[ADMINISTRATIVE ORDER NO. 2018-0002, January 31, 2018]

GUIDELINES GOVERNING THE ISSUANCE OF AN AUTHORIZATION FOR A MEDICAL DEVICE BASED ON THE ASEAN HARMONIZED TECHNICAL REQUIREMENTS

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I. RATIONALE

The fast evolution of medical technology and the essential role of medical devices in the health care delivery system have highlighted the importance of ensuring the safety and effectiveness of these devices through regulation while facilitating trade among the ten member states of the Association of Southeast Asian Nations (ASEAN). Structured and regionally accepted technical requirements were developed through the ASEAN Consultative Committee on Standards and Quality — Medical Device Product Working Group (ACCSQ- MDPWG).

The development of the common submission dossier template (CSDT) was a 'combined effort of the ASEAN member states taking into consideration the global technical requirements developed by the Global Harmonization Task Force. The CSDT is a set of technical requirements for the registration of the medical device products agreed upon by the ten ASEAN member countries. The Philippines is committed to align its regulatory guidelines with this set of technical requirements, thus the issuance of this Administrative Order.

Pursuant to Republic Act No. 9711, the Food and Drug Administration (FDA) Act of 2009 and its implementing Rules and Regulations (IRR), this Administrative Order (A0) is being issued to govern the new sets of documentary requirements for the registration of medical device products.

II. OBJECTIVE

This Order aims to provide guidelines on the documentary requirements for the registration of medical devices and to align the registration requirements to the CSDT based on the provisions ofthe ASEAN Medical Device Directive.

III. SCOPE

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.

IV. DEFINITION OF TERMS

For the purpose of this Administrative Order, the terms below shall be defined as follows:

1. Applicant — refers to any individual, partnership, corporation, association, and/or organization, either a manufacturer, trader, distributor/importer/ exporter applying for a CMDN, a CMDL, and/or a CMDR as defined below.

2. Authorization - refers to any certification issued to the applicant by CDRRHR showing the product has complied on documentary and technical requirements such as Notification and Registration with certificate.

3. Center for Device Regulation, Radiation Health and Research (CDRRHR) — refers to the regulatory office under the Food and Drug Administration (FDA) of the Department of Health (DOH) that is in charge of the regulation of medical devices in the Philippines.

4. Certificate of Medical Device Notification (CMDN) — refers to the authorization issued for a medical device that complies with all the requirements for Notification of a medical device. The CMDN is issued for medical devices that will fall under class A.

5. Certificate of Medical Device Registration (CMDR) — refers to the authorization issued for a medical device that complies with all the requirements for Registration of a medical device. The CMDR is issued for medical devices that fall under classes B, C, and D.

6. Certificate of Medical Device Listing (CMDL) —- refers to the authorization issued for a medical device that is intended for research, clinical trial, exhibit, donation, etc. and that is not intended for sale.

7. Common Submission Dossier Template (CSDT) - is a set of technical requirements agreed upon by the ten member countries of the ASEAN which shall govern the regulation of medical devices in the ASEAN.

8. Country of origin — refers to the country where the device is manufactured or where the device has been registered and/or has been issued a market approval prior to distribution in the Philippines.

9. Distributor/importer/exporter - means any medical device establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets.

10. Distributor/wholesaler - means any medical device establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on a wholesale basis.

11. In-Vitro Diagnostic Medical Device — refers to any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination, intended by the manufacturer to be used in-

vitro for the examination of specimens, including blood and tissue donation, derived from the human body solely or principally for the purpose of

a. providing information concerning a physiological or pathological state; or
b. providing information concerning a congenital abnormality; or
c. determining the safety and compatibility with potential recipients; or
d. monitoring therapeutic measures.

12. Legal Manufacturer —means any foreign medical device establishment with responsibility for the design, manufacture, packaging and labeling of a device before it is placed in the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

13. License to Operate (LTO) — refers to the authorization issued by the FDA to a person or establishment to operate as a manufacturer, trader, distributor/importer/exporter/wholesaler of medical devices.

14. Manufacturer — refers to any medical device establishment engaged in any and all operations involved in the production of a medical device including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labeling with the end in View of its storage, sale or distribution.

15. Medical Device — means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent and calibrator, software, material or other similar or related article:

- intended by the manufacturer/product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease;

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;

- control of conception;

- disinfection of medical devices;

- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

- which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

16. Medical Device System — is composed of different medical devices wherein each device is essential in the operation of the system.

17. Notification —- is the process of seeking authorization to manufacture, import, export, sell and/or distribute Class A medical devices in the Philippines.

18. Product Owner —in relation to a medical device, means any person who:

a. supplies the medical device under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and

b. is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the medical device, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

19. Product Standards — refers to medical device standards set, formulated, developed, and/or established by any of the following:

a. Bureau of Product Standards (Philippine National Standard), b. International Organization for Standardization (ISO),
c. International Electrotechnical Commission (IEC),
d. Other International Standard Bodies recognized by the DOH, or
e. Any foreign standards that may be recognized by the DOH for the purpose of registration.

19. Refurbished Medical Device — refers to a medical device that was previously owned and reconditioned for re—sale and meets the safety and performance parameters set by the manufacturer.

20. Registration — means the process of approval of an application to register medical device prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of medical device products.

21. Trader — means any local establishment that is a registered product owner of a medical device, procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.

V. GENERAL GUIDELINES

1. The classification system of medical devices in this Administrative Order shall follow the classification system as agreed on by the ACCSQ-MDPWG which is rule based and according to the level of risk listed below:

Class	Risk Level
A	Low
B	Low-Moderate

C	Moderate-High
D	High

A guidance document containing the list of medical devices per classification shall be issued. Reclassification of certain devices can be done when the level of risk of the device is changed by a certain incident in the manufacture, distribution or use of the device. This shall be done upon proper consultation with the advisory committee created by the Philippine FDA and/or the ASEAN for this purpose.

2. 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.

3. All medical devices under class A shall apply for notification of the medical device product, while all medical devices under classes B to D shall apply for registration of the medical device product.

4. The Notification Number or Registration Number shall be issued to the device with an approved CMDN or CMDR. The CMDN and the CMDR shall be valid for five (5) years and shall be renewed every five (5) years after the initial approval.

5. The distributor/local manufacturer of the device shall inform the CDRRHR in writing Within thirty (30) calendar days in case the distributor/local manufacturer has ceased the production or distribution of such device.

6. The list of all approved CMDRs and CMDNs shall be posted in the FDA website.

7. Medical devices strictly for research, clinical trial, exhibit, and/or donated brand new medical devices are exempted from Notification and Registration. However, the researcher, institution, and/ or user of such devices shall apply for a Certificate of Medical Device Listing.

8. The CDRRHR reserves the right to ask for any other requirements not indicated in this Order but deemed necessary to support the reliability and authenticity of the submitted documents and safety of the medical device product; or that may arise based on the submitted compliance documents.

9. 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.

VI. SPECIFIC GUIDELINES

1. An application shall be made separately for each specific medical device. In case of the following conditions, only one application can be filed; however, separate certificates of product registration shall be issued: