MDA/GL/IVD-1

May 2014

First Edition

Guidelines for Implementation of medical device regulatory system

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

[Appendix 4 Schedule 3 Medical Device Regulation 2012]

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Introduction

"**IVD Medical Device**" means 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.

This guideline is produced to assist the manufacturer and/or authorized representative to submit online application via Medical Device Centralized Online Application System (MeDC@St) for IVD medical device. Section 5(1) of Medical Device Act 2012 (Act 737) requires a medical device to be registered under the Act before it can be imported, exported or placed in the market. For that purpose, an application for the registration of a medical device must be made according to the requirement under Act 737 and in the manner determined by the Authority in Medical Device Regulation 2012.

Objective

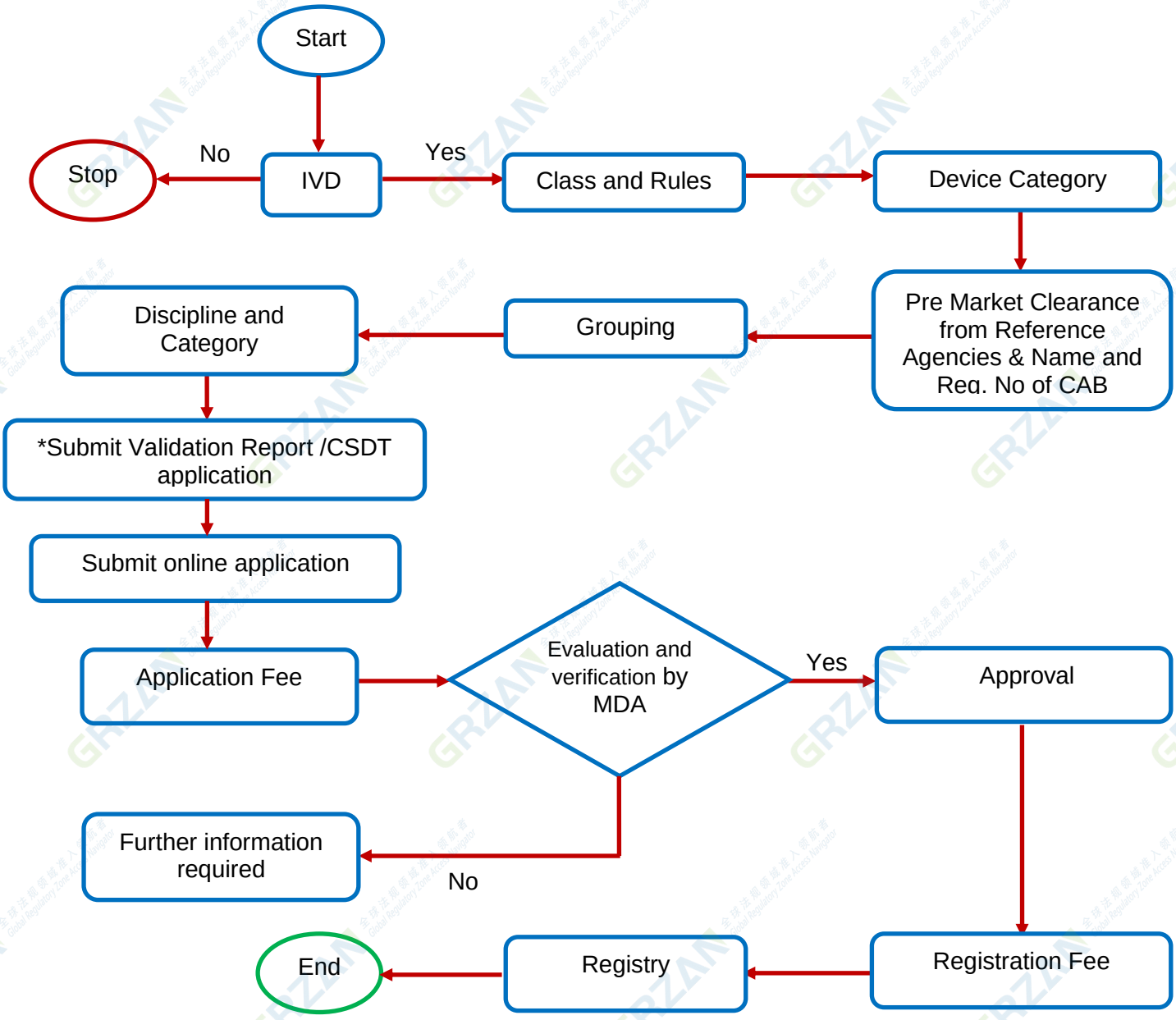
This Guideline is developed to provide information and explanation on how to register IVD medical device via Medc@st.

