Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

04 JAN 2021

FDA CIRCULAR
No. 2021-001

TO: **ALL CONCERNED STAKEHOLDERS AND PARTIES**

SUBJECT: **Hierarchy of Product Standards for Medical Devices to be Complied with for Notification/Registration Purposes**

On 26 January 2018, Department of Health Administrative Order (AO) No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements" was issued to provide guidelines on the documentary requirements for the registration of medical devices and to align the registration requirements to the Common Submission Dossier Template (CSDT) based on the provisions of ASEAN Medical Device Directive.

Part of the CSDT is the submission of the Declaration/Certificates of Conformity (self-declaration by the manufacturer) with product standards for all classes (Classes A, B, C and D) of medical devices. However, "product standards" is defined in AO 2018-0002 as "*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 Electrochemical 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"*

To guide the local manufacturer, importer and/or distributor of the product standards to refer to and comply with prior to applying for a Certificate of Medical Device Notification (CMDN) or Certificate of Medical Device Registration (CMDR) for their medical device product, the following hierarchy of product standards shall apply:

1. Philippine National Standard (PNS)
2. ISO standard or IEC standard (whichever is applicable) in the absence of PNS
3. Standard developed by other International Standard Bodies recognized by the DOH in the absence of PNS, ISO Standard and IEC standard
4. Any foreign standard that may be recognized by the DOH for the purpose of registration in the absence of PNS, ISO Standard, IEC standard and standard developed by other International Standard Bodies recognized by the DOH

All medical devices either imported or locally manufactured that do not comply with any of the above specified standards shall not be issued with CMDN or CMDR.

This Circular shall take effect immediately and shall remain valid unless otherwise revoked, repealed, or rescinded.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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