

ASIA ACTUAL

LIST OF NOTIFIED DEVICES

	LIST OF NOTIFIED MEDICAL DEVICES (REVISED Jan. 4, 2020)	CLASS	NEW CLASS
1	ABDOMINAL PAD	A	
2	ABSORBABLE HEMOSTATIC AGENTS		
	a. Absorbable Hemostatic Agents Non-Collagen Based	C/D	C
	b. Absorbable Hemostatic Agents, Collagen Based	C/D	D
3	ACCESS/INJECTION PORTS	C	
4	ACETABULAR	C	
5	ADAPTOR/CONNECTOR (ALL TYPES)	A	
6	ADHESIVE, ALL TYPES		
6	ADHESIVE		
	a. Adhesive Tape	A	
	b. Adhesive Bandage	A	
7	ADMINISTRATION SET, ALL TYPES / DELIVERY SYSTEM		
	a. With needle	B	
	b. Without needle		
	b.1. Fluid/Medicine/Parenteral Nutrition	A/B	
	b.1.a. Not for connection to an active medical device; intended for channeling or storing body liquids or tissues, liquids or gases		A
	b.1.b. If for connection to an active medical device; for use of channeling blood, or storing or channeling other body liquids, or for storing organs, parts of organs or body tissue; if surgically invasive for transient or short term use		B
	b.2. Blood/Body Liquids/Gases	B	
8	ANCHOR, PREFORMED	A	
9	ANESTHESIA SET	C	
10	ANNULOPLASTY RING	D	
11	APHERESIS KIT/ CELL SEPARATION KIT	B	
12	ARTIFICIAL SALIVA	A	
13	BANDAGE	A	
	a. All types	A	
	b. Self Adhering Wrap	A	
14	BASE PASTE	A	
15	BIOPSY NEEDLE/INSTRUMENT, ALL TYPES	B	
16	BLOOD BAG	C	
17	BLOOD TRANSFUSION SET/KIT	B	
18	BONE MARROW COLLECTION/ TRANSFUSION KIT	B	
19	BONE WAX	C/D	
	a. Does not contain animal cells, tissues and/or derivatives thereof, rendered non-viable or cells, tissues and/or derivatives of microbial or recombinant origin		C
	b. Contains animal cells, tissues and/or derivatives thereof, rendered non-viable or cells, tissues and/or derivatives of microbial or recombinant origin		D
20	BREATHING CIRCUIT	B	
21	BURR, DENTAL/SURGICAL/ORTHOPEDIC	A/B	
	a. Reusable		A
	b. Single use		B
22	CANNULA, ALL TYPES		
	a. Reusable	A	
	b. In contact with the CNS ¹ and CCS ²	D	

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	c. Through body orifice	A, B, C	
	c.1 Transient use		A
	c.2 Short term use		B
	c.3 Long term use		C
	d. Short Term ³ use, Single use, Disposable use	B	
23	CAP (DISINFECTION, SEAL, TAPER, DEAD END)	A	
24	CARDIOTOMY RESERVOIR	B	
25	CATHETER, ALL TYPES		
	a. Short Term ³ use	B	
	b. Long Term ⁴ use	C	
	c. Through body orifice	A, B, C	
	c.1 Transient use		A
	c.2 Short term use		B
	c.3 Long term use		C
	d. In contact with the CNS ¹ and CCS ²	D	
26	CAVITY LINER	B	
27	CEMENT, DENTAL/BONE		
	a. Cement, Dental	B	
	b. Cement, Bone Synthetic	C/D	C
	c. Cement, Bone Natural	D	
	CENTRAL VENOUS BLOOD PRESSURE KIT	D	
	CERVICAL COLLAR	A	
30	CHEST DRAINAGE KIT	B	
31	CLINICAL THERMOMETER		
	a. Active type	B	
	b. Analog type (Except merurial type)	A	
32	CLIP		
	a. Invasive	C/D	
	a. Invasive except those touching CNS and CCS		C
	b. Invasive, touching CNS and CCS		D
	b. Non-invasive	A	
33	CLIP APPLIER		
	a. Reusable	A	
	b. Single use	B	
34	CLOSURE DEVICE; SKIN STAPLER (INCLUDING REMOVER)		
	a. Non invasive	B	
	b. Invasive	C	
	a. Invasive except those touching CNS and CCS		C
	b. Invasive, touching CNS and CCS		D
35	COIL		
	a. Endovascular Coil	C/D	
	a. Vascular Coil		C
	b. Endovascular Coil/Neurovascular Coil	D	D
36	COLLAGEN	D	
37	CONDOM		

