Journey of a Medical Device Products: Roadmap to Philippine Market

By :

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Regulatory Intelligence Committee


Is this the way to FDA ?
Am I on the right route ?

Presentation Topics

*“ What are the **latest updates on medical device registration**?”*

*“Are there any other **regulatory agencies** that I have to know about?”*

*“What are the **regulatory processes** that I have to know prior to medical device distribution / market availability?”*

New Regulatory Requirements for Medical Devices

is based on the

Administrative Order 2018-0002

issued by DOH on 26 January 2018

Guidelines Governing the Issuance of an Authorization for Medical Device based on the ASEAN Harmonized Technical Requirements

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

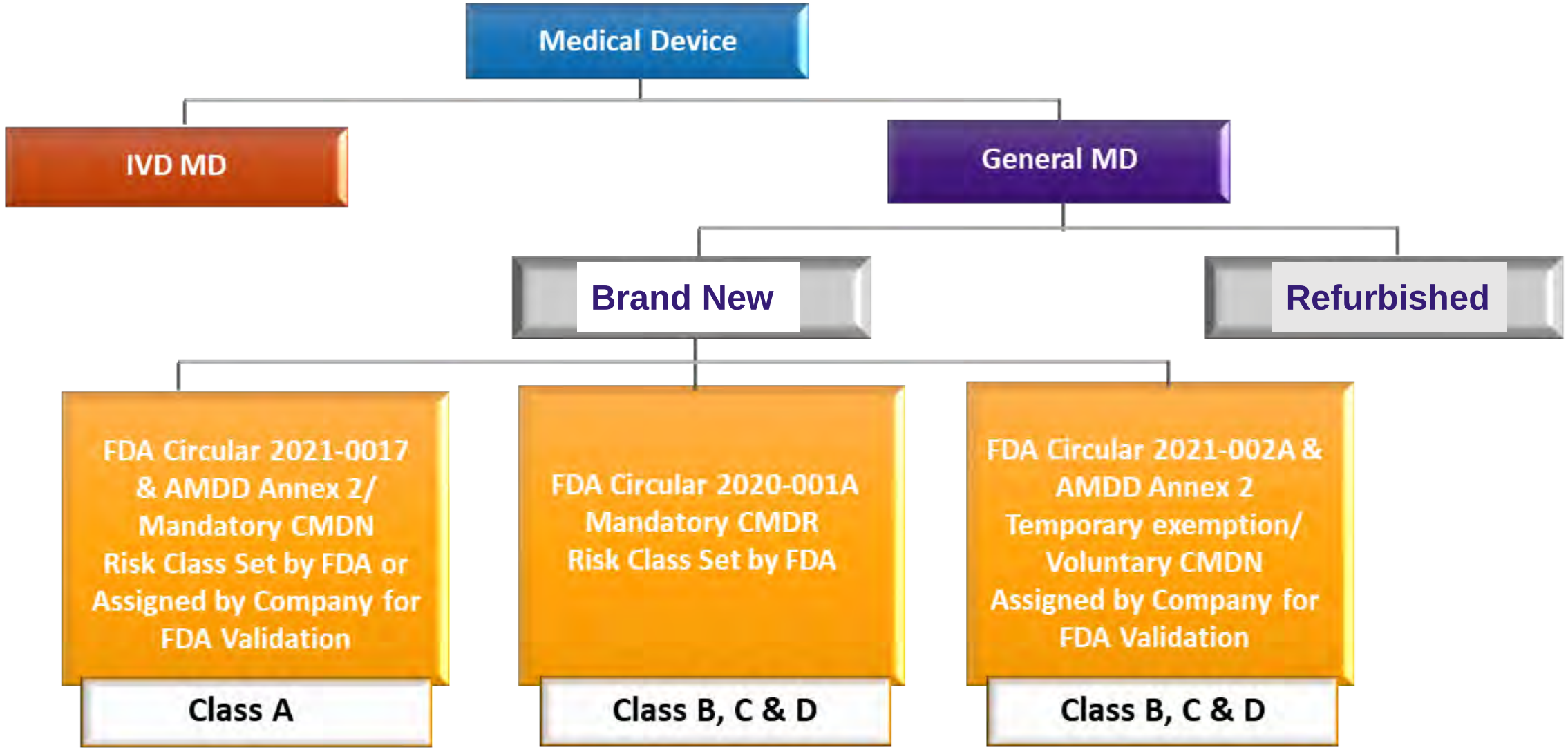
- intended by the manufacturer/product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
  - diagnosis, prevention, monitoring, treatment or alleviation of diseases;
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
  - 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.

