



04 JAN 2021

**FDA CIRCULAR**

No. 2020-001-A

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

**SUBJECT: Amendment to Annex A of FDA Circular No. 2020-001 re: Initial Implementation of Administrative Order No. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements"**

To clarify the classification and update the list of medical devices that are required to be registered with the Food and Drug Administration (FDA) as part of the initial implementation of Administrative Order No. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements", Annex A of FDA Circular No. 2020-001 is hereby amended as follows:

ITEM NO.	FROM		TO	
	NAME OF MEDICAL DEVICE	CLASS	NAME OF MEDICAL DEVICE	CLASS
1	ABSORBABLE HEMOSTATIC AGENTS		ABSORBABLE HEMOSTATIC AGENTS	
	a. Absorbable Hemostatic Agents Non-Collagen Based	C/D	a. Absorbable Hemostatic Agents, Non-Collagen Based	C
	b. Absorbable Hemostatic Agents, Collagen Based	C/D	b. Absorbable Hemostatic Agents, Collagen Based	D
2	ADHESIVE (ALL TYPES)		ADHESIVE	A
	a. Adhesive Tape	A		
	b. Adhesive Bandage	A		



3	ADMINISTRATION SET (ALL TYPES) / DELIVERY SYSTEM		ADMINISTRATION SET (ALL TYPES) / DELIVERY SYSTEM	
	a. With needle	B	a. With needle	B
	b. Without needle		b. Without needle	
	b.1. Fluid/Medicine/Parenteral Nutrition	A/B	b.1. Fluid/Medicine/Parenteral Nutrition	
			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 tissues; if surgically invasive for transient <sup>5</sup> or short <sup>3</sup> term use	B	
b.2. Blood/Body Liquids/Gases	B	b.2. Blood/Body Liquids/Gases	B	
4	BANDAGE	A		
	a. All types	A	BANDAGE	A
	b. Self Adhering Wrap	A		
5	BONE WAX	C/D	BONE WAX	
			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
6	BURR, DENTAL/SURGICAL/ORTHOPEDIC	A/B	BURR, DENTAL/SURGICAL/ORTHOPEDIC	
			a. Reusable	A
			b. Single use	B

7	CANNULA (ALL TYPES)		CANNULA (ALL TYPES)	
	a. Reusable	A	a. Reusable	A
	b. In contact with the CNS <sup>1</sup> and CCS <sup>2</sup>	D	b. In contact with the CNS <sup>1</sup> and CCS <sup>2</sup>	D
	c. Through body orifice	A, B, C	c. Through body orifice	
			c.1 Transient <sup>5</sup> use	A
c.2 Short <sup>3</sup> term use			B	
d. Short term <sup>3</sup> use, Single use, Disposable use	B	d. Short <sup>3</sup> term use, Single use, Disposable use	B	
8	CATHETER (ALL TYPES)		CATHETER (ALL TYPES)	
	a. Short <sup>3</sup> term use	B	a. Short <sup>3</sup> term use	B
	b. Long <sup>4</sup> term use	C	b. Long <sup>4</sup> term use	C
	c. Through body orifice	A, B, C	c. Through body orifice	
			c.1 Transient <sup>5</sup> use	A
c.2 Short <sup>3</sup> term use			B	
d. In contact with the CNS <sup>1</sup> and CCS <sup>2</sup>	D	d. In contact with the CNS <sup>1</sup> and CCS <sup>2</sup>	D	
9	CEMENT, DENTAL/BONE		CEMENT, DENTAL/BONE	
	a. Cement, Dental	B	a. Cement, Dental	B
	b. Cement, Bone Synthetic	C/D	b. Cement, Bone Synthetic	C
c. Cement, Bone Natural	D	c. Cement, Bone Natural	D	
10	CLIP		CLIP	
	a. Invasive	C/D	a. Invasive except those touching CNS <sup>1</sup> and CCS <sup>2</sup>	C
			b. Invasive, touching CNS <sup>1</sup> and CCS <sup>2</sup>	D
b. Non-invasive	A	c. Non-invasive	A	
11	CLOSURE DEVICE; SKIN STAPLER (INCLUDING REMOVER)		CLOSURE DEVICE; SKIN STAPLER (INCLUDING REMOVER)	
	a. Non invasive	B	a. Non invasive	B
	b. Invasive	C	b. Invasive except those touching CNS <sup>1</sup> and CCS <sup>2</sup>	C
c. Invasive, touching CNS <sup>1</sup> and CCS <sup>2</sup>			D	
12	COIL		COIL	
	a. Endovascular Coil	C/D	a. Vascular Coil	C
b. Neurovascular Coil	D	b. Endovascular Coil/Neurovascular Coil	D	
13	CONICAL/CORNEAL RING SEGMENT	B/C	CONICAL/CORNEAL RING SEGMENT	
	a. Short <sup>3</sup> term use		B	
	b. Long <sup>4</sup> term use	C		

