Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No. 2018 _____

SUBJECT: Rules and Regulations Governing the Issuance of an Authorization for an In-Vitro Diagnostic (IVD) Medical Device Based on the ASEAN Harmonized Technical Requirements

I. RATIONALE / BACKGROUND

Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", and its Implementing Rules and Regulations, declare that it is the policy of the state to insure the safety, efficacy and quality of IVD medical devices in the country so as to protect the health of the Filipino people.

The signing of the ASEAN Agreement on Medical Device Directive (AMDD) in 2014, mandated the Philippines to implement the following provisions to a) "require the person responsible for placing the IVD medical devices in that Member State or the authorized representative to register the IVD medical devices with the regulatory authority of that Member State", b) "shall undertake all necessary measures to ensure that only IVD medical devices which conform to the AMDD may be placed on markets of that Member State" and c) "put in place an appropriate system for the registration of IVD medical devices with the Regulatory Authority of that Member State".

The Department of Health through the Food and Drug Administration – Center for Device Regulation, Radiation Health and Research (CDRRHR) hereby adopt, issues and implement the AMDD guidelines on the registration of IVD medical devices and to provide the regulatory requirement and registration process.

II. OBJECTIVE

This Administrative Order aims to specify the rules, guidelines, procedures and requirements of the FDA-CDRRHR relative to the issuance of an authorizations for IVD medical devices adapting the provisions of ASEAN AMDD.

III. SCOPE OF APPLICATION

This Administrative Order shall cover all IVD medical devices and apply to all manufacturers, traders and distributors (e.g. importers, exporters and wholesalers) of IVD medical devices in the Philippines.

IV. DEFINITION OF TERMS

For purposes of this Administrative Order, the following terms shall be defined as follows:

Applicant - refers to any individual, partnership, corporation, association, and/or organization either a manufacturer, trader, distributor, importer, exporter applying for an authorization.

Authorization - means a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution transfer, and/or where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration of accreditation, of compliance, or of exemption or any similar document.

ASEAN Medical Device Directive (AMDD) - refers to the agreement of ASEAN Member States harmonizing the regulation of medical device.

Calibrator - refer to any substance, material or article intended by its product owner to be used in the calibration of a measuring instrument or measuring system.

Certificate of IVD Medical Device Listing (CIVDL) - refers to the authorization issued to all IVD medical device intended for clinical evidence study and clinical research.

Certificate of IVD Medical Device Notification (CIVDN) - refers to the authorization issued to all class A IVD medical device that complies with all the requirements for notification.

Certificate of IVD Medical Device Registration (CIVDR) - refers to the authorization issued to all class B, C and D IVD medical device that complies with all the requirements for registration.

Clinical Performance Study - a study undertaken to establish or confirm performance of an IVD medical device.

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.

Control Materials - refer to any substance, material or article intended by its product owner to verify the performance of an IVD medical device.

Distributor/importer/exporter - means any 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.

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

Establishments - means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of IVD medical devices, including the facilities and installation needed for its activities.

In-Vitro Diagnostic (IVD) 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 providing information:

a. concerning a physiological or pathological state;
b. concerning a congenital abnormality;
c. to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients; or
d. to monitor therapeutic measures,

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its product owner to be used for in vitro diagnostic examination.

Instrument - refers to any equipment or apparatus intended by the product owner to be used as IVD medical device.

Label - written, printed or graphic information provided upon the IVD medical device itself. Where physical constraints prevent, this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple medical devices.

Labelling - the label**,** instructions for use, and/or any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

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

Listing - refers to the process of informing the FDA that such IVD medical device are being manufactured and imported solely for clinical evidence study and research.

Manufacturer - means an establishment engaged in any and all operations involved in the production of IVD medical devices including preparation, processing, compounding, formulating, filling, packing, re-packing, altering, ornamenting, finishing, and labeling with the end view of its storage, sale or distribution.

National Reference Laboratory (NRL) - refers to agency/laboratories mandated to conduct performance evaluation of the IVD medical devices.

Notification - means the process of approval of an application to notify class A IVD medical devices 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 class A IVD medical device.

Performance Testing/Evaluation - refers to the tests being done by the appropriate NRL to IVD medical device to verify compliance to the test criteria set by the NRL or the data submitted by the applicant for the purpose of FDA registration.