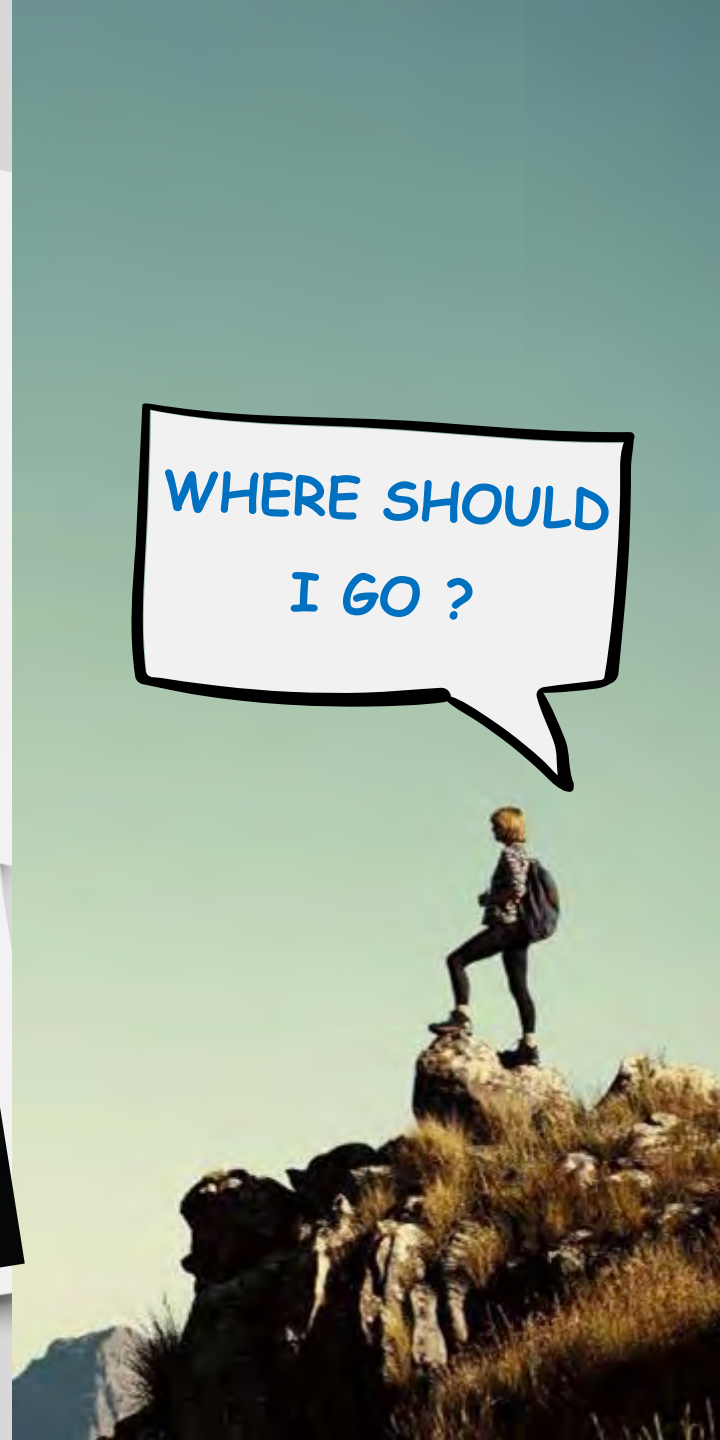
Medical Device definition based on A.O. 2018-0002:

Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements

OVERVIEW OF MEDICAL DEVICE (FDA)



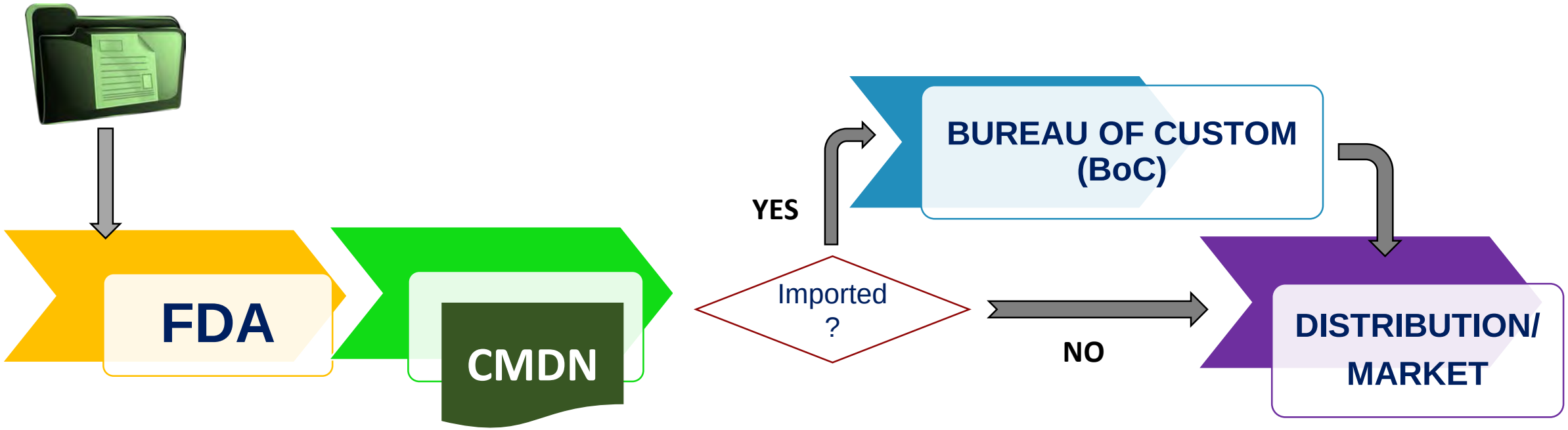

PDA


WHERE SHOULD
I GO ?

