WORLD TRADE ORGANIZATION

G/TBT/N/PHL/329

16 April 2024

(24-3184)

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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 SAMUEL A. ZACATE 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@fda.gov.ph ; bps.smd@dti.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):** OPTICAL, PHOTOGRAPHIC, CINEMATOGRAPHIC, MEASURING, CHECKING, PRECISION, MEDICAL OR SURGICAL INSTRUMENTS AND APPARATUS; PARTS AND ACCESSORIES THEREOF (HS code(s): 90)
5.	**Title, number of pages and language(s) of the notified document:** Extension of the Regulatory Flexibility for Class B, C and D Medical Devices that are Not Included in the List of Registrable Medical Devices Based on FDA Circular No. 2020-001-A entitled "Amendment to Annex A of FDA Circular No. 2020-001 re: Initial Implementation of Administrative Order No. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements""; (3 page(s), in English)
6.	**Description of content:** This Circular aims to provide guidelines on the extension of the regulatory flexibility for Class B, C and D medical devices that are not included in the list of registrable medical devices based on FC No. 2020-001-A.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety

8. **Relevant documents:**

- 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 (FC) No. 2020-001-A entitled "Amendment to Annex A of FDA Circular No. 2020-001 re: Initial Implementation of Administrative Order No. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements""
- FC 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""
- Amendments of FC No. 2021-002 (FC No. 2021-002 A / B / C)

9. **Proposed date of adoption:** Refer to V. Guidelines

Proposed date of entry into force: This Circular shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation and upon filing with the University of the Philippines Law Center Office of the National Administrative Register.

10. **Final date for comments:** Not Applicable

11. **Texts available from: National enquiry point [ ] 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/2024/03/FDA-Circular-No.2024-003.pdf

https://members.wto.org/crnattachments/2024/TBT/PHL/24_02636_00_e.pdf