Guidelines for implementation of medical device regulatory system

HOW TO APPLY FOR 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

(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.

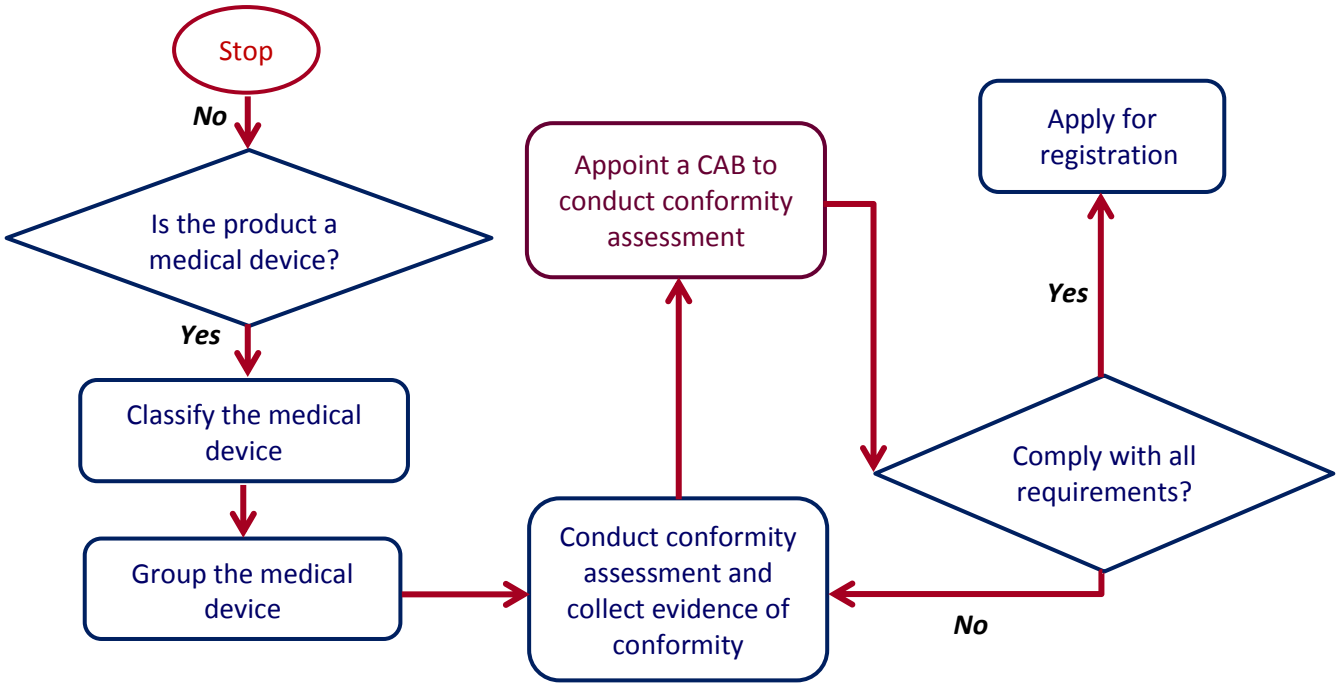

Figure 1: Steps to be taken before making an application for registration of a medical device

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	Fit the definition of "medical device" in Section 2 of Act 737
(2) Appropriately classify the medical device	According to the rules of medical device classification as specified in First Schedule of Medical Device Regulation 2012
(3) Appropriately group the medical device	According to the rules of medical device grouping as specified in Second Schedule of Medical Device Regulation 2012
(4) Conduct conformity assessment and collect	According to Third Schedule of Medical Device Regulation 2012:

Step	Criteria
evidence of conformity	(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 Appendix 2 of Third Schedule of Medical Device Regulation 2012; (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.
(5) 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.
(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 open 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 Medical Device Application Form. 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) 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.
(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 address brand and model of the device.
(viii) Description of medical device	Please provide description of the medical device as detailed out in the CSDT.
(ix) Intended use of the medical device	Please provide the intended use of the medical device as detailed out in the CSDT.

(x) 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.
(xi) 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/.
(xii) 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.
(xiii) 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.
(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.
(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 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.
(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

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

(4) IN VITRO DIAGNOSTIC (IVD) MEDICAL DEVICES

IVD 0100: LIST A REAGENTS AND REAGENT PRODUCTS, INCLUDING RELATED CALIBRATORS AND CONTROL MATERIALS, FOR DETERMINING THE FOLLOWING BLOOD GROUPS

IVD 0101 ABO system

IVD 0102 Rhesus (C, c, D, E, e)

IVD 0103 Anti-Kell

IVD 0200: LIST A REAGENTS AND REAGENT PRODUCTS, INCLUDING RELATED CALIBRATORS AND CONTROL MATERIALS, FOR THE DETECTION, CONFIRMATION AND QUANTIFICATION IN HUMAN SPECIMENS OF MARKERS OF

IVD 0201 HIV infection (HIV 1 and 2)

IVD 0202 HTLV I and II

IVD 0203 Hepatitis B, C and D

IVD 0300: LIST B REAGENTS, REAGENT PRODUCTS AND DEVICES FOR SELF - DIAGNOSIS, INCLUDING RELATED CALIBRATORS AND CONTROL MATERIALS, FOR DETERMINING, DETECTION, QUANTIFICATION, DIAGNOSING, EVALUATING

IVD 0301 Anti-Duffy and anti-Kidd

IVD 0302 Irregular anti-erythrocytic antibodies

IVD 0303 Congenital infections: rubella, toxoplasmosis

IVD 0304 Hereditary disease: phenylketonuria

IVD 0305 Human infections: cytomegalovirus, chlamydia

IVD 0306 HLA tissue groups: DR, A, B

IVD 0307 Tumoral marker: PSA

	IVD 0308	*Risk of trisomy 21 (incl. software)*
	IVD 0309	*Device for self-diagnosis: device for the measurement of blood sugar*
IVD 0400:	*DEVICES FOR SELF-TESTING*	
	IVD 0401	*Clinical chemistry*
	IVD 0402	*Haematology*
	IVD 0403	*Immunology*
	IVD 0404	*Molecular biology*
	IVD 0405	*Pregnancy and ovulation*
	IVD 0406	*Specimen receptacles*

(5) SPECIFICS OF MEDICAL DEVICES AND ACTIVE MEDICAL DEVICES

MDS 7000:	*MD / AIMD SPECIFICS*	
	MDS 7001	*Medical devices incorporating medicinal substances, according to Directive 2001/83/EC*
	MDS 7002	*Medical devices utilising tissues of animal origin, including Directive 2003/32/EC*
	MDS 7003	*Medical devices incorporating derivate of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC*
	MDS 7004	*Medical devices referencing the Directive 2006/42/EC on machinery*
	MDS 7005	*Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)*

(6) SPECIFICS OF IN VITRO DIAGNOSTIC (IVD) MEDICAL DEVICES

MDS 7200:	*IVD SPECIFICS*	
	MDS 7206	*IVDs in sterile condition*
	MDS 7207	*IVDs utilising micromechanics*
	MDS 7208	*IVDs utilising nanomaterials*
	MDS 7209	*IVDs utilising biological active coating and/or material*
	MDS 7210	*IVDs utilising material of human origin*