PROCESS MAP for MEDICAL DEVICE PRODUCTS

Medical Device Product Class A (*FDA Circular 2021-0017 Reference List of Class A Medical Device)*

Medical Device Product Class B, C, D * – NOT included in the current List of Registrable Medical Devices**

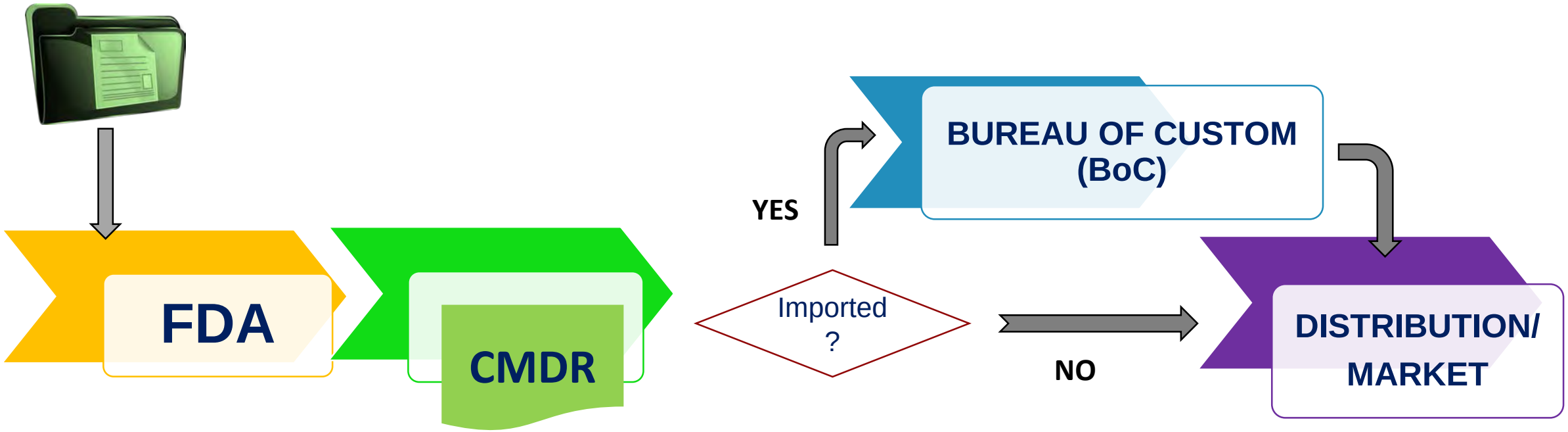


* *FDA Circular 2021-002-B – Start period for CMDN 01 April 2023*

** *FDA No. 2020-001A Circular 2020-001A - Amendment to Annex A of FDA Circular 2020-001*

PROCESS MAP for MEDICAL DEVICE PRODUCTS

Medical Device Product Class B, C, D – INCLUDED current List of Registrable Medical Devices**



** A.O. 2018-0002– Guidelines Governing the Issuance of an Authorization for Medical Device based on ASEAN Harmonized Technical Requirements*

CMDN and CMDR Application Process

RULED BY FDA CIRCULAR 2021-0017
(RISK CLASS SET BY FDA OR ASSIGNED BY COMPANY FOR FDA VALIDATION)

Risk Classification: A	Reqts : A.O 2018-0002	Timeline: 20 working days Based on Citizen Charter	Fee: Basic FDA: P7,575+ Payment Facility Charges	Initial Filing: FDA E-portal/ CMDN	Note: Mandatory CMDN	Certificate Validity: 5 Years	Renewal Pathway: Same

RULED BY FDA CIRCULAR 2021-002A & AMDD ANNEX 2
TEMPORARY EXEMPTION (RISK CLASS ASSIGNED BY COMPANY FOR FDA VALIDATION)

Risk Classification: B, C & D	Reqts : A.O 2018-0002	Timeline: 20 working days Based on Citizen Charter	Fee: Basic FDA: P3,030 + Payment Facility Charges	Initial Filing: FDA E-portal/ CMDN	Mandatory CMDN	Certificate Validity: 2 Years	Renewal Pathway: None, file via CMDR (new)

RULED BY FDA CIRCULAR 2020-001A/ (RISK CLASS SET BY FDA)

Risk Classification: B, C & D	Reqts : A.O 2018-0002	Timeline: 69 (B) -97 (C-D) working days Based on Citizen Charter	Fee: Basic FDA: P7,575 + Payment Facility Charges	Initial: Email & Share link to Google Drive	Note: Mandatory CMDR	Certificate Validity: 5 Years	Renewal Pathway: Follow existing renewal process

EXISTING APPROVED NOTIFICATIONS/REGISTRATIONS

Risk Classification: A, B, C & D	Reqt's: Renewal Checklist (Common) Amendment Checklist (common)	Timeline: 20 working days Based on Citizen Charter	Fee: Basic FDA: P5,050+ Payment Facility Charges Minimum P510 + Payment Facility Charges	Note: Renewal Amendment/Variation	Certificate Validity: 5 Years Will follow expiry date in CPR

Clearance for Customs Release (CFCR) Process - Medical Equipment

Radiation Emitting Device?	CFCR Requirements Completion	CFCR Application with FDA	Certificate of Customs Release
Ionizing Radiation Device: X-ray Non Ionizing: Ultrasound	• Legalized FSC or CFG • Product Brochure or Data sheet • Commercial Invoice • Admin Docs – LTO, Business Permit • Demo Guarantee Letter (if demo)	Maximum of 7 days	Release of Permit

PHILIPPINE HEART CENTER

LUNG CENTER OF THE PHILIPPINES

Other Regulatory Agencies : DOH, PNP, NTC

PROCESS MAP with other REGULATING AGENCIES

with Regulated Dangerous Chemicals?

YES

DDB
(Dangerous Drug Board)

(OACEIS) Exemption / Certification Application

DDB Certificate of Exemption

STORAGE MEDIA, SOFTWARE, DISK WRITER?

YES

OMB
(Optical Media Board)

1. OMB- Establishment License Business Software
2. Portal of OMB for Import / Export Permit

OMB LTO Importer
OMB LTO Distributor
Import Permit

Radio Transmitter/ Transceiver / WLAN/ Bluetooth?

YES

NTC
(National Telecommunications Commission)

1. Dealers' Permit (NTC/NCR)
2. Type Acceptance Certificate

(NSW) Import / Export Permit

Type Certificate
Import Permit
WDN Registration

MARKET DISTRIBUTION

PROCESS MAP with other REGULATING AGENCIES

Radioactive Material?

YES

PNRI

*Philippine Nuclear Research Institute - DOST

PNRI (Application) Appointment Required

RAM License Release Certificate (Import License)

Explosives, PNP Controlled Chemicals?

YES

PNP

For Checking, DTI suspends the regulation.

MARKET DISTRIBUTION

Is this the right way to In-Vitro Diagnostic Medical Device Registration ?

New Regulatory Requirements for Medical Devices

is based on the

Administrative Order 2018-0002

issued by DOH on 26 January 2018

Guidelines Governing the Issuance of an Authorization for Medical Device based on the ASEAN Harmonized Technical Requirements

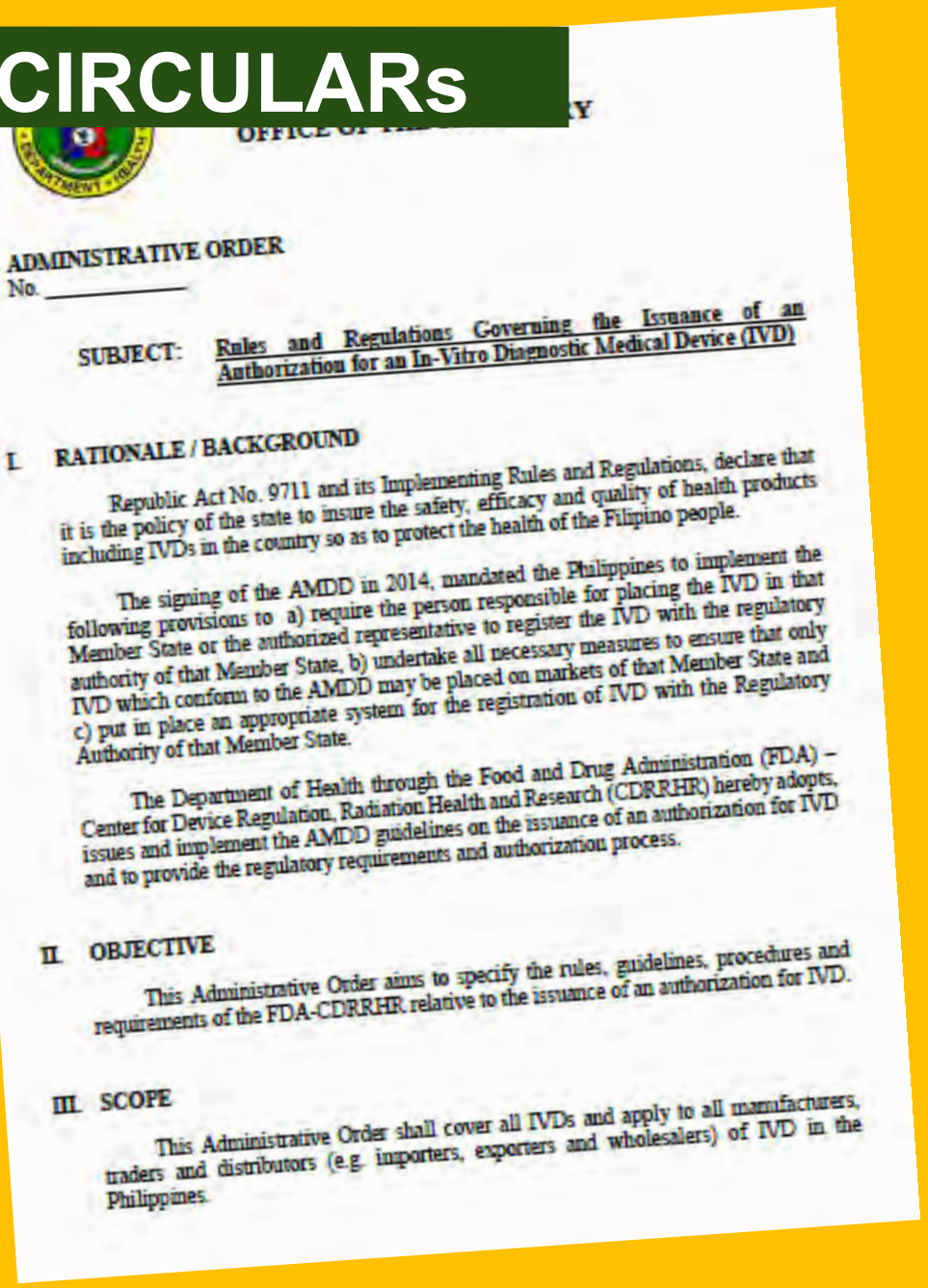
In-Vitro Diagnostic Medical Device definition based on A.O. 2018-0002:

Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements

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.

DRAFT CIRCULARs



OFFICE OF [illegible]RY

ADMINISTRATIVE ORDER
No. _____

SUBJECT: **Rules and Regulations Governing the Issuance of an Authorization for an In-Vitro Diagnostic Medical Device (IVD)**

I. RATIONALE / BACKGROUND

Republic Act No. 9711 and its Implementing Rules and Regulations, declare that it is the policy of the state to insure the safety, efficacy and quality of health products including IVDs in the country so as to protect the health of the Filipino people.

The signing of the AMDD in 2014, mandated the Philippines to implement the following provisions to a) require the person responsible for placing the IVD in that Member State or the authorized representative to register the IVD with the regulatory authority of that Member State, b) undertake all necessary measures to ensure that only IVD 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 with the Regulatory Authority of that Member State.

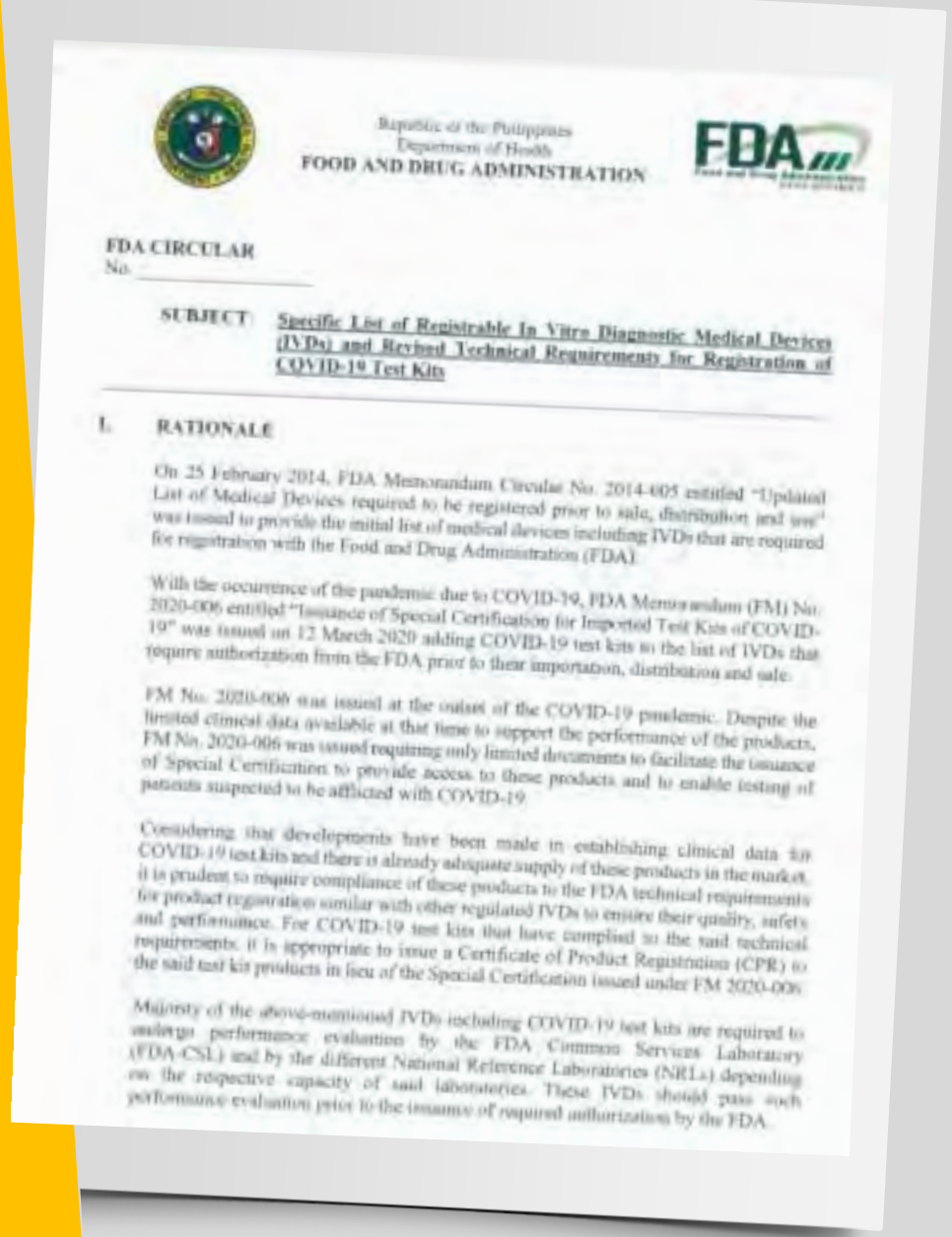
The Department of Health through the Food and Drug Administration (FDA) – Center for Device Regulation, Radiation Health and Research (CDRRHR) hereby adopts, issues and implement the AMDD guidelines on the issuance of an authorization for IVD and to provide the regulatory requirements and authorization 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 authorization for IVD.

III. SCOPE

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



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. _____

SUBJECT: **Specific List of Registrable In Vitro Diagnostic Medical Devices (IVDs) and Revised Technical Requirements for Registration of COVID-19 Test Kits**

I. RATIONALE

On 25 February 2014, FDA Memorandum Circular No. 2014-005 entitled "Updated List of Medical Devices required to be registered prior to sale, distribution and use" was issued to provide the initial list of medical devices including IVDs that are required for registration with the Food and Drug Administration (FDA).

