



**NOTIFICATION**

*Addendum*

The following communication, dated 17 May 2022, is being circulated at the request of the delegation of the Philippines.

**Title:** Administrative Order - The New Documentary Requirements for the Registration of Medical Device Products (19 pages, in English)

<b>Reason for Addendum:</b>	
<input type="checkbox"/>	Comment period changed - date:
<input type="checkbox"/>	Notified measure adopted - date:
<input type="checkbox"/>	Notified measure published - date:
<input checked="" type="checkbox"/>	Notified measure enters into force - date: 21 April 2022
<input checked="" type="checkbox"/>	Text of final measure available from <sup>1</sup> : <a href="https://www.fda.gov.ph/wp-content/uploads/2022/04/FDA-Circular-No.2021-002-B-1.pdf">https://www.fda.gov.ph/wp-content/uploads/2022/04/FDA-Circular-No.2021-002-B-1.pdf</a>
<input type="checkbox"/>	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
<input type="checkbox"/>	Content or scope of notified measure changed and text available from <sup>1</sup> : New deadline for comments (if applicable):
<input type="checkbox"/>	Interpretive guidance issued and text available from <sup>1</sup> :
<input type="checkbox"/>	Other:

**Description:** FDA Circular No.2021-002-B 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"" 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.

<sup>1</sup> This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained.