WORLD TRADE ORGANIZATION

G/TBT/N/PHL/186/Add.1

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated 22 March 2018, is being circulated at the request of the delegation of the Philippines.

Title:

Administrative Order No.: 2018-0002 Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements.

Agency:

Center for Device Regulation, Radiation Health, and Research
Food and Drug Administration
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Summary:

This addendum provides information on the Philippines' Food and Drug Administration – Center for Device Regulation, Radiation Health, and Research's (CDRRHR) Administrative Order (AO) No. 2018-0002 issued on 26 January 2018. This was previously notified under document G/TBT/N/PHL/186 which provides the guidelines on the new documentary requirements for the registration of medical device products.

The Order applies to all medical devices to be sold, imported, exported, manufactured, and, used in the Philippines, except for in-vitro diagnostic and refurbished medical devices, for which separate Administrative Orders shall be issued on.

The implementation of the registration of medical devices following the new set of regulatory requirements shall be one (1) year after the effectivity of this Administrative Order.

https://members.wto.org/crnattachments/2018/TBT/PHL/18_1607_00_e.pdf

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