



FDA
Food and Drug Administration
PHILIPPINES

Updates on the Philippine Medical Device Regulation

14 September 2023 | Radisson Hotel Bandar Seri Begawan

Product Research and Standards Development Division
Center for Device Regulation, Radiation Health and Research



BACKGROUND

BACKGROUND ON AO No. 2018-0002



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JAN 26 2018

ADMINISTRATIVE ORDER

No. ~~2017~~ - 2018-0002
de

SUBJECT: Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements

Published: The Manila Times (Feb 27, 2018) and Malaya (Mar 15, 2018)



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BACKGROUND ON AO NO. 2018-0002

Objective

To provide guidelines on the documentary requirements for the registration of medical devices to align the registration requirements to the CSDT based on the provisions of the AMDD

Scope

All medical devices except IVDs and refurbished medical devices



BACKGROUND

- 13 Artificial Saliva
- 14 Atopical Cream/Non-steroidal Cream
- 15 Bandage
- 16 Base Paste
- 17 Biopsy Needle/Instrument
- 18 Blade, all types
- 19 Blood Bag
- 20 Blood Collection Tube/Kit; Blood Sampling Tube/Kit
- 21 Blood Transfusion Set
- 22 Blunt
- 23 Bone Marrow Collection/transfusion Kit
- 24 Bone Wax
- 25 Breathing Circuit
- 26 Burette
- 27 Burr, Dental/Surgical/Orthopedic
- 28 Cannula, all types
- 29 Cap (disinfection, seal, taper, dead-end)
- 30 Cardiotomy Reservoir
- 31 Catheter, all types
- 32 Cavity Liner
- 33 Cell Regeneration Kit
- 34 Cell Separation Kit
- 35 Cement, Dental/Bone
- 36 Central Venous Blood Pressure Kit
- 37 Cervical Collar
- 38 Cervix Set
- 39 Chest Drainage Kit
- 40 Clave
- 41 Clinical Thermometer, all types except mercurial
- 42 Clip/Clip Applier
- 43 Closure Device; Skin Stapler (including remover)
- 44 Collagen
- 45 Condom
- 46 Conical Ring Segment
- 47 Contact lens solution
- 48 Contact Lens, including cosmetic contact lenses
- 49 Corset Cast
- 50 Cotton
- 51 Cytology Brush
- 52 Delivery System
- 53 Dental Bone
- 54 Dental Restorative Material/Filler/Agent/Tooth Bonding/Etching/Varnish
- 55 Dental Suspension
- 56 Dialysate Concentrate for Hemodialysis
- 57 Dialyzer
- 58 Diamond Disc
- 59 Dilatation Device
- 60 Disinfectant of Medical Devices
- 61 Dissector
- 62 Drainage Pouche

- 63 Drape, Sterile
- 64 Dressing
- 65 Drill, Bone/Surgical
- 66 Drug Delivery Embolization System
- 67 Duodenal Tube
- 68 Ear Wax Remover
- 69 Earpiercing Device
- 70 Ecodrop - Inject
- 71 Electrode needle/pencil (electrosurgical)
- 72 Embolic Protective Device/System

- 113 Lubricating Gel/Jelly
- 114 Luer lock
- 115 Lumbar Puncture Tray
- 116 Manual Resuscitator with Mask
- 117 Mask (facemask, full mask, anesthesia, oxygen)
- 118 Moisture/Lubricating Eyedrop
- 119 Nasal Spray
- 120 Nasopharyngeal Airway
- 121 Nebulizing Kit with mask
- 122 Needle (all types) except for tattoo and acupuncture

- 163 Synthetic Cast Padding
- 164 Syringe (with or without needle)
- 165 Tape, surgical/medical
- 166 Thrombectomy Set
- 167 Tissue Expander

180 Registrable Medical Devices

- 96 Implantable Pacemakers
- 97 Implantable Prosthesis
- 98 Impression Material
- 99 Inflation Device
- 100 Infusion Fluid Thermal Warmer
- 101 Infusion System
- 102 Injectors
- 103 Intraocular Lens
- 104 Introducer Kit
- 105 IUD
- 106 IV Container
- 107 Knife, all types, sterile
- 108 Knot Pusher
- 109 Lancet
- 110 Laryngeal mask
- 111 Ligating Clip
- 112 Light Shield

