**ADMINISTRATIVE ORDER**

No. \_\_\_\_\_\_\_\_\_\_

**SUBJECT: Amendment to Administrative Order No. 2018-0002 dated 26 January 2018, re: Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements**

Administrative Order No. 2018-0002 dated 26 January 2018 is hereby amended with the following changes:

1. **Section III - Scope**

From: The new documentary requirements shall apply to all medical devices to be sold, imported, exported, manufactured, and used in the Philippines, except in-vitro diagnostic and refurbished medical devices, for which Separate Administrative Orders shall be issued.

To: The new documentary requirements shall apply to all medical devices to be sold, imported, exported, manufactured, and used in the Philippines, except in-vitro diagnostic, for which Separate Administrative Order shall be issued.

1. **Section V – General Guidelines, Item No. 1**

From: A guidance document containing the list of medical devices per classification

shall be issued.

To: A guidance document containing the risk classification rules for medical devices shall be issued.

1. **Section V – General Guidelines, Item No. 2**

From: The applicant shall classify the device based on the list of medical devices per classification issued by the CDRRHR. If the product is not included in the list, the company shall classify the device based on the intended use and on the classification rules of the ASEAN Medical Device Directive. The CDRRHR shall verify the classification made by the applicant and shall reclassify the device if another classification is deemed to be more appropriate.

To: The applicant shall classify the device based on the risk classification rules issued by the CDRRHR. The CDRRHR shall verify the classification made by the applicant and shall reclassify the device if another classification is deemed to be more appropriate.

1. **Section V – General Guidelines, Item No. 9**

Delete “Disapproved applications shall be returned to the applicant. In case the applicant does not claim the disapproved applications within 90 calendar days, the application documents shall be destroyed and discarded”.

1. **Section V – General Guidelines**

To Add as Item No. 10:

10. For products with local brand names, companies shall submit approval of brand name issued by Intellectual Property Office of the Philippines.

To Add as Item No. 11:

11. All companies are required to secure License to Operate as Medical Device Importer/Distributor/Manufacturer/Trader (whichever is applicable) prior to securing a CMDR and/or CMDN.

1. **Section IX – Phases of Implementation**

From: This AO shall cover initially all registrable products listed in FDA Memorandum Circular No. 2014-005: “Updated List of Medical Devices required to be registered prior to sale, distribution and use” and its amendments; the Notification of all class A medical devices; and the Medical Device Listing. The CDRRHR shall release the list of medical devices per classification based on the classification set forth in the ASEAN Medical Device Directive.

To: This AO shall cover initially all registrable products listed in FDA Memorandum Circular No. 2014-005: “Updated List of Medical Devices required to be registered prior to sale, distribution and use” and its amendments; the Notification of all class A medical devices; and the Medical Device Listing.

All provisions of Administrative Order No. 2018-0002 shall remain valid and in effect.

**FRANCISO T. DUQUE III, MD, MSc**

Secretary of Health