	Wheelchair, Powered
131	Wheelchair, Special Grade
132	Wheelchair, Stair Climbing



133	Wheelchair, Standup
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### M. 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



DRAFT FOR COMMENT