- 147 Skin Barrier for Ostomy Use
- 148 Skin Traction Set
- 149 Sodium Hyaluronate
- 150 Spinal Anaesthesia Tray
- 151 Spine System
- 152 Stent
- 153 Sterilant for medical device
- 154 Stoma Adhesive Protective Powder/wafer
- 155 Stoma Bag
- 156 Stop-cock
- 157 Suction, Airway Kit
- 158 Surgical Mesh
- 159 Surgical Milk
- 160 Surgical Pack/Surgical Kit
- 161 Suture (with or without needle)
- 162 Suture Anchor

- 179 Wound Drainage Kit
- 180 All other implantable medical devices (in parts or in system)

to the patient or will be used to pass any type of
nt's body)
dicine)





Authorizations issued for medical devices

CMDN

- Class A medical devices

CMDR

- Class B, C and D medical device

CMDL

- Medical device that is intended for research, clinical trial, exhibit, donation, etc. that is not intended for sale



FDA CIRCULAR NO. 2021-002-A

Title	Date Issued	Date Published
Addendum to FDA Circular No. 2021-002 Re: Full 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"	9 August 2021	11 November 2021 The Manila Times Date of Effectivity: 26 November 2021

OBJECTIVE:



To provide guidelines for the transition period wherein the manufacturers, traders, and distributors/importers/exporters of medical devices covered by FC No. 2021-002 may apply for CMDN and may be allowed to manufacture, import, export, distribute, transfer, sell or offer for sale their medical device products pending the issuance of the CMDN.



FDA CIRCULAR NO. 2021-002-A

SCOPE:

- ❑ Class B, C and D medical devices that are not included in the list of registrable medical devices in FC No. 2020-001-A

GUIDELINES:

- ❑ All Class B, C and D medical devices that are already in the Philippine market prior to the effectivity of this issuance may continue to be manufactured, imported, exported, distributed, transferred, sold or offered for sale without CMDN until **31 March 2022**. The LTO of the medical device establishment shall be provided at the point of entry and/or part of the bidding requirements.

Extended until **31 March 2023**
(FC No. 2021-002-B)



FDA CIRCULAR NO. 2021-002-A

SCOPE:

- ❑ Class B, C and D medical devices that are not included in the list of registrable medical devices in FC No. 2020-001-A

GUIDELINES:

- ❑ All Class B, C and D medical devices that are already in the Philippine market prior to the effectivity of this issuance may continue to be manufactured, imported, exported, distributed, transferred, sold or offered for sale without CMDN until **31 March 2022**. The LTO of the medical device establishment shall be provided at the point of entry and/or part of the bidding requirements.

Ex

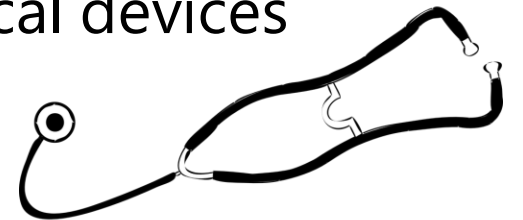
Further extended until **31 March 2024**
(FC No. 2021-002-C)



FDA CIRCULAR NO. 2021-002-A

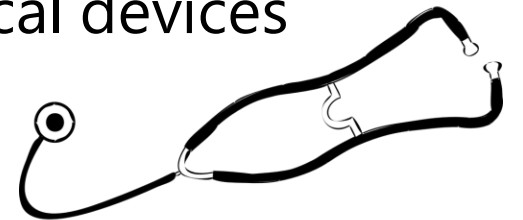
GUIDELINES:

- Starting 1 April 2022, only class B, C and D medical devices with issued CMDN or with pending application for CMDN shall be allowed to be exported from the Philippines or manufactured, imported, distributed, transferred, sold or offered for sale in the country.
- Application for CMDN for Class B, C and D medical devices shall be accepted until 31 March 2023 only.
- Receiving of application for CMDN for Class B, C and D medical devices shall cease starting 1 April 2023



GUIDELINES:

- Starting **1 April 2022**, only class B, C and D medical devices with issued CMDN or with pending application for CMDN shall be allowed to be exported from the Philippines or manufactured, imported, distributed, transferred, sold or offered for sale in the country.
- Application for CMDN for Class B, C and D medical devices shall be accepted until 31 March 2023 only.
- Receiving of application for CMDN for Class B, C and D medical devices shall cease starting 1 April 2023



GUIDELINES:

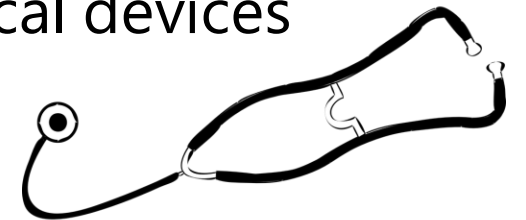
❑ Starting **1 April 2022**, only class B, C and D medical devices without CMDN or with pending application for CMDN exported from the Philippines or imported, transferred, sold or offered for sale in the country.

