FDA Circular
No. 2020-001

73JAN70D

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

SUBJECT: 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"

I. BACKGROUND AND RATIONALE

On 25 February 2014 and on 3 June 2015, FDA Memorandum Circular No. 2014-005 and FDA Memorandum Circular No. 2014-005-A were issued respectively, to attain systematic regulation for medical devices. The said FDA issuances provide a list of medical devices that are required to be registered prior to sale, distribution and use.

On 21 November 2014, the Philippines, represented by the Secretary of Trade and Industry, together with 9 other ASEAN countries, agreed on a harmonized medical device regulations and common technical documents. Only medical devices which conform to the provisions of the ASEAN Agreement on Medical Device Directive (AMDD) and its Annexes may be placed on the markets of the Member State.

On 26 January 2018, DOH Administrative Order No. 2018-0002 entitled "Guideline Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements" was issued to provide guidelines on the documentary requirements for the registration of medical devices and to align the registration requirements to the CSDT (Common Submission Dossier Template) based on the provisions of AMDD.

With the implementation of AO 2018-0002, the FDA through the Center for Device Regulation, Radiation Health and Research (CDRRHR) is also mandated to release list of medical devices per classification based on the classification set forth in the ASEAN AMDD.

In compliance with Section IX of AO 2018-0002 and to implement the initial phase of the implementation of the said policy which covers all registrable products listed in FDA Memorandum Circular No. 2014-005 and FDA Memorandum Circular No. 2014-005-A, this issuance is hereby issued.

This Circular includes modifications in the list of medical devices in FDA Memorandum Circular No. 2014-005 and FDA Memorandum Circular No. 2014-005-A (see Annex A).

II. OBJECTIVE

This issuance aims to provide information regarding the acceptance of applications based on AO 2018-0002, validity of issued Certificate of Exemption (COE), and application fees for identified marketing authorizations. This shall guide establishments engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, and where applicable, the use, testing, promotion, advertising, or sponsorship of medical devices.

This Circular also aims to provide guidance for the medical device industry and all concerned regarding the classification of medical devices listed in FDA Memorandum Circular No. 2014-005 and FDA Memorandum Circular No. 2014-005-A according to the level of risk as specified below:

Class	Risk Level
A	Low
B	Low-Moderate
C	Moderate-High
D	High

III. POLICIES AND GUIDELINES

1. The Center for Device Regulation, Radiation Health, and Research (CDRRHR) shall be accepting applications for the following marketing authorizations

    a. Certificate of Medical Device Registration (CMDR) for medical devices with risk classification of B, C, and D which are included in FDA Memorandum Circular 2014-005 and 2014-005-A (see annex A).

    b. Certificate of Medical Device Notification (CMDN) for all medical devices with risk classification A whether or not included in FDA Memorandum Circular No. 2014-005 and FDA Memorandum Circular No. 2014-005-A.

    c. Certificate of Medical Device Listing (CMDL) for research, clinical trial, exhibit, personal use and/or donated, brand new medical devices.

1. Classification of medical devices that are not included in Annex A shall follow the classification rules of AMDD as stated in item 2 of Section V. General Guidelines of AO 2018-0002.

2. All Certificate of Exemption for Class A medical devices issued from 25 February 2014 shall remain valid only until 03 November 2021 or within 2 years from date of effectivity of this Circular whichever is earlier. This is to give ample time for the industry to apply for CMDN.

3. All Certificates of Product Registration (CPR) that were issued for Class A medical devices shall be deemed equivalent to CMDN only until the validity of the CPR. CMDN shall be issued upon renewal of the issued CPR.

4. The list of in-vitro diagnostic (IVD) medical devices that are registrable in Section B of FDA Memorandum Circular No. 2014-005 remains the same; however, the blood collection tube listed in Section A of the said FDA Memorandum Circular shall be added under the list of IVD since it has been re-classified as in-vitro diagnostic (IVD) medical devices based on the definition of IVD in the ASEAN AMDD.

5. Issuance of COE shall cease. All Class B, C and D medical devices that are not included in item 1.a of this Circular and in-vitro diagnostic (IVD) devices that are not included in FDA Memorandum Circular No. 2014-005 shall be considered non-registrable products. The License to Operate (LTO) of the establishment shall be provided in lieu of the COE at the point of entry and/or as part of bidding requirements.

6. The fees for the following issuances shall be in accordance with Administrative Order No. 50 s. 2001, until such time of modification, supersession, and/or revocation, with the following clarification:

   a. Payment for initial application of CMDN and CMDR is ₱7,500.00 + Legal Research Fee (LRF) based on the current fee for initial registration of ₱1,500.00 + LRF x 5 years validity.
   b. Payments for renewal applications of CMDN and CMDR are ₱5,000.00 + LRF.
   c. Payment for application of CMDL is ₱500.00 + LRF.
   d. LRF is 1% of the filing fee imposed but in no case lower than Ten Pesos (₱10.00), based on FDA Circular No. 2011-003 "Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856".

