Updates on the Philippine Medical Device Regulation

14 September 2023 I 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 2 6 2018

ADMINISTRATIVE ORDER
No. ~~2017~~ 2018-0002

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)

FDA Food and Drug Administration PHILIPPINES

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

180 Registrable Medical Devices

Food and Drug Administration
PHILIPPINES

BACKGROUND ON AO NO. 2018-0002

Authorizations issued for medical devices

CMDN	CMDR	CMDL
• Class A medical devices	• Class B, C and D medical device	• 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

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

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.

FDA Food and Drug Administration PHILIPPINES

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

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

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.

FDA Food and Drug Administration PHILIPPINES

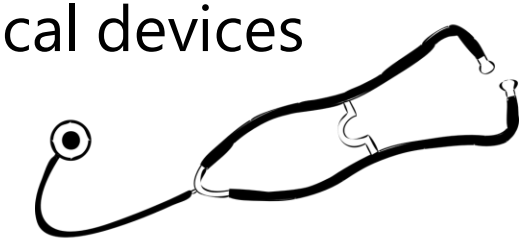
FDA CIRCULAR NO. 2021-002-A

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



FDA CIRCULAR NO. 2021-002-A

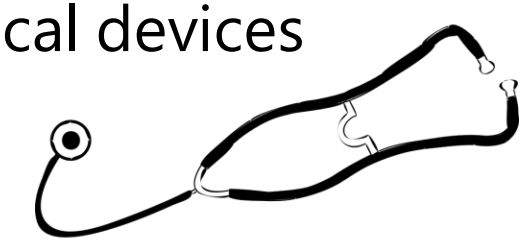
Amended to **1 April 2023**
(FC No. 2021-002-B)

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



Food and Drug Administration PHILIPPINES

FDA CIRCULAR NO. 2021-002-A

Amended to 1 April 2023

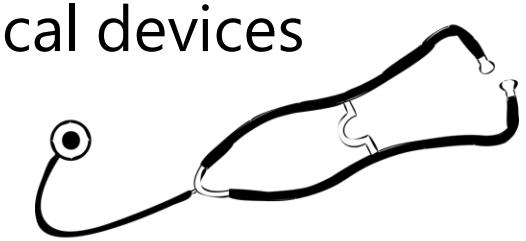
GUIDELINES:

*"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/CMDR shall be prohibited."*
(FC No. 2021-002-C)

- Starting **1 April 2022**, only class
  CMDN or with pending applicati
  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



Food and Drug Administration PHILIPPINES

FDA CIRCULAR NO. 2021-002-A

Amended to 1 April 2023

GUIDELINES:

- Starting **1 April 2022**, only class
  CMDN or with pending applicati
  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/CMDR 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,
  shall cease starting 1 April 2023

FDA Food and Drug Administration PHILIPPINES

FDA CIRCULAR NO. 2021-002-A

Amended to 1 April 2023

GUIDELINES:

- Starting **1 April 2022**, only class
  CMDN or with pending applicati
  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/CMDR shall be prohibited."*
(FC No. 2021-002-C)

- Application for CMDN for Class B, C and D me
  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**

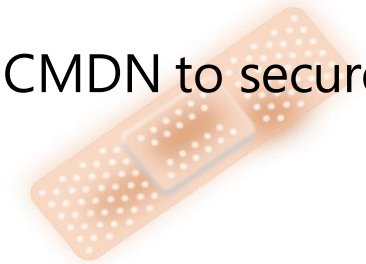
Amended to **1 April 2024**
(FC No. 2021-002-C)
*Companies may opt to apply for CMDR instead of CMDN prior to this date.

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



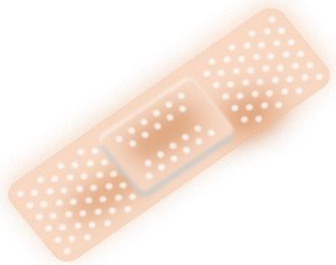
FDA Food and Drug Administration PHILIPPINES

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.



END

THANK YOU!

cdrrhr@fda.gov.ph

www.fda.gov.ph

info@fda.gov.ph