14	CYTOLOGY BRUSH (Biopsy, General & Plastic Surgery)	B	CYTOLOGY BRUSH (Biopsy, General & Plastic Surgery)	
	a. Body orifice	A	a. Body orifice	A
	b. Surgically Invasive	B	b. Surgically Invasive	B
15	DENTAL RESTORATIVE MATERIAL	B	DENTAL RESTORATIVE MATERIAL	
	a. Filler, agent, tooth bonding	B	a. Transient <sup>5</sup> use, not absorbed by mucus membrane	A
	b. Etching Varnish Suspension	A/B	b. Short <sup>3</sup> term or long <sup>4</sup> term use	B
16	DISSECTOR	B	DISSECTOR	
	A. Reusable	A	A. Reusable	A
	B. Single Use	B	B. Single Use	B
17	FILTER (to filter bacterial and/or viral cross contamination which will be introduced to the patient)	B	FILTER (to filter bacterial and/or viral cross contamination which will be introduced to the patient)	
			a. Intended to filter pathogens	A
			b. Intended to filter liquids and gases	B
18	GLOVES	A	GLOVES	
	a. Examining, Non-sterile gloves	A	a. Examining, Non-sterile gloves	A
	b. Surgical, Sterile Gloves	B	b. Surgical, Sterile Gloves	B
19	GRAFT	C/D	GRAFT	
	a. Absorbable	D	a. Absorbable	D
	b. Non-Absorbable	C	b. Non-Absorbable	C
20	IMPLANTABLE PROSTHESIS	C/D	IMPLANTABLE PROSTHESIS	
			a. Not in direct contact with the heart, CNS <sup>1</sup> and CCS <sup>2</sup>	C
			b. In direct contact with the heart, CNS <sup>1</sup> and CCS <sup>2</sup>	D
21	LUBRICATING GEL/JELLY		LUBRICANT/TRANSMISSION GEL/JELLY	
	a. External	A	a. External	A
	b. Internal	A	b. Internal	B
22	MASK (silicone facemask, full mask, anesthesia, oxygen)	B	MASK	
			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 mask, etc.)	A
			b. Mask - used in the channeling of gases, drugs or medicine and connected to an active device (anesthesia, oxygen, etc.)	B

23	NEEDLE (All types, except for tattoo and acupuncture)	B	NEEDLE (ALL TYPES, EXCEPT FOR TATTOO AND ACUPUNCTURE)	
			a. Except those touching CNS <sup>1</sup> and CCS <sup>2</sup>	B
			b. Touching CNS <sup>1</sup> and CCS <sup>2</sup>	D
24	OPHTHALMIC VISCOELASTIC DEVICE	B/D	OPHTHALMIC VISCOELASTIC DEVICE	
			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	B
			b. Contains animal cells, tissues and/or derivatives thereof, rendered non-viable or cells, tissues and/or derivatives of microbial or recombinant origin	D
25	ORTHOPAEDIC WIRE	B/C	ORTHOPAEDIC WIRE	
			a. Short <sup>3</sup> term use	B
			b. Long <sup>4</sup> term use	C
26	PERCUTAENOUS RETRIEVAL DEVICE	B	PERCUTAENOUS RETRIEVAL DEVICE	
			a. Except those touching CNS <sup>1</sup> and CCS <sup>2</sup>	B
			b. Touching CNS <sup>1</sup> and CCS <sup>2</sup>	D
27	PLASTER/PLASTIC STRIP (ALL TYPES)	A	PLASTER/PLASTIC STRIP (ALL TYPES)	
		A	a. Plaster	A
		B	b. Plaster with medicine	D
		D	c. Plaster with biologic	D
		D		
28	RECONSTRUCTION KIT/DEVICE; FIXATION DEVICE	B/C	RECONSTRUCTION KIT/DEVICE; FIXATION DEVICE	
			a. Reusable	A
			b. Short <sup>3</sup> term use	B
			c. Long <sup>4</sup> term use	C
29	SILICON OIL IN VIAL FOR OPHTHALMIC USE	C	SILICON OIL (INTRAOCULAR FLUID)	C