7. Additional details shall be provided in subsequent issuances regarding the succeeding phases

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

The list in Annex A supersedes the list of medical devices in section A of FDA Memorandum Circular No. 2014-0005 and FDA Memorandum Circular No. 2014-0005- A.

Provisions on previous circulars and memoranda 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 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.

Roland Enrique Domingo, MD, DBPO
Undersecretary of Health
Officer-in-Charge, Director General

Appendix A

	LIST OF MEDICAL DEVICE	CLASS
1	ABDOMINAL PAD	A
2	ABSORBABLE HEMOSTATIC AGENTS	
	a. Absorbable Hemostatic Agents Non-Collagen Based	C/D
	b. Absorbable Hemostatic Agents, Collagen Based	C/D
3	ACCESS/INJECTION PORTS	C
4	ACETABULAR	C
5	ADAPTOR/CONNECTOR (ALL TYPES)	A
6	ADHESIVE, ALL TYPES	
	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.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 TWES	B
16	BLOOD BAG	C
17	BLOOD TRANSFUSION SET/KIT	B
18	BONE MARROW COLLECTION/ TRANSFUSION KIT	B
19	BONE WAX	C/D
20	BREATHING CIRCUIT	B
21	BURR, DENTAL/SURGICAL/ORTHOPEDIC	A/B
22	CANNULA, ALL TYPES	
	a. Reusable	A
	b. In contact with the CNS[1] and CCS[2]	D
	c. Through body orifice	A,B,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[3] term use	B
	b. Long[4] term use	C
	c. Through body orifice	A,B,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. 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
	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
35	COIL	
	a. Endovascular Coil	C/D
	b. Neurovascular Coil	D
36	COLLAGEN	D
37	CONDOM	
	a. Condone All Types	C
	b. Condom with spermicide	D
	c. Condom - Natural Membrane	D
38	CONICAL CORNEAL RING SEGMENT	B/C
39	CONTACT LEN S SOLUTION	C
40	CONTACT LENS. INC LUDING COSMETIC CONTAC T LENSES	B
41	CO RSET 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
45	DIALYSATE CONCENTRATE FOR HEMODIALYSIS	C
46	DIALYZER	B
47	DIAMOND DISC	A
4S	DISINFECTANT OF MEDICAL DEVICES	C
49	DISSECTOR	B
	A. Reusable	A
	B. Single Use	B
50	DRAINAGE POUCHE (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 SY STEM	D
54	DRY POWDER INHALER (WITHOUT MEDICINE)	A
55	EAR WAX REMOVER (NON ACTIVE)	A
56	ELECTRODE NEEDLE PENCIL (ELECTROSURG ICAL)	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
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
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 DEFIBRILLATO R	D
74	IMPLANTABLE HEARING DEVICE	C
75	IMPLANTABLE LEAD	D
76	IMPLANTABLE PACEMAKERS	D
77	IM PLANTABLE PROSTH ESIS	C/D
78	IMPRESSION MA f ERIAL	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	
	a. External	A
	b. Internal	A
87	LUER LOCK	A
88	LUMBAR PUNCTURE TRAY/KIT	C
89	MASK (silicone facemask, full mask, anesthesia, oxygen)	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
94	NEUROVASCULAR REMODELLING DEVICE	D
95	NON-STEROIDAL CREAM/ SKIN BARRIER (TOPICAL)	B

96	OPHTHALMIC DROP/SOLUTION	B
97	OPHTHALMIC VISCOELASTIC DEVICE	B/D
98	ORTHOPAEDIC WIRE	B/C
99	PEN INJECTOR	A
100	PERCUTAENOUS RETRIEVAL DEVICE	B
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
103	RECONSTRUCTION KIT/DEVICE; FIXATION DEVICE	B/C
104	RENAL DILATATION SET	B
105	REVASCULARIZATION DEVICE	D
106	RETRACTOR	
	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
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[3] or Long Term[4] touching CNS' and CCS'	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
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
	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
133	UMBILICAL CLAMP	A
134	VASCULAR ACCESS SYSTEM	D
135	VENTICULAR 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

Footnote:
CNS[1] Central Nervous System - refers to the brain, meninges and spinal cord.
CCS[2] Central Circulatory System - means the major internal blood vessels including the following:

- 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 use[3] Normally intended for continuous use for between 60 minutes and 30 days
Long term use[4] Normally intended for continuous use for more than 30 days