Person - refers to any individual, partnership, corporation, association and/or organization.

Post market surveillance performance testing/evaluation - refers to the test being done by the appropriate NRL to IVD medical device after the issuance of CPR to verify its continuous compliance to the test criteria set by the NRL or the data submitted by the applicant.

Product Standards - refers to in-vitro medical devices standards set, formulated, and or/established by the following:

a. Bureau of Philippine Standards (Philippine National Standard)
b. International Standardization Organization (ISO)
c. International Electrochemical Commission (IEC)
d. Other International Standard Body or any person standards which may be accepted by FDA for the purpose of registration.

Product Owner – refers to any person who:

a. supplies the IVD 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 IVD medical device, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

Quality Management System (QMS) Certification - refers to a document issued by an accredited certifying body to an establishment that conforms to the requirements of quality management system for IVD medical devices.

Reagent - refers to any chemical, biological or immunological components, solutions or preparations intended by the product owner to be used as IVD medical devices.

Registration - means the process of approval of an application to register class B, C and D IVD medical devices 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 class B, C, and D IVD medical device.

Safety - means that the product will not impose any danger, injury, damage or undesirable effect to a person.

Self-Testing – testing/monitoring performed by lay persons.

Scientific Research – is the systematic investigation of scientific theories and hypothesis.

Trader - means any establishment which is registered owner of a health product and 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. POLICIES AND GUIDELINES

A. General Guidelines

1. All establishments that intend to place IVD medical devices in the Philippine market shall apply first for a License to Operate consistent with the current rules and regulations on unified licensing of FDA before applying for registration or notification of their IVD medical devices.

2. The certificate of IVD medical device notification and registration shall be issued by the CDRRHR upon the approval of the Center Director or his/her authorized representative if the application is found to be meritorious; otherwise, the application shall be disapproved.

3. The Notification Number or Registration Number shall be issued to the IVD medical devices with approved CIVDN or CIVDR.

4. The initial CIVDR shall be valid for three (3) years as long there is no change in the composition, packaging, intended use, process and components of the IVD medical devices and shall be renewed every five (5) years.

5. The CIVDN shall be valid for one (1) year as long there is no change in the composition, packaging, intended use, process and components of the IVD medical devices and shall be renewed every one (1) year.

6. The validity of the CIVDR is independent with the validity of the performance testing/evaluation set by the concerned NRL. The validity of performance testing/evaluation shall be reflected at the back of the CIVDR.

7. All registered IVD medical devices that has its performance tested/evaluated by appropriate NRL prior to its registration shall undergo post market surveillance performance testing/evaluation within 2 to 3 years after the issuance of the CIVDR.

8. The FDA through CDRRHR in coordination with NRL shall issue guidelines on the conduct of post market surveillance of all registered IVD medical devices.

9. Reagents, reagent product, calibrator, control, material, kit, instruments, apparatus, equipment or systems manufactured, sold or represented by manufacturers not for use in in-vitro diagnostic application purposes are not classified as IVD medical device.

B. Specific Guidelines

1. The applicant shall classify the IVD medical devices based on the ruling in the ASEAN Medical Device Directive. The classification of IVD medical devices as follows:

Class	Risk Level
A	Low Individual Risk and Low Public Health Risk
B	Moderate Individual Risk and/or Low Public Health Risk
C	High Individual Risk and/or Moderate Public Health Risk
D	High Individual Risk and High Public Health Risk

The FDA shall issue guidelines on the classification of IVD medical devices.

2. The CDRRHR shall verify the classification and shall reclassify certain IVD medical devices when the level of risk is changed by a certain incident in the manufacture, distribution or use of the IVD medical devices upon proper consultation with the advisory committee set forth by the Philippine FDA and/or the ASEAN.

3. The applicant shall follow the current FDA policy/guidelines on the submission of application.

4. All IVD medical devices under class A shall apply for notification, while all under class B, C and D shall apply for registration.

5. IVD medical devices intended solely for clinical performance study and scientific research are exempted from notification and registration. However, the researcher, institution and/user of such devices shall apply for CIVDL.