With the occurrence of the pandemic due to COVID-19, FDA Memorandum (FM) No. 2020-006 entitled "Issuance of Special Certification for Imported Test Kits of COVID-19" was issued on 12 March 2020 adding COVID-19 test kits to the list of IVDs that require authorization from the FDA prior to their importation, distribution and sale.

FM No. 2020-006 was issued at the outset of the COVID-19 pandemic. Despite the limited clinical data available at that time to support the performance of the products, FM No. 2020-006 was issued requiring only limited documents to facilitate the issuance of Special Certification to provide access to these products and to enable testing of patients suspected to be afflicted with COVID-19.

Considering that developments have been made in establishing clinical data for COVID-19 test kits and there is already adequate supply of these products in the market, it is prudent to require compliance of these products to the FDA technical requirements for product registration similar with other regulated IVDs to ensure their quality, safety and performance. For COVID-19 test kits that have complied to the said technical requirements, it is appropriate to issue a Certificate of Product Registration (CPR) to the said test kit products in lieu of the Special Certification issued under FM 2020-006.

Majority of the above-mentioned IVDs including COVID-19 test kits are required to undergo performance evaluations by the FDA Common Services Laboratory (FDA-CSL) and by the different National Reference Laboratories (NRLs) depending on the respective capacity of said laboratories. These IVDs should pass such performance evaluation prior to the issuance of required authorization by the FDA.

Current List of Registrable In-vitro Diagnostic Medical Device
(FDA Memo Circular No. 2014-005)

FDA Circular 2020-001:
Blood collection Tube is registrable and added as IVD medical device

*In lieu of the COE, the **LTO of the establishment** shall be provided as the point of entry and/or as part of bidding requirements*

B. In-Vitro Diagnostic (IVD) Medical Devices:

1. **HIV (antibody and/or antigen), HBV (HBsAg and other markers), HCV (antibody and/or antigen) and syphilis** (Treponemal and nontreponemal) kits for:
    - Screening Test
    - Confirmatory Test
    - Other marks for nucleic application systems for in-vitro diagnostic use and test to monitor disease activity (e.g. iral load test, other serologic markers for Hepatitis B)
2. **Single or combination drug screening test kits/reagents** for THC/marijuana, Shabu/MET, Cocaine, Benzodiazepine, Ecstacy/MDMA and Opiates/Morphine
3. **Blood Typing Sera** for Anti-A, Anti-B, Anti-D, Anti-AB
4. **Anti-human Globulin Reagents**
5. **Potentiators** such as enzyme, LISS and albumin
6. **Column Agglutination test** for crossmatching & blood typing
7. **Pregnancy test kits/reagents**
8. **Leptospirosis test kits/reagents**

PROCESS MAP with other REGULATING AGENCIES

with Regulated Dangerous Chemicals?

YES

DDB
(Dangerous Drug Board)

(OACEIS) Exemption / Certification Application

DDB
Certificate of Exemption

STORAGE MEDIA, SOFTWARE, DISK WRITER?

YES

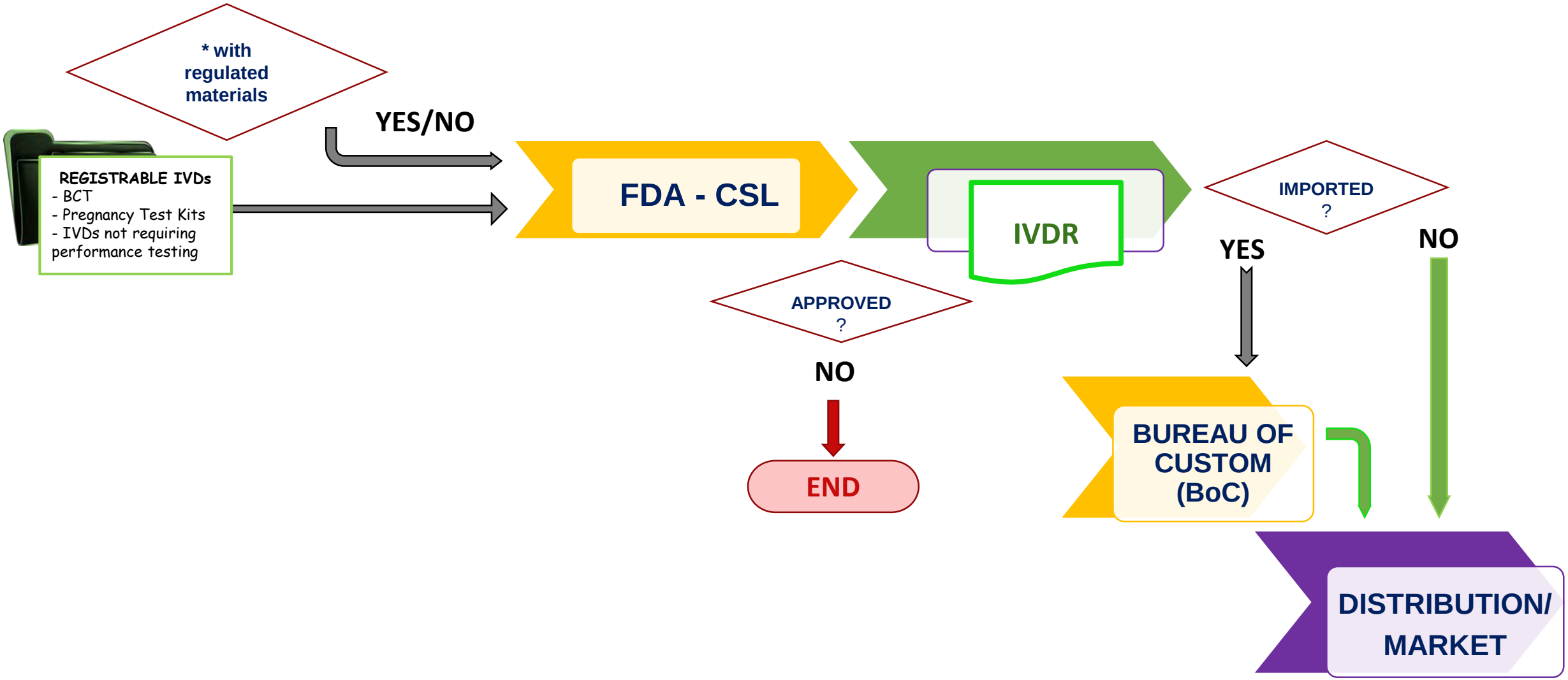
OMB
(Optical Media Board)

