



26 January 2022

(22-0606)

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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 OIC-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 (CDRRHR) 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): In-Vitro Diagnostic Medical Devices; In vitro diagnostic test systems (ICS 11.100.10)
5. Title, number of pages and language(s) of the notified document: Draft Administrative Order entitled "Rules and Regulations Governing the Issuance of an Authorization for an In-Vitro Diagnostic Medical Device (IVD) (25 page(s), in English)
6. Description of content: This Administrative Order aims to specify the rules, guidelines, procedures and requirements of the FDA-CDRRHR relative to the issuance of an authorization for IVD.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety; Other
8. Relevant documents: Republic Act No. 9711 and its Implementing Rules and Regulations ASEAN Medical Device Directive (AMDD)

9. Proposed date of adoption: This Administrative Order shall take effect fifteen (15) days following its publication in one (1) newspaper of general circulation or upon filing of the same to the Office of the National Administrative Register, University of the Philippines

Proposed date of entry into force: This Administrative Order shall take effect fifteen (15) days following its publication in one (1) newspaper of general circulation or upon filing of the same to the Office of the National Administrative Register, University of the Philippines

10. Final date for comments: 7 February 2022

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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<https://www.fda.gov.ph/draft-for-comments-rules-and-regulations-governing-the-issuance-of-an-authorization-for-an-in-vitro-diagnostic-medical-device-ivd/>
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