6. An application shall be made separately per specific IVD medical devices. Single application can be filed for IVD medical devices; however, a separate authorization shall be issued provided that such IVD medical devices meet the following conditions:

    a. with accessories that are intended to be sold separately;
    b. manufactured in multiple manufacturing sites and shall co-exist in the market;
    c. system where the use of one part of the system is needed to be used together with all or any part of the system;
    d. with the same intended use and the same manufacturing process but differ in one or more raw materials;
    e. with the same intended use and the same manufacturing process but differ in the design;
    f. with the same raw materials but differ in types or shapes resulting in different specific intended use.

    The fee for this type of application shall be equivalent to the total fees for all the individual authorization issued.

7. All applicants shall submit the legal requirements (see annex A) and appropriate CSDT of IVD medical devices. FDA shall issue guideline on the submission of CSDT.

8. All IVD medical devices shall follow the labeling requirements of FDA existing rules on labelling of medical device and IVD medical device.

9. All appropriate requirements shall be submitted in Filipino and/or American Standard English version.

10. The CDRRHR shall have the right to ask for additional documents not indicated in this Order that may arise based on the submitted compliance documents.

11. All initial applications that do not comply with the requirements of FDA shall be notified through a letter and shall be given a one-time chance to correct the deficiencies within ninety (90) calendar days for registration and thirty (30) calendar days for notification. If the applicant still fails to comply with the

requirements, he/she will be given a chance to re-apply, with a corresponding fee, and to submit the complete compliance documents within sixty (60) calendar days for registration and thirty (30) calendar days for notification. Failure to comply with the required documentation within the given period shall be a ground for disapproval of the application.

12. All application for renewal of the certificates of product registration or notification shall be filed 90 calendar days prior to its expiration.

13. Application for renewal of certificates of product registration or notification filed after the validity date shall be imposed with corresponding penalty in accordance with the existing rules and regulations on fees and charges.

14. An application for renewal filed after one hundred twenty (120) calendar days shall be considered as initial application. IVD medical devices with expired validity and whose application was turned into an initial application shall cease the selling of such device until such time that the certification of product registration is approved. The applicant can, however, opt to request the retention of the product registration/notification number.

15. An application for renewal filed from within 120 calendar days from its original expiry the CPR shall be consider valid and existing until FDA decision or resolution rendered on the renewal application.

16. All renewal applications that do not comply with the requirements of FDA shall be notified through a letter and shall be given a one-time chance to correct the deficiencies within thirty (30) calendar days.

17. All IVD medical devices that need to undergo performance testing/evaluation prior to its initial and renewal registration shall be endorsed to the appropriate NRL (see annex B). The CDRRHR shall inform the applicant regarding the endorsement.

18. Applicants shall follow rules and guidelines of the appropriate NRL during the conduct of performance testing/evaluation.

19. The applicant shall coordinate with the NRL for the submission of samples, laboratory testing fee and other documentary requirements within two (2) months after the endorsement. Non-coordination and Non-compliance within the prescribed period shall make the application disapproved.

20. NRL's shall give feedback report to FDA regarding the status of the endorsed applications.

21. NRL's shall submit the report of performance testing and/or evaluation to the FDA.

22. Approval and/or disapproval of the application shall be based on the applicant's compliance with the requirements of the CDRRHR and the results of the performance testing/evaluation conducted by the appropriate NRL.

23. The list of all approved CIVDRs and CIVDNs shall be posted in the FDA website.

24. All applicants seeking for CIVDL shall submit all necessary documentary requirements (see Annex C).

C. Fees and Charges

1. Payment of initial and renewal application fees and other charges (surcharges, penalties, legal research fund fees etc.) shall be collected as may be allowed subject to the existing rules and regulations of the FDA.

2. NRL shall collect payment for the fees and other charges on the conduct of performance and interval performance testing/evaluation as may be allowed subject to the existing rules and regulations of the appropriate NRL.

D. Grounds for Disapproval of Application, Cancellation, Revocation and/or Non-Renewal of CIVDN and CIVDR

In addition to the provisions of R.A. 9711 and its Implementing Rules and Regulations the following are the grounds for disapproval of application, cancellation, revocation and/or non-renewal of CIVDN and CIVDR:

1. The manufacture, sale, offering for sale or transfer of IVD medical device that does not meet all the requirements of safety, quality and efficacy;

2. Misrepresentation or concealment of significant data or information about the product sought to be registered;

3. Alteration, mutilation, destruction, obliteration or removal of any part of the IVD and labeling;

4. IVD medical device that has a biological, chemical or physical property that may cause an unacceptable health risk;

5. Submission of falsified document(s);

6. Alteration or falsification of issued CIVDN or CIVDR.

VI. SANCTIONS

Any violation of this Administrative Order consistent with Republic Act No. 3720 and Republic Act No. 9711 and its implementing rules and regulations shall be a ground for filing appropriate administrative charges and/or imposition of administrative sanctions such as, but not limited to, imposition of fines, suspension, cancellation or revocation of any license, permit or registration issued by FDA.