OMB LTO Importer
OMB LTO Distributor
Import Permit

1. OMB- Establishment License Business Software
2. Portal of OMB for Import / Export Permit

MARKET DISTRIBUTION

PROCESS MAP for IN-VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCT



PROCESS MAP for IN-VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCT

REGISTRABLE IVDs requiring performance testing

with Regulated Dangerous Chemicals and other regulated materials

YES/NO

FDA

FDA Endorsement Letter to NRLs

NRLs

1. RITM
2. SLH
3. EAMC
4. LCP
5. NKTI
6. PHC* designated through DPO no. 2009-5148

Product Performance Result

FDA

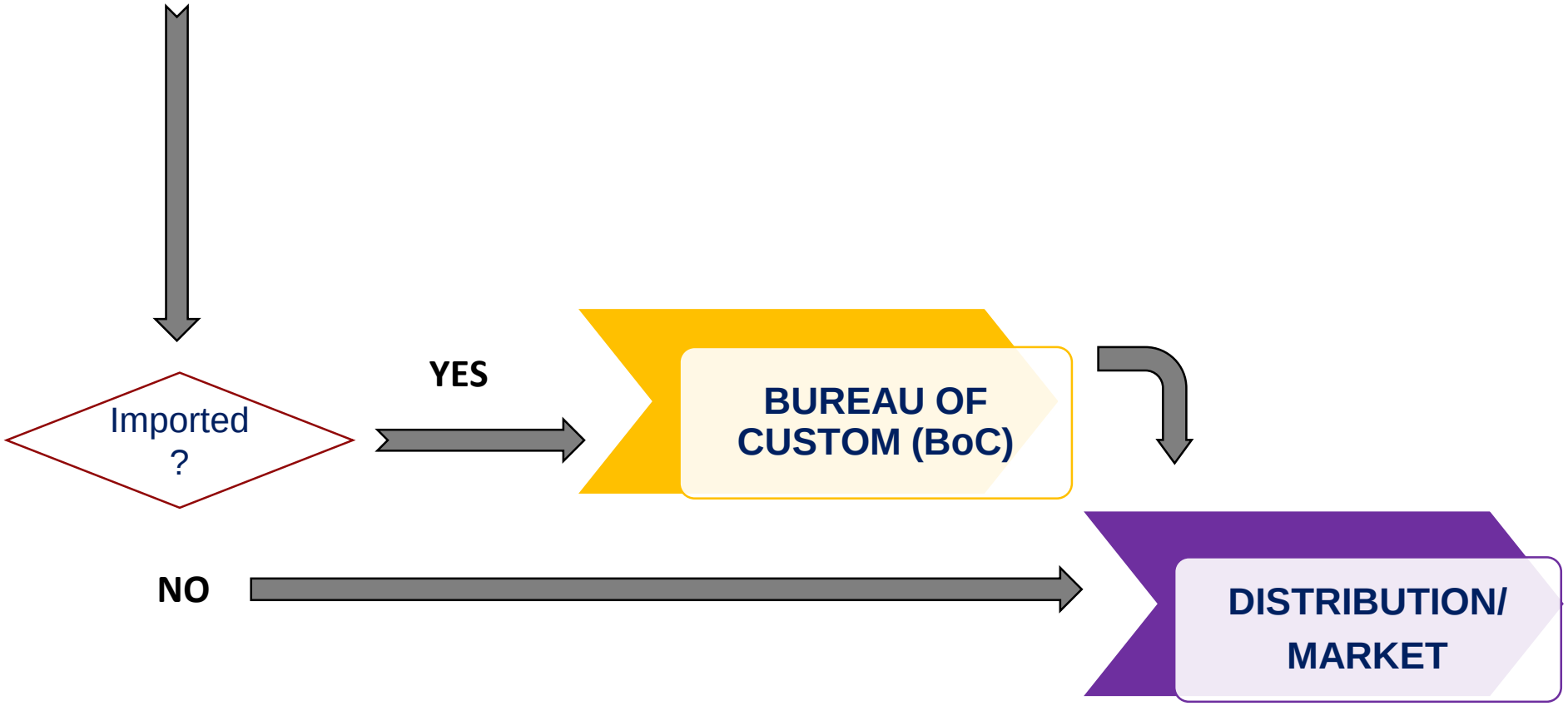
APPROVED ?

YES

IVDR

NO

END



PROCESS MAP for IN-VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCT

NATIONAL REFERENCE LABORATORIES (NRLs)

East Avenue Medical Center:

1. NRL for Environmental & Occupational Health
2. NRL for Toxicology
3. NRL for Micronutrient Assay
4. NRL for Industrial and Chemical Emergencies
   **Single or combination drug screening test kits/reagents

National Kidney and Transplant Institute:

1. NRL for Hematology
2. NRL for Immunohematology
3. NRL for Urinalysis
4. NRL for Anatomic Pathology for Renal Diseases and other Unassigned Organ Systems
5. NRL for Cellular-Based Product Testing
   AO No. 2013-0012 “Rules and Regulations Governing Accreditation of Health Facilities Engaging in Human Stem Cell and Cell Based or Cellular Therapies in the Philippines”

Lung Center of Philippines:

1. NRL for General Clinical Chemistry
2. NRL for Anatomic Pathology for Pulmonary and Pleural Diseases

San Lazaro Hospital - STD AIDS Cooperative Central Laboratory (SACCL):

1. NRL for HIV/AIDS
2. NRL for Hepatitis B and Hepatitis C
3. NRL for Syphilis and Other Sexually-Transmitted Infections

Philippine Heart Center:

1. National Reference Laboratory for Anatomic Pathology for Cardiac Diseases
2. National Reference Laboratory for Cardiac Markers

Research Institute for Tropical Medicine:

1. NRL for Antimicrobial Resistance
2. National Tuberculosis Reference Laboratory
3. NRL for Transfusion-Transmissible Infections
4. NRL for Dengue and Other Arboviruses*
5. NRLfor Influenza and Other Respiratory Viruses*
6. NRL for Emerging and Re-Emerging Bacterial Diseases*
7. NRL for Leptospirosis*
8. NRLfor Special Pathogens*
9. NRL for Mosquito Vectors of Human Diseases*
10. NRL for Malaria and Other Parasites*
11. NRL for Schistosomiasis*
12. NRL for Rabies and other Lyssaviruses**
13. NRL for Polio and other Enteroviruses
14. NRL for Measles and other Exanthems
15. NRL for Invasive Bacterial Vaccine Preventable Diseases
16. NRL for Rotavirus and other Enteric Viruses***
    AO No. 2015-0050 “Designation of RITM as the National Reference Laboratory for Rotavirus and other Enteric Viruses
1. NRL for Bacterial Enteric Diseases**
2. NRL for Mycology

- COVID-19 TEST KITS

* These NRLSs shall support the Emerging and Re-emerging Infectious Disease Control Program
** These NRLSs shall support the Neglected Tropical Disease Control Program
***These NRLs shall support the Food and Waterborne Disease Control Program

IVD Medical Device Application Process

IVD Devices/REAGENTS			
Timeline: 90 working days **Based on Citizen Charter**	**Fees to be Paid** Php1,500.00 + 1% LRF for initial with 1-year validity* **Additional Php1,000.00 + 1%** LRF if the product is for the detection of hCG (pregnancy test) which requires performance evaluation testing	**Initial Filing :** Email & Share Google Link Drive	**Performance Evaluation Fees and Timeline varies per NRLs**
24 working days **Based on Citizen Charter**	Php 5,000.00 + 1% LRF for renewal with 5 years validity	**Renewal** **Filing :** Email & Share Google Link Drive *** CPR Extension**	**Performance Evaluation Fees and Timeline varies per NRLs**

In Summary ……..

*“ What are the **latest updates on medical device registration**?”*

*“Are there any other **regulatory agencies** that I have to know about?”*

*“What are the **regulatory processes** that I have to know prior to medical device distribution / market availability?”*

KEY TAKE AWAYS :

1. Be knowledgeable about your products

2. Conduct a detailed product assessment upon receipt of the documents from principal/supplier prior to FDA submission

3. Identify the regulatory body/agencies that regulate your product other than FDA

4. Expand your medical device knowledge; attend to various trainings and seminars

5. Take time to read medical device updates cascaded by Regulatory Intelligence Committee

References:

DEPARTMENT ORDER: No. 2020-0820- Institutionalizing and Strengthening the National Reference Laboratories in the Philippines

Link:https://www.fda.gov.ph/department-order-no-2020-0820-institutionalizing-and-strengthening-the-national-reference-laboratories-in-the-philippines/

DDB Certification and Exemption

Link: https://www.ddb.gov.ph/legal-services/certification-and-exemption

Rules and Regulations implementing RA No. 9239 known as the “Optical Media Act of 2003” -

Link: https://www.omb.gov.ph/wp-content/uploads/Implementing-Rules-and-Regulations-.pdf

FDA Citizen Charter - CDRRHR

Link: https://www.fda.gov.ph/wp-content/uploads/2022/04/FDA-Citizen_s-Charter-CDRRHR_CPR_-31-March-2022.pdf

FDA Circular No.2021-002-B || Amendment to FDA Circular No. 2021-002-A entitled “Addendum to FDA Circular No. 2021-002 Re: Full Implementation of Administrative Order No. 2018-0002 entitled “Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements””

https://www.fda.gov.ph/fda-circular-no-2021-002-b-amendment-to-fda-circular-no-2021-002-a-entitled-addendum-to-fda-circular-no-2021-002-re-full-implementation-of-administrative-order-no-2018-0002-entitled/


A good plan is like a road map:
it shows the final destination and usually the
best way to get there.
H. Stanley Judd
THANK YOU FOR LISTENING !