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	a. Condom All Types	C	
	b. Condom with spermicide	D	
	c. Condom - Natural Membrane	D	
38	CONICAL/CORNEAL RING SEGMENT	B/C	
	a. Short term use		B
	b. Long term use		C
39	CONTACT LENS SOLUTION	C	
40	CONTACT LENS. INCLUDING COSMETIC CONTACT LENSES	B	
41	CONTACT CAST	A	
42	COTTON (medical/hospital use)		
	a. Cotton	A	
	b. Paddie, Cottonoid	B	
43	CYTOLOGY BRUSH (Biopsy, General & Plastic Surgery)	B	
	a. Body orifice	A	
	b. Surgically Invasive	B	
44	DENTAL RESTORATIVE MATERIAL	B	
	a. Filler, agent, tooth bonding	B	
	b. Etching Varnish Suspension	A/B	
	a. Transient use, not absorbed by mucus membrane		A
	b. Short term or long term use		B
45	DIALYSATE CONCENTRATE FOR HEMODIALYSIS	C	
46	DIALYZER	B	
47	DIAMOND DISC	A	
48	DISINFECTANT OF MEDICAL DEVICES	C	
49	DISSECTOR	B	
	A. Reusable	A	
	B. Single Use	B	
50	DRAINAGE POUCH (ALL TYPES)	A	
51	DRESSING		
	a. Dressing	A	
	b. Dressing w/ absorbable component	B	
	c. Dressing with medicine	D	
	d. Dressing with biologic	D	
52	DRILL BIT, BONE/SURGICAL	A	
53	DRUG DELIVERY EMBOLIZATION SYSTEM	D	
54	DRY POWDER INHALER (WITHOUT MEDICINE)	A	
55	EAR WAX REMOVER (NON ACTIVE)	A	
56	ELECTRODE NEEDLE PENCIL (ELECTROSURGICAL)	B	
57	EMBOLIC PROTECTIVE DEVICE, SYSTEM	D	
58	ENDOSCOPIC HARVESTING INSTRUMENT		
	a. Re-usable	A	
	b. Single Use	B	
59	EPIDURAL PROBE	B	
60	EVACUATOR	A	
61	EYE LIGHT SHIELD	A	

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62	FEEDING SET		
	a. Feeding Set thru body orifice	B	
	b. Feeding Set surgically invasive	C	
63	FILLER		
	a. Absorbable (All Types)	D	
	b. Non-Absorbable	C	
64	FILTER (to filter bacterial and/or viral cross contamination which will be introduced to the patient)	B	
	a. Intended to filter pathogens		A
	b. Intended to filter liquids and gases		B
65	FLOW METER (All Types)	A	
66	GASTRIC BAND	C	
67	GAUZE		
	a. Gauze	A	
	b. Gauze, internal sponge	B	
	c. Gauze with medicine	D	
	d. Gauze with biologic	D	
68	GINGIVA FORMER	B	
69	GLOVES	A	
	a. Examining, Non-sterile gloves	A	
	b. Surgical, Sterile Gloves	B	
70	GRAFT	C/D	
	a. Absorbable	D	
	b. Non-Absorbable	C	
71	GUIDEWIRE, GUIDE CATHETER	B	
72	HEART VALVE	D	
73	IMPLANTABLE DEFIBRILLATOR	D	
74	IMPLANTABLE HEARING DEVICE	C	
75	IMPLANTABLE LEAD	D	
76	IMPLANTABLE PACEMAKERS	D	
77	IMPLANTABLE PROSTHESIS	C/D	
	a. Not in direct contact with the heart, CNS and CCS		C
	b. In direct contact with the heart, CNS and CCS		D
78	IMPRESSION MATERIAL	A	
79	INFLATION DEVICE	A	
80	INTRAOCULAR LENS	C	
81	INTRAUTERINE CONTRACEPTIVE DEVICE (IUD)	D	
82	INTRODUCER	B	
83	KNOT PUSHER		
	a. Reusable	A	
	b. Single use	B	
84	LANCET	B	
85	LARYNGEAL MASK	B	
86	LUBRICATING GEL/JELLY		
86	LUBRICANT/TRANSMISSION GEL/JELLY		

