Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

12 MAR 2020

FDA MEMORANDUM
No. 2020-006

TO: **ALL MEDICAL DEVICE MANUFACTURERS, IMPORTERS, TRADERS, DISTRIBUTORS AND OTHER CONCERNED PARTIES**

SUBJECT: **Issuance of Special Certification for Imported Test Kits of COVID-19**

Pursuant to Section III. 6, Policies and Guidelines of FDA Circular No. 2018-0002, "Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements", the issuance of Certificate of Exemption shall cease for all non-registrable medical devices including in vitro diagnostic devices (IVD).

However, with the expanding global outbreak of a respiratory illness caused by COVID-19, the Center for Device Regulation, Radiation Health and Research shall be issuing a special certification for imported in-vitro diagnostic (IVD) kits used for diagnosis and screening of COVID-19. The following are the requirements:

1. Letter of Intent regarding exemption of the device/product from registration;
2. Valid License to Operate as Medical Device Distributor/Importer/Exporter;
3. Fee of Php500.00 plus LRF (Php10.00); and
4. Product registration issued by the regulatory agency or their accredited third party from the countries with established regulation such as but not limited to US Food and Drug Administration, Therapeutic Goods Authority, European Union, Health Science Authority, Pharmaceutical and Medical Device Authority, Ministry of Food and Drug Safety (Korea), and Health Canada; OR WHO pre-qualification or EUL

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