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Third Edition

Guidelines for implementation of medical device regulatory system

HOW TO APPLY FOR MEDICAL DEVICE REGISTRATION UNDER MEDICAL DEVICE ACT 2012 (ACT 737)

[Regulation 8 Medical Device Regulation 2012]

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Revision History Table

Edition Number	Changed Section(s)	Description	Date of Change
Third	Return of Application	Addition of sentence number 18	March 2019
	Refusal to register a medical device	Addition of sentence number 19	

Introduction

(1) 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.

(2) Starting from 1 July 2013 when Act 737 comes into effect, all medical devices to be placed in Malaysian market are required to be registered under the Act. The application for medical device registration shall be made to the Authority through an online, web-based system called "Medical Device Centralized Online Application System (MeDC@St)".

Objective

(3) This Guideline is developed to provide information and explanation on how to register a medical device under Act 737 using the MeDC@St.

Scope and application

(4) The scope of this Guideline covers all 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 is a medical device?

(5) The term "medical device" covers any product used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap but excludes drugs.

(6) The complete definition of medical device is given in Section 2 of Medical Device Act 2012 (Act 737).

Who is the person responsible for registration of a medical device?

(7) The persons responsible for registering a medical device under Act 737 are—

(i) the manufacturer of medical device as defined in Section 2 of Act 737; and

(ii) in the case of a medical device manufactured in foreign country, the authorized representative of the foreign manufacturer, as defined in Section 2 of Act 737.

What are the steps and criteria for medical device registration?

(8) Figure 1 shows the steps to be taken by an applicant before making an application to register a medical device under Act 737.

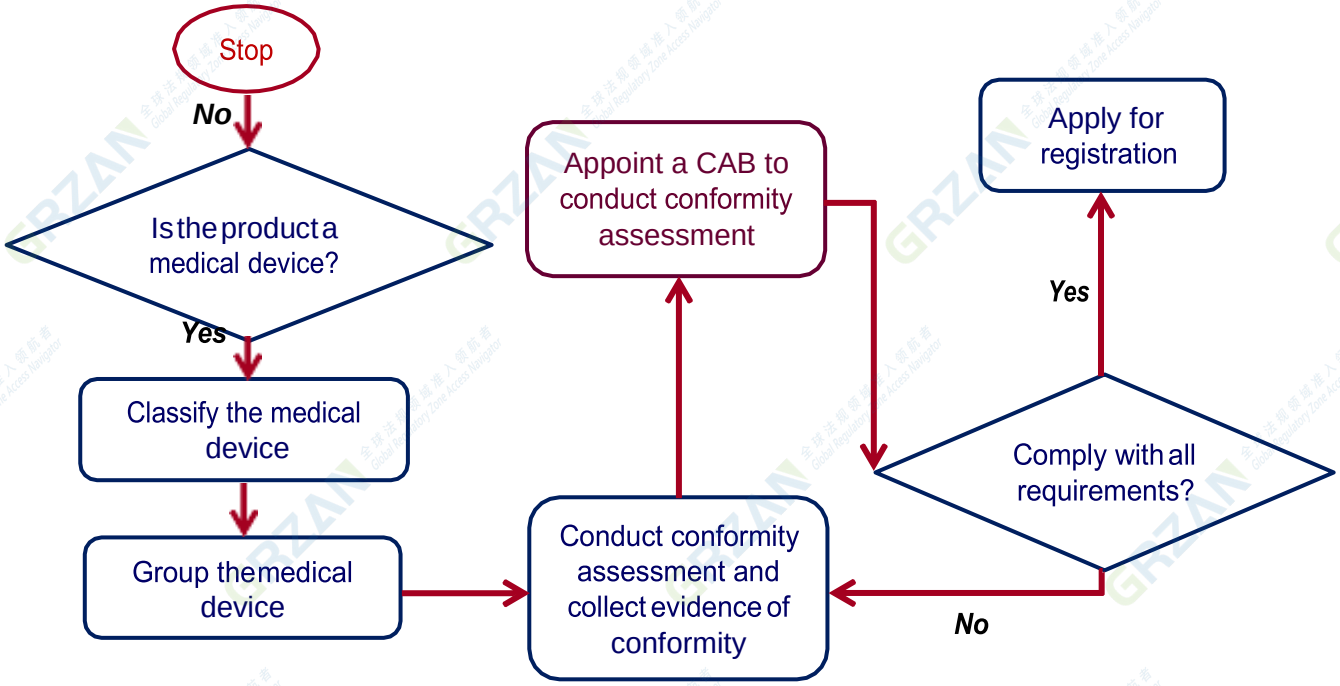


Figure 1: Steps to be taken before making an application for registration of a medical device

Explanation of the steps

Table 1 explains the steps to be taken before making an application for registration of a medical device.

Step	Criteria
(1) Determine whether the product is a medical device	The determination of the product will be based on the definition of "medical device" in as specified in Section 2 of Act 737 and further elaborated in the Guidance Document on Definition of Medical Device (MDA/GD-01).
(2) Appropriately classify the medical device	The classification of medical device should be done according to the rules of medical device classification as specified in First Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on The rules of Classification for general medical devices (MDA/GD-04).
(3) Appropriately group the medical device	The grouping of medical device should be done according to the rules of medical device grouping as specified in Second Schedule of Medical Device Regulation 2012 and

Step	Criteria
	further elaborated in the Guidance Document on Grouping of Medical Device.
(4) Conduct conformity assessment and collect evidence of conformity	According to Third Schedule of Medical Device Regulation 2012: (i) the evidence of conformity has to be 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 and further elaborated in the Guidance Document on Essential Principles of Safety and Performance of Medical Device (MDA/GD-02); (ii) the evidence of conformity has to be compiled according to the Common Submission Dossier Template (CSDT) as specified in Appendix 2 of Third Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on Common Submission Dossier Template (MDA/GD- 03); (iii) the Declaration of Conformity according to the template in Appendix 1A of Third Schedule of Medical Device Regulation 2012 has to be duly prepared, signed and stamped.
(5) Appoint CAB to conduct conformity assessment	According to 3rd Schedule of Medical Device Regulation 2012 (i) the evidence of conformity has to be verified or validated by the registered CAB; (ii) the CAB has to issue certificate of conformity and the report upon completion of the conformity assessment.
(6) Apply to register medical device using MeDC@St	(i) Application for registration of medical device may be made after the criteria are met and the information and supporting documents to support the criteria are available; (ii) Application for medical device registration shall be made via MeDC@St; (iii) Applicant must create an account before making application via MeDC@St.

Table 1: Steps to be taken before making an application for registration of a medical device.

Application form for medical device registration

Application form for 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. After the account is created, applicant can log in to the system and complete the application form.

(9) After logging in to the system, an applicant must click to —New Application Form‖ link to retrieve the Application Form for Medical Device Registration. The form consists of 8 parts as follows—

(i) General information;

(ii) Information of manufacturer;

(iii) Grouping of medical device;

(iv) Common Submission Dossier Template (CSDT);

(v) Supporting documents for CSDT;

(vi) Post-market vigilance history;

(vii) Declaration of Conformity

(viii) Attestation for medical device registration application;

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

How to complete the form

(11) Before filling in all information in the form, the applicant need to indicate the role of establishment for the medical device applied for registration.

(12) The applicant need to provide all information required in the form especially the field marked with (*). The details on how to complete the application form for medical device registration and information to be furnished are explained in Table 2.

(1) **General Information**	
(i) Is the medical device for export only*	Please indicate whether the medical device is for export only or not.
(ii) Is the medical device contains any active ingredient, poison or drug?*	Please indicate whether the medical device contains any active ingredient, poison or drug or not.
(iii) Type of medical device*	Please indicate type of your device, whether it is a general medical device or in-vitro medical device
(iv) Class of medical device*	Please select the class of medical device based on the classification rules of medical device as specified in Second Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on The rules of Classification for general medical devices (MDA/GD-04).

