REQUIREMENTS & PROCEDURES FOR IN-VITRO DIAGNOSTIC (IVD) REGISTRATION

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M A L A Y S I A

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Introduction

- **MEDICAL DEVICE**: A regulated item under the Medical Device Act 2012 (Act 737) and its regulation

- **THE OBJECTIVE**: to ensure medical devices enter Malaysia market are safe, effective and perform as intended by the manufacturer

- Pre market clearance/approval is required before importation, exportation and placement of medical device in the market – **REGISTRATION OF MEDICAL DEVICE** *(Section 5 of Act 737)*

Introduction

What is an IVD?

IVD medical device:

A device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

Scope of the Regulation Section 2 of Act 737

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

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:
   (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
   (ii) compensation for an injury;
   (iii) investigation, replacement, modification, or support of the anatomy or of a physiological process;
   (iv) supporting or sustaining life;
   (v) control of conception;
   (vi) disinfection of medical devices;
   (vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;

   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

b) any instrument, apparatus, implement, machine, appliance, implant, *in-vitro* reagent or calibrator, software, material or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, public health or public risk, declare to be a medical device by order published in the *Gazette*

Requirements of IVD Medical Device Registration Application

- The requirements are stipulated in
  - **Medical Device Act 2012 (Act 737)** –
    - Section 6: Application for registration of medical device
  - **Medical Device Regulation 2012** –
    - Regulation 5: Application for registration

Procedures for Application of IVD Medical Device

- An application shall be made to the Authority in the FORMs to be determined by the Authority [Reg. 5(1)].
- An application shall be accompanied with the following:
  a) Application fee as specified in the Fifth Schedule;
  b) Document or information as specified in the **FORMs**;
  c) Other additional information, particulars, document on application or sample of the medical device [Reg. 5(2)];
- **(c)** shall be submitted within **90 days** from the date of request by the Authority [Reg. 5(3)]

Reference Documents

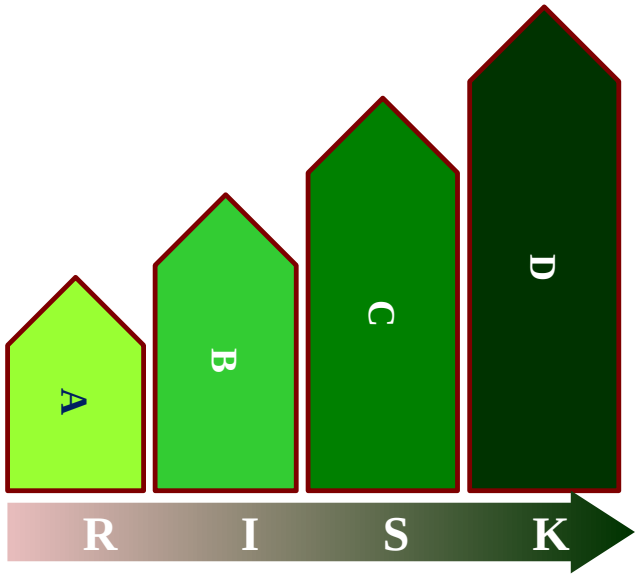
- Guidelines:

i. How to Apply for In-Vitro Diagnostic (IVD) Medical Device Registration under Medical Device Act 2012 (Act 737)

- Guidance documents:

i. IVD Medical Device Classification System;
ii. Grouping of medical device;
iii. Essential Principles of Safety & Performance (EPSP) for IVD Medical Device;
iv. Common Submission Dossier Template (CSDT) of IVD Medical Device;
v. ConformityAssessment for IVD Medical Devices;

Documentation for IVD Medical Device Registration



Comprehensiveness of the information required

Class	Document to be submitted
Class A,	Only DoC
Class A(S)	Report/cert on the validation of sterilization process and DoC
Class A(M)	Report/cert on the validation of measuring function and DoC
Class B	CSDT and its supporting documents and DoC
Class C	*CSDT and its supporting documents and DoC
Class D	

Application Form for IVD Medical Device Registration

- Via MeDC@St system
- Web-based online application form
- Applicant must create a MeDC@St account (www.mdb.gov.my).
- After the account is created, applicant can log in to the system and complete the application form.
- The form is divided into 8 parts (as shown in the diagram)
- Information & supporting documents must be provided as required in the form.
- Supporting document should be in PDF format and the size should not exceed 10MB

General Information

- The information required in this part;
  - Role of establishment
  - Type of medical device (IVD medical device);
  - Whether the medical device is for export only or not;
  - IVD medical device name;
  - Description of device;
  - Intended use;
  - Class and rules of medical device;
  - IVD medical device category;
  - HS Code and GMDN code;
- The information must be keyed-in, chose and checked the field provided in the Form

FIRST SCHEDULE (PART II)
MEDICAL DEVICE CLASSIFICATION

Classification rules

3. (1) A manufacturer shall be responsible to classify its medical device

(2) All medical devices shall be classified into four classes, namely, Class A, Class B, Class C and Class D depending on the level of risk it poses to patients, users and other persons.

(3) The manufacturer may use—

the classification rules in APPENDIX 2 of this Schedule to classify *in vitro* diagnostic medical devices.

Risk Classes

Class D IVD - High Individual Risk and High Public Health Risk

E.G. HIV blood donor screening, HIV blood diagnostic, Blood grouping or tissue typing to ensure compatibility where there is an individual high risk, eg ABO, rhesus, Kell, Kidd and Duffy

Class C IVD – High Individual and/or Moderate Public Health Risk

E.G. Blood glucose self-testing, HLA typing, PSA screening, Rubella

Class B IVD – Moderate Individual and/or Low Public Health Risk

E.G. Vitamin B12, pregnancy self-testing, Anti-Nuclear Antibody, Urine test strips

Class A IVD – Low Personal/No Public Health Risk

E.G. Clinical Chemistry Analyser, prepared selective culture media

Why classify?

- Class determines the relevant conformity assessment procedures
- Amount of fees to be paid upon registration.

Grouping of medical device

- Information on grouping of medical device to be registered;
- The grouping should be done in accordance to the Rule of Grouping as stipulated in 2nd Schedule of the Regulation;
  - Single
  - System
  - Family
  - Set
  - IVD Test Kit
  - IVD cluster

Grouping of medical device

- There is a wide range of medical devices from a simple medical device to a highly complex and sophisticated medical device. The various components can be sold as a separate component, individual customized pack or group and can be categorized as SINGLE, FAMILY, SYSTEM, SET, IVD TEST KIT, and IVD CLUSTER. Each of the categories mentioned can be submitted in the medical device registration application.

Grouping of medical device

- **General Principles of Grouping**
- Medical devices can be grouped into one of the following **five categories &** can be submitted in one application for product registration and listing in the **Malaysia Medical Device Register (MMDR):**
-
- ❖ SINGLE
- ❖ FAMILY
- ❖ SYSTEM
- ❖ SET
- ❖ IVD TEST KIT,
- ❖ IVD CLUSTER
-
- Three basic rules must all be fulfilled for the grouping to apply. These are:
- ❑ one generic proprietary name;
- ❑ one manufacturer; and
- ❑ one common intended purpose.
- For the purpose of grouping, the corporate headquarters may be regarded as the manufacturer for its subsidiaries and regional manufacturing sites.

Post-market vigilance history

- Information on the history of post-market vigilance;
  - Recalls status
  - Reportable adverse incidents
  - Banning or restriction of the medical device in other countries
  - Field safety corrective action

CSDT and its supporting documents

- CSDT and its supporting documents are required for registration;
- The elements are as listed in the on-line form;
- Submission of the documents is done by way of uploading the *softcopy of the documents into the system;
- Multiple Uploading is allowed in an element – 1 document can be uploaded in one time

Elements of CSDT

- Executive summary
- Relevant essential principles and rule used to demonstrate conformity
- Description of medical device
- Summary of design verification and validation documents
- Pre-clinical studies
- Software validation studies
- Medical device containing biological material
- Clinical Evidence
- Use of existing bibliography
- Medical device labelling **{Sixth Schedule Requirements For Labelling [Regulation 16]}**
- Risk analysis
- Manufacturer information

Preparation of CSDT

- CSDT is a compilation of objective evidences to show compliance to the relevant EPSP and other requirements specified by the Authority;
- It should be prepared in accordance with requirements stipulated in Appendix 2 of Third Schedule of Medical Device Regulation 2012;
- The documentation is depending on the EPSP and CSDT elements that is applicable to the device;
- Should be verified and validated by the CAB – conformity assessment on technical documentation.

Note: *not all principles of EPSP and CSDT elements are applicable to a medical device*

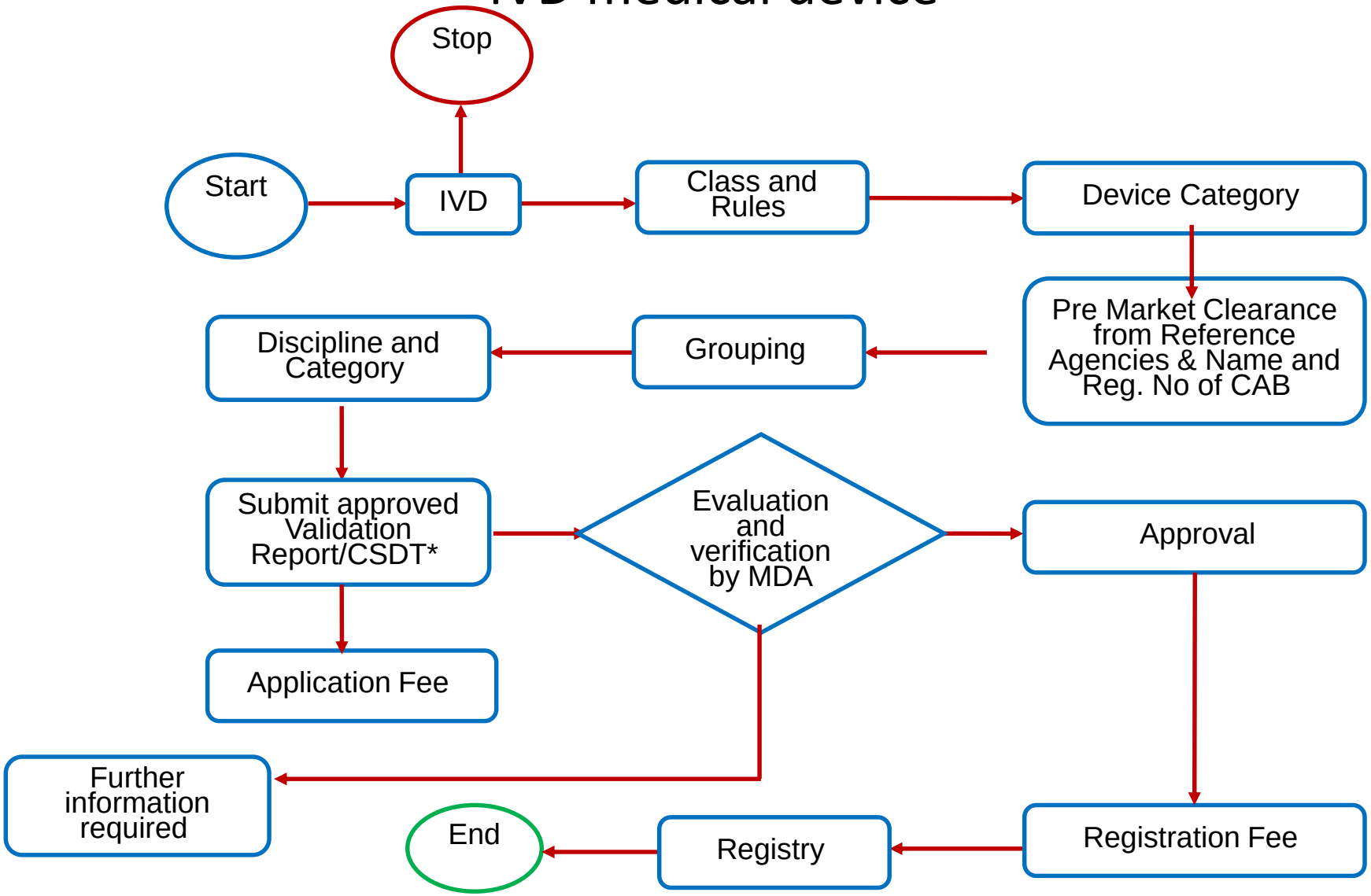
Declaration of Conformity (DoC)

- An attestation of conformity to the EPSP and compliance to the requirements to the Act and its regulation.
- Pre-requisite for medical device registration.
- The preparation of DoC should be in accordance to Appendix 3 of Schedule 3 in Medical Device Regulation 2012.
- The DoC need to be signed and uploaded in the MeDC@St system

Attestation for Medical Device Registration

- Attestation on:
  - The correctness and validity of the information and documents provided
  - the compliance to the regulatory requirement
  - any claims made relating to the quality, safety and performance of medical device
  - The undertaken of responsibility on any legal matters or implications pertaining to medical device registration
  - Should be done by the person who do the application on behalf of the Person Responsible (Top management)

The process flow for application and registration of IVD medical device



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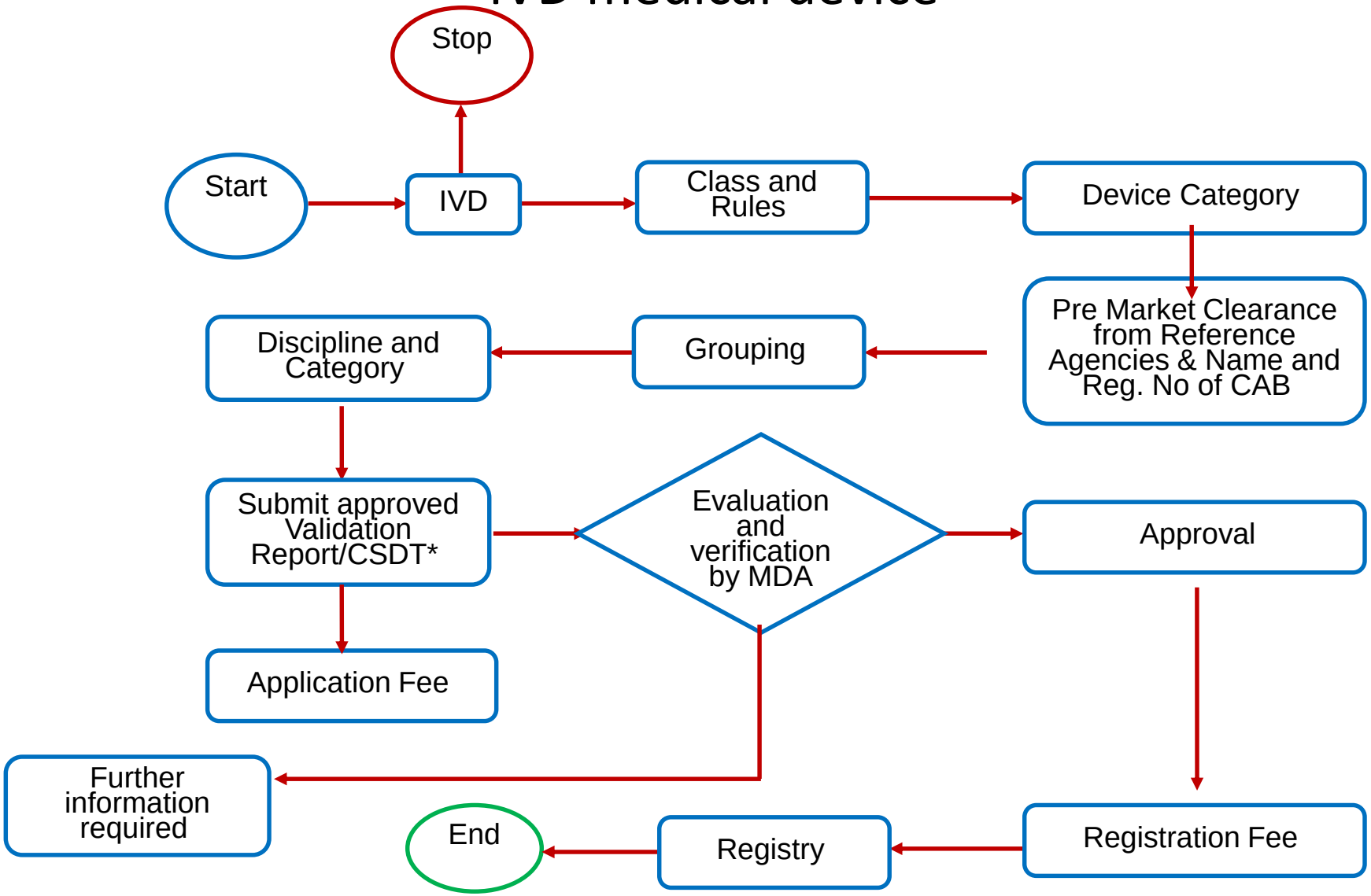

Thank You For Your Attention