Scope and application

The scope of this Guideline covers IVD medical devices to be registered under Act 737 and placed in the Malaysian market and is applicable to any persons who are required by the Act to register the medical devices.

What are the steps and criteria for IVD medical device registration?

Figure 1 shows the steps to be taken by an applicant when submitting an application online to register IVD medical device under Act 737.



** Validation report for Class A with measuring function and Sterile / CSDT for Class B, C and D must be certified by registered CAB. For Non Sterile and Non Measuring Function Class A need not to be certified by CAB.*
[6(2) of Third Schedule in Medical Device Regulation 2012]

Figure 1: Steps to be taken when submitting an application for registration of IVD medical device.

Explanation of the steps

Table 1 explains the steps to be taken when submitting an application for registration of IVD medical device

Step	Criteria
(1) Determine whether the product is IVD medical device	Fit the definition of - medical device in Section 2 of Act 737
(2) Appropriately determine the class and rules	According to the rules of medical device grouping as specified in Second Schedule of Medical Device Regulation 2012
(3) Appropriately choose the IVD medical device category	The category consist of Point of Care Testing (POCT), self-testing and laboratory testing
(4) Pre Market Clearance and Name and Registration No. Of CAB	State the appropriate Pre Market Clearance by 5 founding members of GHTF and the relevant CAB Name and Registration No. in Malaysia
(5) Appropriately group the medical device	According to the rules of medical device classification specified in Appendix 2 of First Schedule of Medical Device Regulation 2012
(6) Appropriately choose the right Discipline	The discipline consist of biochemistry, immunology, haematology, histo/cytology, microbiology and genetic testing (molecular biology)
(7) Submit approved Validation Report/CSDT	According to Third Schedule of Medical Device Regulation 2012: (i) the evidence of conformity has been collected to demonstrate compliance to applicable Essential Principles of Safety and Performance of Medical Device as specified in Appendix 1 of Third Schedule of Medical Device Regulation 2012; (ii) the evidence of conformity has been compiled according to the Common Submission Dossier Template (CSDT) as specified in guidance document MDA/GD/IVD-4 (iii) the Declaration of Conformity according to the template in Appendix 1A of Third

	Schedule of Medical Device Regulation 2012 has been duly filled, signed and stamped. Note: Appoint CAB to conduct conformity assessment According to 3rd Schedule of Medical Device Regulation 2012 (i) the evidence of conformity has been verified or validated by the registered CAB; (ii) the CAB has issued certificate of conformity.
(8) Application fee	According to Table of Fees under Fifth Schedule of Medical Device Regulation 2012
(9) Evaluation and verification by MDA	Verify the validation report (Class A), CSDT (Class B,C and D) and Declaration of Conformity (DoC)
(10) Approval	To be approved by MDA
(11) Registration Fee	According to Table of Fees under Fifth Schedule of Medical Device Regulation 2012
(12) Registry	According to Section (67) of Medical Device Act 737

Table 1: Steps to be taken when submitting an application for registration of IVD medical device

Application form for IVD medical device registration

Application form for IVD medical device registration is embedded in the MeDC@St system. It is a web-based online application form which can be accessed via internet. To make an application, an applicant must create a MeDC@St account (refer to www.mdb.gov.my). After the account is created, applicant can log in to the system and complete the application form.

(9) After logging into the system, an applicant must click on In Vitro Device Registration - New Application Form link to retrieve the IVD Medical Device Application Form. The form consists of 8 parts as follows–

(i) General information;

(ii) Information of manufacturer;

(iii) Details of Reference Agency

(iv) Grouping of medical device;

(v) Post-market vigilance history;

(vi) Information on Validation

(vii) Attestation for medical device registration application

(viii) Application submission

(10) Applicant must furnish all the information and upload relevant supporting documents as required in the form.

How to complete the form?

(11) The details on how to complete the application form for IVD medical device registration and information to be furnished are explained in Table 2.

(1) General Information	
(i) Role of Establishment	Please choose either Manufacturer or Authorized Representative
(ii) Type of medical device	IVD medical device
(iii) Is the IVD medical device for export only	Please indicate whether the medical device is for export only or not.
(i) IVD medical device name	Please provide the name of the IVD medical device. The name should address brand and model of the device.
(ii) Description of medical device	Please provide description of the IVD medical device as detailed out in the CSDT.
(iii) Intended use of the medical device	Please provide the intended use of the medical device as detailed out in the CSDT.

(i) Class and rules of medical device	Please select the class of IVD medical device based on the classification rules of medical device as specified in Appendix 2 of First Schedule of Medical Device Regulation 2012. *For Class A, select either non-sterile/non-measuring function, sterile or measuring function
(ii) IVD medical device category	Please select the category of IVD medical device which consist of Point of Care Testing (POCT), self-testing and laboratory testing
(iii) HS code	Please provide the HS Code for the medical device, if applicable. HS Code is Harmonized Tariff Nomenclature & Coding System which was created for international use by the Custom Department to classify commodities when they are being declared at the custom frontiers by exporters and importers. For reference of HS Codes, you may search from Search Tariff function at JKDM HS – Explorer Website at http://tariff.customs.gov.my. For more info, please visit http://www.customs.gov.my.
(iv) GMDN code	Please provide the GMDN Code for the medical device, if applicable. GMDN Code is an international nomenclature system used by other medical device regulatory bodies to consistently describe medical device., Please visit http://www.gmdnagency.com/.
(2) Information of Manufacturer	
All the fields	Please provide the details of the manufacturer. The details include the address, telephone number, fax number and its official website.

(3) Details of Reference Agencies	
(i) Premarket clearance	Please indicate any pre market clearance or approval received from the Authority listed in the form. Please provide copy of certificate of pre market clearance/approval to show evidence of pre market.
(ii) Conformity assessment done by CAB	Please indicate whether conformity assessment of the medical device is done by a registered CAB (if applicable). Please provide the name and registration number of CAB who do the conformity assessment of the medical device.
(4) Grouping of Medical Device	
(i) Medical device grouping	Please select the group of IVD medical device according to the rules of medical device grouping as specified in Second Schedule of Medical Device Regulation 2012. <u>Grouping:</u> IVD cluster - Please refer to <u>Appendix 1</u> Set Family System IVD test kit } Please refer to <u>Appendix 2</u>
(ii) Same manufacturer	Please specify whether or not constituent-components or IVD medical devices that are grouped together are manufactured by the same manufacturer.
(iii) Discipline	Please select the discipline from the list which consist of biochemistry, immunology,haematology, histo/cytology, microbiology and genetic testing (molecular biology)
(iv) Category	Please select the category from the list as stated in Appendix 1 Second Schedule of Medical Device Regulation 2012.

(5) Post-Market vigilance history	
(i) History of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies	Please indicate whether the device has any history of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies.
(ii) Has the application/ registration been rejected/ suspended in other countries	Please indicate if the application of registration or the registration of the device has been rejected or suspended in other countries. If yes, please provide reasons for the rejection/suspension of the device application/ registration.
(6) Information on Validation	
(a) Common Submission Dossier Template (CSDT)	
(i) Please upload CSDT	Please upload the CSDT documents for the IVD medical device at the link provided in the right column. The template for CSDT should be in accordance with guidance document MDA/GD/IVD-4.
(ii) Supporting Documents for CSDT	Please provide supporting documents to support the information written in the CSDT.
(b) Declaration of Conformity (DoC)	
Please upload the complete, signed and certified Declaration of Conformity.	The template for Declaration of Conformity can be downloaded from the link. The DoC need to be printed on the establishment's letterhead, filled and signed by the Person Responsible that is declared in Establishment Licence.
(7) Attestation for medical device registration application	
Please print, sign and stamp the Attestation for Medical Device Registration and upload the document into the system. The attestation letter need to be printed out on the establishment's letterhead and signed and stamped by the contact person declared in the establishment licence.	
(8) Application Submission	
Please preview your application form by selecting the 'Preview Application Form' button before submitting the form.	

Appendix 1

Submission Template for In Vitro Diagnostic Medical Devices (CLUSTER)

LIST OF CONFIGURATIONS OF MEDICAL DEVICE TO BE REGISTERED

Guidelines on completing the table below:

To copy this worksheet, please copy and paste the full worksheet to prevent loss of formatting information.

1. This "list of config (IVD CLUSTER)" worksheet is to be completed for IVD CLUSTER only.

2. The IVD CLUSTER name should be in the format of manufacturer_methodology_CLUSTER Category.

3. For the “Subgroup of CLUSTER” column, indicate the subgroup category of the reageants or articles within an IVD CLUSTER, into either IVD TEST KIT, SYSTEM, FAMILY or SINGLE.-

4. For the “Subgroup Name as per label” column, list the names for each subgroup as per label.

5. For the “Identifier of Subgroup” column, provide the identifier for each of the subgroup. Identifier refers to a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the product owner and that identifies it and distinguishes it from similar devices. Examples of an identifier for a device are a barcode, catalogue, model or part number. Note: If the subgroup is a FAMILY, please indicate as 'not applicable'.

6. For the "Intended purpose of Subgroup" column, provide the intended purpose for each of the subgroup.

7. For the 'Name of Reagent or Article (in the subgroup) as per label" column, list down as per device label, all the reagents or articles within that subgroup. Enter the identifier associated with each reagent or article in the “Identifier” column.

8. For the “Identifier of Reagent or Article” column, provide the identifier for all the reagent and articles. Identifier refers to a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the product owner and that identifies it and distinguishes it from similar devices. Examples of an identifier for a device are a barcode, catalogue, model or part number.

9. For the “Brief Description of Reagent or Article” column, give a brief description of the key distinguishing attributes or specifications of each item, including intended purpose and equation of reaction.

10. For the "Associated Reference/Calibrator/Control" and "Associated Analyzer" column, provide the name of the associated reference, calibrators, controls and analyser. Also to include its identifier.

11. For the manufacturing site information columns, please state the names and addresses of the manufacturing sites for each of the components. If there are more than one manufacturing site for each component, please add in additional rows. For each manufacturing site, please include the ISO certificate number, issuing agency and ISO certificate expiry date.

12. For the device information columns, please state if the component is supplied sterile. If it is, please indicate the method of sterilisation. if it is not a sterile component, please fill in this column as 'Not applicable'. For sterile components, please indicate if the sterilisation validation report has been provided. if it is not sterile, please select the "Not applicable' option. State the proposed shelf life or the projected useful life for each of the components.

13. For the summary of reference agency approvals columns: Please state the reference agency to be used as reference, The date of registration in that reference agency, the approval type, intended use as approved in the reference agency and the first year of global introduction.

No	Components of Cluster							Manufacturing site information (Including sterilisation sites)				Device information				Approval by Local Registered CAB				Summary of Reference agency approval				
	Subgroup type of CLUSTER (Please select one)	Subgroup Name as per label	Identifier of Subgroup (Indicate "not applicable" for FAMILY)	Intended purpose of Subgroup	Name of Reagent or Article (in the subgroup) as per Label	Identifier of Reagent or Article	Brief Description of Reagent or Article	Name and Address of manufacturing site (If there are multiple sites, indicate as site 1, 2, 3….)	ISO certificate number:	ISO certificate Issuing agency	ISO certificate Expiry date	Sterility (Is the device supplied sterile)	If supplied sterile, indicate method of sterilisation	Sterilisation validation report provided?	Proposed shelf life/ projected useful life	Name of CAB	Approval date	Certificate number	Report number	Approval by 5 founding Reference Agencies			Date of registration	Approval type and certificate number	Intended use as approved in reference agency	Year of first introduction, globally
		-																							
		-																							
		-																							
		-																							
		-																							

GRZAN 全球法规领航者入领航者 Global Regulatory Zone Access Navigator

Appendix 2

Submission Template for In Vitro Diagnostic Medical Devices

LIST OF CONFIGURATIONS OF IVD MEDICAL DEVICE TO BE REGISTERED

Guidelines on completing the table below:

1. For the “Name as per Device Label” column:

(a) For a medical device family, list the names of the constituent members in this column. Enter the identifier associated with each constituent member in the “Identifier” column.

(b) For a medical device set, list the names of the constituent medical devices in this column. Enter the identifier associated with each constituent medical device in the “Identifier” column.

(c) For a medical device system, list the names of every constituent component in this column. Enter the identifier associated with each constituent component in the “Identifier” column.

(d) For an IVD test kit, list the names of every constituent reagent and article in this column. Enter the identifier associated with each constituent reagent and article in the “Identifier” column.

Note: For an IVD cluster, please use the "list of config (IVD CLUSTER)" worksheet.

2. For the “Identifier” column, identifier refers to a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices. Examples of an identifier for a device are a barcode, catalogue, model or part number.

3. For the “Brief Description of Item” column, give a brief description of the key distinguishing attributes or specifications of each item. Examples of a brief description of a constituent member of a family include the following:
A system which consists of the same parameters but different throughput of the sample or reagent with different packaging volume.

4. A list of configurations is to be provided with each FAMILY/SET/IVD TEST KIT/SYSTEM medical device application.

Name of Medical Device FAMILY/SET/IVD TEST KIT/SYSTEM:	
Proposed Grouping for Medical Device (FAMILY/SET/IVD TEST KIT/SYSTEM):	

No	Components of IVD Medical Device FAMILY/SET/IVD TEST KIT/SYSTEM					Manufacturing site information (Including sterilisation sites)				Device information				Approval by Local Registered CAB				Summary of Reference agency approval							
	Name as per Device Label	Intended purpose of the device	Name of Reagent or Article as per Label	Identifier of Reagent or Article	Brief Description of Reagent or Article	Name and Address of manufacturing site (If there are multiple sites, indicate as site 1, 2, 3….)	ISO certificate number:	ISO certificate Issuing agency	ISO certificate Expiry date	Sterility (Is the device supplied sterile)	If supplied sterile, indicate method of sterilisation	Sterilisation validation report provided?	Proposed shelf life/ projected useful life	Name of CAB	Approval date	Certificate number	Report number	Approval by 5 founding Reference Agencies				Date of registration	Approval type and certificate number	Intended use as approved in reference agency	Year of first introduction, globally