WORLD TRADE ORGANIZATION

G/TBT/N/PHL/280

11 February 2022

(22-1215)

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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:** PHILIPPINES **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; cdrrhr-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 (ICS:11.100.10)
5.	**Title, number of pages and language(s) of the notified document:** Draft FDA Circular entitled "Specific List of Registrable In Vitro Diagnostic Medical Devices (IVDs) and Revised Technical Requirements for Registration of COVID-19 Test Kits" (10 page(s), in English)
6.	**Description of content:** This FDA Circular aims to a) provide the specific list of the different registrable IVDs based on the capacity of FDA-Common Services Laboratory and National Reference Laboratories; and b) provide guidelines on the transition from the issuance of Special Certification to Certificate of Product Registration for COVID-19 test kits and on the revised technical requirements for the registration of COVID-19 test kit products.
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)
- FDA Memorandum Circular No. 2014-005 "Updated List of Medical Devices required to be registered prior to sale, distribution and use"
- FDA Memorandum (FM) No. 2020-006 "Issuance of Special Certification for Imported Test Kits of COVID-19"
- FDA Memorandum No. 2021-009 "Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection"

9. **Proposed date of adoption:** This Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified true copies with the University of the Philippines Law Center – Office of the National Administrative Register.

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

10. **Final date for comments:** 4 March 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/wp-content/uploads/2022/02/Specific-List-of-Registrable-In-Vitro-Diagnostic-Medical-Devices-IVDs-and-Revis.pdf

https://members.wto.org/crnattachments/2022/TBT/PHL/22_1544_00_e.pdf