*“Beginning **April 1, 2024**, the manufacture, importation, exportation, distribution, transfer, selling or offering for sale of all Class B, C and D medical devices covered under this Circular without CMDN/CDMR or with pending application for CMDN/CDMR shall be prohibited.”*

(FC No. 2021-002-C)

❑ Application for CMDN for Class B, C and D medical devices shall be accepted until 31 March 2023 only.

❑ Receiving of application for CMDN for Class B, C and D medical devices shall cease starting 1 April 2023



FDA CIRCULAR NO. 2021-002-A

Amended to 1 April 2023
(FC No. 2021-002-C)

GUIDELINES:

- ❑ Starting **1 April 2022**, only class B, C and D medical devices with CMDN or with pending application for CMDN may be imported, exported from the Philippines or transferred, sold or offered for sale in the country.
- ❑ Application for CMDN for Class B, C and D medical devices shall be accepted until **31 March 2023** only.
- ❑ Receiving of application for CMDN for Class B, C and D medical devices shall cease starting 1 April 2023

*“Beginning **April 1, 2024**, the manufacture, importation, exportation, distribution, transfer, selling or offering for sale of all Class B, C and D medical devices covered under this Circular without CMDN/CDMR or with pending application for CMDN/CDMR shall be prohibited.”*

(FC No. 2021-002-C)

Amended to **31 March 2024**
(FC No. 2021-002-C)



FDA CIRCULAR NO. 2021-002-A

Amended to 1 April 2023
(FC No. 2021-002-C)

GUIDELINES:

❑ Starting **1 April 2022**, only class B, C and D medical devices with a valid CMDN or with pending application for CMDN may be imported, exported from the Philippines or transferred, sold or offered for sale in the country.

*“Beginning **April 1, 2024**, the manufacture, importation, exportation, distribution, transfer, selling or offering for sale of all Class B, C and D medical devices covered under this Circular without CMDN/CDMR or with pending application for CMDN/CDMR shall be prohibited.”*

(FC No. 2021-002-C)

❑ Application for CMDN for Class B, C and D medical devices shall be accepted until **31 March 2023** only.

Amended to **31 March 2024**
(FC No. 2021-002-C)

❑ Receiving of application for CMDN for Class B, C and D medical devices shall cease starting **1 April 2023**.



Amended to **1 April 2024**
(FC No. 2021-002-C)

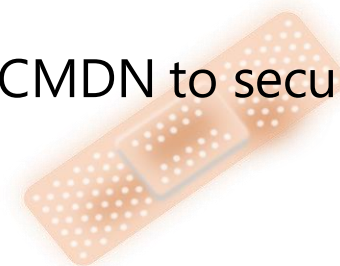
*Companies may opt to apply for CDMR instead of CMDN prior to this date.

FDA CIRCULAR NO. 2021-017

Title	Date Issued	Date Published
Reference List of Class A Medical Devices	19 August 2021	16 October 2021 The Manila Times Date of Effectivity: 31 October 2021

OBJECTIVES:


-  To guide the manufacturers, importers, distributors and all other concerned stakeholders regarding the list of medical devices classified as Class A
-  To help the industry to determine the appropriate authorization specifically CMDN to secure for their medical device product that fall under Class A classification

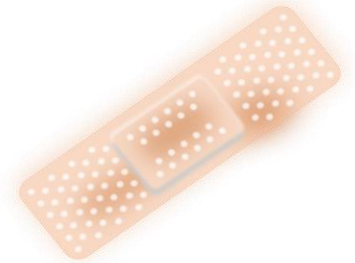


FDA CIRCULAR NO. 2022-008

Title	Date Issued	Date Published
Abridged Processing of Application of Medical Devices Approved by the National Regulatory Authority of Any ASEAN Member Country	22 September 2022	

OBJECTIVES:

-  Provide guidelines on the abridged processing of application for registration of medical devices with product with product approval issued by the NRA of any ASEAN member country under the AMDD-CSDT requirements.



THANK YOU!

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