	For Class A medical device, please indicate whether the device is non-sterile/non measuring function or sterile or with measuring function.
(v) Classification rules*	Please select the classification rule that applies to the medical device based on the classification rules of medical device as specified in Second Schedule of Medical Device Regulation 2012 to justify the class chose above.
(vi) Medical device category*	Please select the medical device category that is applicable to the device. The medical device category is listed in Table 3 in Annex 1.
(vii) Medical device name*	Please provide the name of the medical device. The name should reflect the proprietary name registered and trademarked by the manufacturer. It may also address the brand and model of the device.
(viii)Description of medical device*	Please provide description of the medical device as detailed out in the CSDT (refer to the Guidance Document on Common Submission Dossier Template (MDA/GD-03).
(ix) Information on the product formulation* (applicable for medical device contains the active ingredient/poison/drug)	Please provide the information on the active ingredient/poison/drug contained in the medical device. You may list all in a template provided in the link for batch uploading.
(x) Intended use of the medical device*	Please provide the intended use of the medical device as detailed out in the CSDT (refer to the Guidance Document on Common Submission Dossier Template (MDA/GD-03).
(xi) 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.
(xii) 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. For more info, please visit http://www.gmdnagency.com/.
(xiii)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.
(xiv) 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.
(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) **Grouping of Medical Device**	
(i) Medical device grouping	Please select the grouping that is applicable to your device. The grouping should be done in accordance with the Rules of Grouping as specified in the Second Schedule of the Medical Device Regulation 2012 and further elaborated in the Guidance Document on Grouping of Medical Device.
(ii) Same manufacturer*	Please specify whether or not constituent-components or medical devices that are grouped together are manufactured by the same manufacturer.
(iii) List of Constituent-components/ medical devices*	Please list the constituent-components or medical devices that are grouped together in fields provided. You may list all in a template provided in the link for batch uploading.
(4) **Information on Validation (applicable for Class A Sterile or With Measuring Function)**	
Please upload your validation report	Please upload the validation report on the sterility or measuring function.
(5) **Common Submission Dossier Template (CSDT)**	
(i) Please upload CSDT	Please upload the CSDT documents for the medical device at the link provided in the right column. The template for CSDT should be in accordance with Appendix 2 of Third Schedule of the Medical Device Regulation (You may refer to the Guidance Document on Common Submission Dossier Template (MDA/GD-03) for further information.
(ii) Supporting Documents for Common Submission Dossier Template	Please provide supporting documents to support the information written in the CSDT.
(iii) For CSDT element 2 and 3	Please check at the relevant box or boxes to indicate the sub-elements that are addressed in the supporting

	document uploaded.
(6) **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.
(7) **Declaration of Conformity**	
(i) Please upload the complete, signed and certified DeclarationofConformity.	The template for Declaration of Conformity can be downloaded from the link. The DoC need to be printed on the manufacturer's letterhead, filled and signed by the manufacturer.
(ii) Attestation for medical device registration	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. The template can be downloaded by clicking the "download" button.

Table 2: How to complete application form for medical device registration

Return of Application

(13) An application may be returned to the applicant due to;

i- Insufficient or unsatisfactory information is provided;

ii- Supporting document is not attached;

iii- Wrong supporting document is attached and etc.

(14) Notification on the returned application will be given to the applicant via email.

(15) The details of the remarks on the returned application will appear on the applicant "Dashboard" in the MeDC@St.

(16) The applicant must login to the MeDC@St account to take necessary action on the returned application.

(17) Any additional information requested by the Authority need to be furnished and submitted to the Authority via MeDC@St within 90 days from the request date.

