NOTIFICATION

Addendum

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

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

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| **Reason for Addendum:** |
| [ ] | Comment period changed - date:  |
| [ ] | Notified measure adopted - date:  |
| [ ] | Notified measure published - date:  |
| [X] | Notified measure enters into force - date: 21 April 2022 |
| [X] | Text of final measure available from[[1]](#footnote-1): <https://www.fda.gov.ph/wp-content/uploads/2022/04/FDA-Circular-No.2021-002-B-1.pdf> |
| [ ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |
| [ ] | Content or scope of notified measure changed and text available from1: New deadline for comments (if applicable):  |
| [ ] | Interpretive guidance issued and text available from1:  |
| [ ] | 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.

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1. 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. [↑](#footnote-ref-1)