30	SURGICAL MESH	C	SURGICAL MESH	
			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
31	TUBE, Other Types	A/B	TUBE (ALL TYPES)	
			a. Not connected to an active device	A
			b. Connected to an active device	B

Furthermore, the following products shall be added in the list of medical devices in Annex A:

	NAME OF MEDICAL DEVICE	CLASS
1	RESUSCITATOR	
	a. Manually Controlled	A
	b. Automatic Controlled	B
2	VENTILATOR	C

The classification of the following medical devices included in Annex A shall remain the same and shall not be affected by this issuance:

ITEM NO.	LIST OF MEDICAL DEVICE	CLASS
1	ABDOMINAL PAD	A
2	ACCESS/INJECTION PORTS	C
3	ACETABULAR	C
4	ADAPTOR/CONNECTOR (ALL TYPES)	A
5	ANCHOR, PREFORMED	A
6	ANESTHESIA SET	C
7	ANNULOPLASTY RING	D
8	APHERESIS KIT/ CELL SEPARATION KIT	B
9	ARTIFICIAL SALIVA	A
10	BASE PASTE	A
11	BIOPSY NEEDLE/INSTRUMENT (ALL TYPES)	B
12	BLOOD BAG	C
13	BLOOD TRANSFUSION SET/KIT	B
14	BONE MARROW COLLECTION/ TRANSFUSION KIT	B
15	BREATHING CIRCUIT	B
16	CAP (DISINFECTION, SEAL, TAPER, DEAD END)	A
17	CARDIOTOMY RESERVOIR	B
18	CAVITY LINER	B
19	CENTRAL VENOUS BLOOD PRESSURE KIT	D

20	CERVICAL COLLAR	A
21	CHEST DRAINAGE KIT	B
22	CLINICAL THERMOMETER	
	a. Active type	B
	b. Analog type (Except mercurial type)	A
23	CLIP APPLIER	
	a. Reusable	A
	b. Single use	B
24	COLLAGEN	D
25	CONDOM	
	a. Condom (All types)	C
	b. Condom with spermicide	D
	c. Condom - Natural Membrane	D
26	CONTACT LENS SOLUTION	C
27	CONTACT LENS, INCLUDING COSMETIC CONTACT LENSES	B
28	CORSET CAST	A
29	COTTON (medical/hospital use)	
	a. Cotton	A
	b. Paddie, Cottonoid	B
30	DIALYSATE CONCENTRATE FOR HEMODIALYSIS	C
31	DIALYZER	B
32	DIAMOND DISC	A
33	DISINFECTANT OF MEDICAL DEVICES	C
34	DRAINAGE POCHE (ALL TYPES)	A
35	DRESSING	
	a. Dressing	A
	b. Dressing w/ absorbable component	B
	c. Dressing with medicine	D
	d. Dressing with biologic	D
36	DRILL BIT, BONE/SURGICAL	A
37	DRUG DELIVERY EMBOLIZATION SYSTEM	D
38	DRY POWDER INHALER (WITHOUT MEDICINE)	A
39	EAR WAX REMOVER (NON-ACTIVE)	A
40	ELECTRODE NEEDLE/PENCIL (ELECTROSURGICAL)	B
41	EMBOLIC PROTECTIVE DEVICE/SYSTEM	D
42	ENDOSCOPIC HARVESTING INSTRUMENT	
	a. Re-usable	A
	b. Single Use	B
43	EPIDURAL PROBE	B
44	EVACUATOR	A
45	EYE LIGHT SHIELD	A
46	FEEDING SET	
	a. Feeding Set thru body orifice	B
	b. Feeding Set surgically invasive	C
47	FILLER	
	a. Absorbable (All types)	D
	b. Non-Absorbable	C

48	FLOWMETER (All types)	A
49	GASTRIC BAND	C
50	GAUZE	
	a. Gauze	A
	b. Gauze, internal sponge	B
	c. Gauze with medicine	D
	d. Gauze with biologic	D
51	GINGIVA FORMER	B
52	GUIDEWIRE, GUIDE CATHETER	B
53	HEART VALVE	D
54	IMPLANTABLE DEFIBRILLATOR	D
55	IMPLANTABLE HEARING DEVICE	C
56	IMPLANTABLE LEAD	D
57	IMPLANTABLE PACEMAKERS	D
58	IMPRESSION MATERIAL	A
59	INFLATION DEVICE	A
60	INTRAOCULAR LENS	C
61	INTRAUTERINE CONTRACEPTIVE DEVICE (IUD)	D
62	INTRODUCER	B
63	KNOT PUSHER	
	a. Reusable	A
	b. Single use	B
64	LANCET	B
65	LARYNGEAL MASK	B
66	LUER LOCK	A
67	LUMBAR PUNCTURE TRAY/KIT	C
68	MOISTURE/LUBRICATING EYEDROP	B
69	NASAL SPRAY (WITHOUT CLAIMS)	A
70	NASOPHARYNGEAL AIRWAY	A
71	NEUROVASCULAR REMODELLING DEVICE	D
72	NON-STEROIDAL CREAM/ SKIN BARRIER (TOPICAL)	B
73	OPHTHALMIC DROP/SOLUTION	B
74	PEN INJECTOR	A
75	PLASTER OF PARIS	A
76	RENAL DILATATION SET	B
77	REVASCLARIZATION DEVICE	D
78	RETRACTOR	
	a. Reusable	A
	b. Single-use	B
79	SCALP VEIN INFUSION SET	B
80	SEALANT	
	a. Wound Sealant	B
	b. From animal source	D
81	SHUNT SYSTEM	
	a. All types, except for CNS <sup>1</sup> and CCS <sup>2</sup>	C
	b. For CNS <sup>1</sup> and CCS <sup>2</sup>	D
82	SKIN BARRIER FOR OSTOMY USE	A
83	SKIN TRACTION SYSTEM	A



84	SODIUM HYALURONATE	
	a. Animal source	D
	b. Non-animal source	B
85	SPINAL ANAESTHESIA KIT	D
86	SPINE SYSTEM	
	a. Implantable with Direct contact with CNS <sup>1</sup>	D
	b. Implantable	C
	c. External or Non-implantable	A
87	STENT	
	a. Short <sup>3</sup> term use except those touching CNS <sup>1</sup> and CCS <sup>2</sup>	B
	b. Long term <sup>4</sup> use except those touching CNS <sup>1</sup> and CCS <sup>2</sup>	C
	c. Short <sup>3</sup> or Long Term <sup>4</sup> use touching CNS <sup>1</sup> and CCS <sup>2</sup>	D
88	STOMA ADHESIVE PROTECTIVE POWDER/WAFER	A
89	STOP COCK	A
90	SURGICAL BLADES (ALL TYPES)	
	A. Reusable	A
	B. Single Use	B
91	SURGICAL DRAPE, STERILE	
	a. Drape	A
	b. Drape with Self Retaining Finger Cot	B
92	SURGICAL KNIFE, STERILE	B
93	SUTURE (WITH OR WITHOUT NEEDLE)	
	a. Suture, Nonabsorbable, Synthetic	
	a.1 In contact with CNS <sup>1</sup> , CCS <sup>2</sup>	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
	e. Suture, Non-absorbable, short <sup>3</sup> term use	B
	f. Suture, Steel	C
94	SUTURE ANCHOR	
	a. Non-absorbable	C
	b. Absorbable	D
95	SYNTHETIC CAST PADDING	A
96	SYRINGE	
	a. Syringe with Needle	B
	b. Syringe without Needle	A
97	TAPE, SURGICAL/MEDICAL	A
98	THROMBECTOMY SET	D
99	TISSUE EXPANDER	
	a. For breast implant	D
	b. Other parts of the body	C
100	TRACHEOSTOMY KIT	B
101	TROCAR SYSTEM	
	a. Single use	B
	b. Reusable	A
102	UMBILICAL CLAMP	A
103	VASCULAR ACCESS SYSTEM	D

104	VENTICULAR PROBE	D
105	WOUND DRAINAGE KIT	B
106	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

Footnote:

CNS<sup>1</sup> Central Nervous System - refers to the brain, meninges and spinal cord  
CCS<sup>2</sup> Central Circulatory System -means the major internal blood vessels including the following:

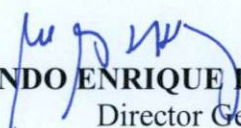
- arteriae pulmonales (pulmonary artery);
- aorta ascendens (ascending aorta);
- arteriae coronariae (coronary artery);
- arteria carotis communis (common carotid artery);
- arteria carotis externa (external carotid artery);
- arteria carotis interna (internal carotid artery);
- arteriae cerebrates (cerebella 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 use<sup>3</sup> Normally intended for continuous use for between 60 minutes and 30 days

Long term use<sup>4</sup> Normally intended for continuous use for more than 30 days

Transient use<sup>5</sup> Normally intended for continuous use for less than 60 minutes

This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and upon acknowledgement of receipt of a copy hereof by the Office of the National Administrative Register.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
 Director General

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