(18) If any additional information requested by the Authority is not given by the applicant within 90 days or any other extension period granted by the Authority, the application is deemed

to be withdrawn, and will be dropped from MeDC@St. However, this shall not affect the rights of the applicant to make a fresh application.

Refusal to register a medical device

(19) The application may be refused if the Authority is dissatisfied with the additional information, particulars or document given by the applicant which include :

i- Does not meet registration requirement

ii- The product is not a medical device

The product does not fit into the definition of medical device according to Section 2 of Act 737.

iii- Wrong classification of medical device

The device is classified not in accordance with the rules of classification as specified in the First Schedule of Medical Device Regulations 2012.

ANNEX 1 : Medical Device Category

Medical Device Category is listed in Table 3 below;

(1) MEDICAL DEVICES, NON-ACTIVE

MD 0100: GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES

MD 0101	*Non-active devices for anaesthesia, emergency and intensive care*
MD 0102	*Non-active devices for injection, infusion, transfusion and dialysis*
MD 0103	*Non-active orthopaedic and rehabilitation devices*
MD 0104	*Non-active medical devices with measuring function*
MD 0105	*Non-active ophthalmologic devices*
MD 0106	*Non-active instruments*
MD 0107	*Contraceptive medical devices*
MD 0108	*Non-active medical devices for disinfecting, cleaning, rinsing*
MD 0109	*Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)*

MD 0200: NON-ACTIVE IMPLANTS

MD 0201	*Non-active cardiovascular implants*
MD 0202	*Non-active orthopaedic implants*
MD 0203	*Non-active functional implants*
MD 0204	*Non-active soft tissue implants*

MD 0300: DEVICES FOR WOUND CARE

MD 0301	*Bandages and wound dressings*
MD 0302	*Suture material and clamps*
MD 0303	*Other medical devices for wound care*

MD 0400: NON-ACTIVE DENTAL DEVICES AND ACCESSORIES

MD 0401	*Non-active dental equipment and instruments*
MD 0402	*Dental materials*
MD 0403	*Dental implants*

(2) MEDICAL DEVICES, ACTIVE

MD 1100: GENERAL ACTIVE MEDICAL DEVICES

MD 1101	*Devices for extra-corporal circulation, infusion and haemopheresis*
MD 1102	*Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia*
MD 1103	*Devices for stimulation or inhibition*
MD 1104	*Active surgical devices*

	MD 1105	*Active ophthalmologic devices*
	MD 1106	*Active dental devices*
	MD 1107	*Active devices for disinfection and sterilisation*
	MD 1108	*Active rehabilitation devices and active prostheses*
	MD 1109	*Active devices for patient positioning and transport*
	MD 1110	*Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)*
	MD 1111	*Software*
MD 1200:	***DEVICES FOR IMAGING***	
	MD 1201	*Imaging devices utilising ionizing radiation*
	MD 1202	*Imaging devices utilising non-ionizing radiation*
MD 1300:	***MONITORING DEVICES***	
	MD 1301	*Monitoring devices of non-vital physiological parameters*
	MD 1302	*Monitoring devices of vital physiological parameters*
MD 1400:	***DEVICES FOR RADIATION THERAPY AND THERMO THERAPY***	
	MD 1401	*Devices utilising ionizing radiation*
	MD 1402	*Devices utilising non-ionizing radiation*
	MD 1403	*Devices for hyperthermia / hypothermia*
	MD 1404	*Devices for (extracorporal) shock-wave therapy (lithotripsy)*

(3) ACTIVE IMPLANTABLE MEDICAL DEVICES

AIMD 0100:	***GENERAL ACTIVE IMPLANTABLE MEDICAL DEVICES***	
	AIMD 0101	*Active implantable medical devices for stimulation / inhibition*
	AIMD 0102	*Active implantable medical devices delivering drugs or other substances*
	AIMD 0103	*Active implantable medical devices substituting or replacing organ functions*

MEDICAL DEVICE AUTHORITY

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