



11 February 2022

(22-1216)

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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 Food and Drug Administration DEPARTMENT OF HEALTH 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 [], 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 11.040)
5. Title, number of pages and language(s) of the notified document: Adoption of the Post-Marketing Alert System (PMAS) Requirements, Annex 5 of the ASEAN Medical Device Directive (AMDD) (3 page(s), in English)
6. Description of content: The issuance aims to officially adopt and incorporate the provisions of Annex 5 of the AMDD "Post Marketing Alert System (PMAS) Requirements, Annex 5 of the ASEAN Medical Device Directive (AMDD).
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8. Relevant documents: Republic Act 9711 "Food and Drug Administration (FDA) Act of 2009" ASEAN Medical Device Directive -Annex 5- Post Marketing Alert System (PMAS) Requirements

9. Proposed date of adoption: This Order shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified copies to the University of the Philippines Law Center.

Proposed date of entry into force: This Order shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified copies to the University of the Philippines Law Center.

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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