VII. TRANSITORY PROVISIONS

The implementation of the registration and notification of IVD medical devices following the new set of regulatory requirements shall be one (1) year upon the effectivity of this Administrative Order. However, IVD medical devices establishments may voluntarily comply with the new sets of requirements within the said 1year period of transition.

NRL's shall inform and update FDA its capability to conduct performance testing/evaluation of IVD medical devices. FDA shall issue updated list of IVD medical devices that need to undergo performance testing/verification of NRL's prior to registration.

VIII. REPEALING AND SEPARABILITY CLAUSE

All administrative orders, rules and regulations and administrative issuances or parts thereof inconsistent with the provision of this order are hereby repealed or modified accordingly.

If any provision in this Administrative Order, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Administrative Order shall not be affected.

IX. EFFECTIVITY

This Administrative Order shall take effect fifteen (15) days following its publication in two (2) newspaper of national circulation and upon filing to the University of the Philippines Law Center Office of the National Administrative Register.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

ANNEX A

Legal Documentary Requirements for the Application of Initial/Renewal Notification and Registration of IVD Medical Devices

1. Notarized Application Form
2. Copy of the valid License to Operate (LTO) issued by FDA
3. Copy of Letter of Authorization. (indicating the duration of agreement). For imported IVD medical devices, the copy of the Letter of Authorization shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the authorization is true and correct.
4. A government – issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. For imported medical devices, the copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
5. For imported IVD medical devices, the Certificate of Product Notification or Registration or any equivalent document attesting to the safety, quality and effectiveness of the IVD medical device issued by the National Regulatory Agency or accredited notified body in the country of origin. The copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.

ANNEX B
National Reference Laboratories

I. East Avenue Medical Center:
a. Environmental and Occupational Health
b. Toxicology
c. Micronutrient Assay
d. Industrial and Chemical Emergencies

II. Lung Center of the Philippines:
a. General Clinical Chemistry
b. Anatomic Pathology for Pulmonary Diseases

III. National Kidney and Transplant Institute:
a. Hematology and Immunohematology
b. Urinalysis
c. Anatomic Pathology for Renal Diseases (to include unassigned organ systems)
d. Cellular-Based Product Testing

IV. Philippine Heart Center:
a. Anatomic Pathology for Cardiac Diseases
b. Cardiac Markers

V. Research Institute for Tropical Medicine:
a. Antimicrobial Resistance
b. National Tuberculosis
c. Malaria and Other Parasites
d. Schistosomiasis
e. Dengue and Arboviruses
f. Influenza and Other Respiratory Viruses
g. Polio and Other Enteroviruses
h. Rotavirus and Other Enteric Viruses
i. Measles and Other Exanthems
j. Bacterial Enteric Diseases
k. Emerging and Re-Emerging Bacterial Diseases
l. Invasive Bacterial Vaccine Preventable Diseases
m. Leptospirosis
n. Mycology
o. Transfusion-Transmissible Infections
p. Rabies and Other Lyssaviruses
q. Special Pathogens
r. Public Health Entomology

VI. STD AIDS Cooperative Central Laboratory (SACCL) – San Lazaro Hospital:
a. HIV/AIDS
b. Hepatitis B
c. Hepatitis C
d. Syphilis
e. Other Sexually Transmitted Infections

ANNEX C
IVD Medical Device Listing Documentary Requirements

I. Notarized letter addressed to the Director, CDRRHR, stating that the IVD medical device will be used solely for clinical performance study and scientific research and is not intended for sale. The letter should contain the following information:
    a. Complete list of the IVD medical device indicating the quantity, brand and the name of the manufacturer of the product
    b. Declaration that the organization shall be the sole entity responsible for the IVD medical devices and that the DOH, FDA-CDRRHR will not be held liable for any safety issue concerning the product
II. Study Design/Protocol
III. Sample of IVD medical device if applicable