



31 March 2022

(22-2616)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>Philippines</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: DR. OSCAR G. GUTIERREZ, JR., MPA Officer-in-Charge Director General FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: MARIA CECILIA C. MATIENZO Director IV Center for Device Regulation, Radiation Health and Research Email: mccmatienzo@fda.gov.ph ; cdrhr-prsdd@fda.gov.ph www.fda.gov.ph
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], other :
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Medical equipment (ICS code(s): 11.040)
5. Title, number of pages and language(s) of the notified document: Draft FDA Circular entitled "Abridged Processing of Application for Registration/Notification of Medical Devices Approved by National Regulatory Authority of Any ASEAN Member Country"; (4 page(s), in English)
6. Description of content: The Circular aims to carry out good reliance practices in the regulatory processes of medical devices. Specifically, it intends to provide guidelines on the abridged processing of application for registration of medical devices with product approval issued by the National Regulatory Authority of any ASEAN member country under the ASEAN Medical Device Directive- Common Submission Dossier Template requirements.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety

8. Relevant documents:

- Republic Act No. 9711 and its implementing rules and regulations
- ASEAN Medical Device Directive (AMDD)
- Administrative Order No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements"
- FDA Circular No. 2021-002 entitled "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. Proposed date of adoption: This Circular shall take effect fifteen (15) days after its publication in an Official Gazette or in a newspaper of general circulation and filing three (3) certified true copies with the University of the Philippines Law Center - Office of the Administrative Register.

Proposed date of entry into force: This Circular shall take effect fifteen (15) days after its publication in an Official Gazette or in a newspaper of general circulation and filing three (3) certified true copies with the University of the Philippines Law Center - Office of the Administrative Register.

10. Final date for comments: 60 days from notification

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:

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