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	a. External	A	
	b. Internal	A	B
87	LUER LOCK	A	
88	LUMBAR PUNCTURE TRAY/KIT	C	
89	MASK	B	
	a. Mask – used to protect against respiratory pathogens (face mask, surgical mask, N95, etc.); for channeling or storing body liquids or tissues, liquids or gases (oxygen masks, etc.)		A
	b. Mask – used in the channeling of gases, drugs or medicine and connected to an active device (anesthesia, oxygen, etc.)		B
90	MOISTURE/LUBRICATING EYEDROP	B	
91	NASAL SPRAY (WITHOUT CLAIMS)	A	
92	NASOPHARYNGEAL AIRWAY	A	
93	NEEDLE (ALL TYPES, EXCEPT FOR TATTOO AND ACUPUNCTURE)	B	
	a. Except those touching CNS and CCS		B
	b. Touching CNS and CCS		D
94	NEUROVASCULAR REMODELLING DEVICE	D	
95	NON-STEROIDAL CREAM/ SKIN BARRIER (TOPICAL)	B	
96	OPHTHALMIC DROP/SOLUTION	B	
97	OPHTHALMIC VISCOELASTIC DEVICE	B/D	
	a. Does not contain animal cells, tissues and/or derivative thereof, rendered non-viable or cells, tissues and/or derivative of microbial or recombinant origin		B
	b. Contains animal cells, tissues and/or derivative thereof, rendered non-viable or cells, tissues and/or derivative of microbial or recombinant origin		D
98	ORTHOPAEDIC WIRE	B/C	
	a. Short term use		B
	b. Long term use		C
99	PEN INJECTOR	A	
i00	PERCUTAENOUS RETRIEVAL DEVICE	B	
	a. Except those touching CNS and CCS		B
	b. Touching CNS and CCS		D
101	PLASTER OF PARIS	A	
102	PLASTER/PLASTIC STRIP (ALL TYPES)	A	
	a. Gauze	A	
	b. Gauze, internal sponge	B	
	c. Gauze with medicine	D	
	d. Gauze with biologic	D	
	a. Plaster		A
	b. Plaster with medicine		D
	c. Plaster with biologic		D
103	RECONSTRUCTION KIT/DEVICE; FIXATION DEVICE	B/C	
	a. Reusable		A
	b. Short term use		B
	c. Long term use		C
104	RENAL DILATATION SET	B	
105	REVASCULARIZATION DEVICE	D	
106	RETRACTOR		

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	a. Reusable	A	
	b. Single-use	B	
107	SCALP VEIN INFUSION SET	B	
108	SEALANT		
	a. Wound Sealant	B	
	b. From animal source	D	
109	SHUNT SYSTEM		
	a. All types, except for CNS ¹ and CCS ²	C	
	b. For CNS ¹ and CCS ²	D	
110	SILICON OIL IN VIAL FOR OPHTHALMIC USE	C	
110	SILICON OIL (INTRAOCULAR FLUID)		C
111	SKIN BARRIER FOR OSTOMY USE	A	
112	SKIN TRACTION SYSTEM	A	
113	SODIUM HYALURONATE		
	a. Animal source	D	
	b. Non animal source	B	
114	SPINAL ANAESTHESIA KIT	D	
115	SPINE SYSTEM		
	a. Implantable with Direct contact with CNS ¹	D	
	b. Implantable	C	
	c. External or Non-implantable	A	
116	STENT		
	a. Short Term ³ except those touching CNS ¹ and CCS ²	B	
	b. Long Term ⁴ except those touching CNS ¹ and CCS ²	C	
	c. Short Term ³ or Long Term ⁴ touching CNS ¹ and CCS ²	D	
117	STOMA ADHESIVE PROTECTIVE POWDER/WAFER	A	
118	STOP COCK	A	
119	SURGICAL BLADES, ALL TYPES		
	A. Reusable	A	
	B. Single Use	B	
120	SURGICAL DRAPE, STERILE		
	a. Drape	A	
	b. Drape with Self Retaining Finger Cot	B	
121	SURGICAL KNIFE, STERILE	B	
122	SURGICAL MESH	C	
	a. Does not contain animal cells, tissues and/or derivative thereof, rendered non-viable or cells, tissues and/or derivative of microbial or recombinant origin		C
	b. Contains animal cells, tissues and/or derivative thereof, rendered non-viable or cells, tissues and/or derivative of microbial or recombinant origin		D
123	SUTURE (WITH OR WITHOUT NEEDLE)		
	a. Suture, Nonabsorbable, Synthetic		
	a.1 In contact with CNS ¹ , CCS ²	D	
	a.2 In contact with deep tissue	B	
	b. Suture, Absorbable (from animal source)	D	
	c. Suture, Absorbable, Synthetic	D	
	d. Suture, Dental	B	

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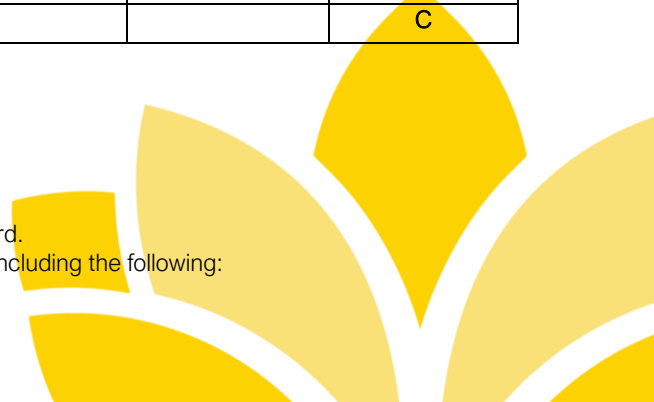
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	e. Suture, Non-absorbable, short-term	B	
	f. Suture, Steel	C	
124	SUTURE ANCHOR		
	a. Non-absorbable	C	
	b. Absorbable	D	
125	SYNTHETIC CAST PADDING	A	
126	SYRINGE		
	a. Syringe with Needle	B	
	b. Syringe without Needle	A	
127	TAPE, SURGICAL/MEDICAL	A	
128	THROMBECTOMY SET	D	
129	TISSUE EXPANDER		
	a. For breast implant	D	
	b. Other parts of the body	c	
130	TRACHEOSTOMY KIT	B	
131	TROCAR SYSTEM		
	a. Single use	B	
	b. Reusable	A	
132	TUBE, Other Types	A/B	
132	TUBE (ALL TYPES)		
	a. Not connected to an active device		A
	b. Connected to active device		B
133	UMBILICAL CLAMP	A	
134	VASCULAR ACCESS SYSTEM	D	
135	VENTRICULAR PROBE	D	
136	WOUND DRAINAGE KIT	B	
137	ALL OTHER IMPLANTABLE MEDICAL DEVICES (IN PARTS OR IN SYSTEM)		
	a. Active Implants	D	
	b. Heart Implants	D	
	c. Brain Implants	D	
	d. Breast Implants	D	
	e. Spinal Implants	D	
	f. Dental Implants including Abutment	B	
	g. Orthopaedic Implants	C	
	h. All other implants	C	
138	RESUSCITATOR		
	a. Manually Controlled		A
	b. Automatic Controlled		B
139	VENTILATOR		C

Additional Information:

CNS¹ Central Nervous System - refers to the brain, meninges and spinal cord.

CCS² Central Circulatory System - means the major internal blood vessels including the following:



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- arteriae pulmonales (pulmonary artery);
- arteriae coronariae (coronary artery);
- arteria carotis communis (common carotid artery);
- arteria carotis externa (external carotid artery);
- arteria carotis interna (Internal carotid artery);
- arteriae cerebrates (cerebella arteries);
- truncus brachiocephalicus (brachiocephalic trunk);
- venae cordis (cardiac veins);
- venae pulmonales (pulmonary vein);
- venae cava superior (superior vena cava);
- venae cava inferior (inferior vena cava);
- arcus aorta (aortic arch);
- thoracica aorta (thoracic aorta);
- abdominalis aorta (abdominal aorta);
- arteriae ilica communis (common iliac arteries);
- aorta descendens to the bifurcatio aortae (descending aorta to the bifurcation of aorta)

Short term use³ Normally intended for continuous use for between 60 minutes and 30 days

Long term use⁴ Normally intended for continuous use for more than 30 days

