Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2021-002-B

21 APR 2022

SUBJECT : **Amendment to FDA Circular No. 2021-002-A entitled "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""**

I. RATIONALE

On 9 August 2021, FDA Circular (FC) No. 2021-002-A entitled "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"" was issued to provide guidelines for the transition period for the application of a Certificate of Medical Device Notification (CMDN) for Class B, C and D medical devices covered by FC No. 2021-002. This issuance stated that these medical devices may continue to be manufactured, imported, exported, distributed, transferred, sold or offered for sale without CMDN until 31 March 2022. On 1 April 2022, these medical devices are required to have an approved CMDN or at least with an ongoing application for CMDN. However, beyond these dates, the availability of these medical devices in the Philippines may be affected.

In the interest of service and to ensure the availability of the aforestated medical devices during the transition period in applying for a CMDN, this Circular is hereby issued.

II. OBJECTIVE

This Circular aims to extend the date wherein all the non-registrable Class B, C and D medical devices stated in Section III of this Circular may continue to be manufactured, imported, exported, distributed, transferred, sold or offered for sale without CMDN. Furthermore, this Circular also aims to amend the start period for requiring CMDN or at least with pending CMDN application for the aforementioned medical devices.

III. SCOPE

This issuance shall cover Class B, C and D medical devices that are not included in the list of registrable medical devices based on FC No. 2020-001-A entitled "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"".

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IV. GUIDELINES

Section V (1) of FC No. 2021-002-A is hereby amended as follows:

A. The date when all Class B, C and D medical devices that are already in the Philippine market prior to the effectivity of FC No. 2021-002-A may continue to be manufactured, imported, exported, distributed, transferred, sold or offered for sale without CMDN shall be extended until **31 March 2023**. The License to Operate of the medical device establishment shall be provided at the point of entry and/or part of bidding requirements.

B. The start period for requiring CMDN or at least with pending CMDN application for class B, C and D medical devices shall be amended **from 1 April 2022 to 1 April 2023**.

V. REPEALING CLAUSE

Section V (1) of FC No. 2021-002-A is hereby modified, repealed, and/or revoked accordingly.

VI. SEPARABILITY CLAUSE

All other provisions of FDA Circular No. 2021-002 and FDA Circular 2021-002-A not affected by this Circular shall remain in effect.

VII. EFFECTIVITY

This Circular shall take effect fifteen (15) days following its publication in the Official Gazette or in a newspaper of general circulation and upon filing three (3) certified true copies with the University of the Philippines Law Center – Office of the National Administrative Register.

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Secretary of Health

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