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GUIDELINE FOR RE-REGISTRATION OF REGISTERED MEDICAL DEVICE

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents Page

Preamble

This present guideline serves as guidance for the submission of re-registration application of registered medical device.

Irrespective of the requirements of this Guideline Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA reserves the right to amend any part of the guideline whenever it deems fit.

CONTACT INFORMATION

For further information, please contact:

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Email: mda@mda.gov.my
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1 Introduction

1.1 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 Regulations (MDR) 2012.

1.2 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)".

1.3 The medical device will be registered for 5 years with the Authority. Upon expiry of medical device registration certificate, the registration holder shall apply for re-registration of medical device before it can be imported, exported or placed in the market.

2 Objective

To provide information and explanation to the establishment on how to submit re-registration of registered medical device application under Act 737 and MDR 2012.

3 Scope and Application

3.1 The scope of this guideline is to specify re-registration process of registered medical device under Act 737 and MDR 2012.

3.2 This guideline covers all medical device classes and it is applicable to any persons who are required by the Act to register the medical devices.

3.3 This document prescribes requirements for re-registration of registered medical devices for near expiry or expired medical device registration applications.

4 Re-registration Stages of Registered Medical Device

4.1 The re-registration process of medical device shall undergo the following two stages as below:

Stage 1: Application for conformity assessment conducted by Conformity Assessment Body (CAB)

The conformity assessment procedure will be conducted by CAB for Class B, C and D excluding Class A medical device. Prior to re-registration of registered medical device via MeDC@St, registration holder shall apply for conformity assessment as elements stipulated in Third Schedule of MDR 2012 as follows:

i) Conformity assessment of quality management system (QMS);

ii) Conformity assessment of post market surveillance system;

iii) Conformity assessment of technical documentation; and

iv) Conformity assessment of declaration of conformity (DoC).

CAB will also review change notification documents that has been approved by MDA.

Stage 2: Application for re-registration of medical device via MeDC@St.

i) Application for re-registration shall be submitted through the MeDC@St application system.

ii) The re-registration button will appear within 1 year prior to expiry date.

iii) If you have done any change notification, the re-registration button can be found on the completed change notification application. The re-registration button will not appear if the application is incomplete.

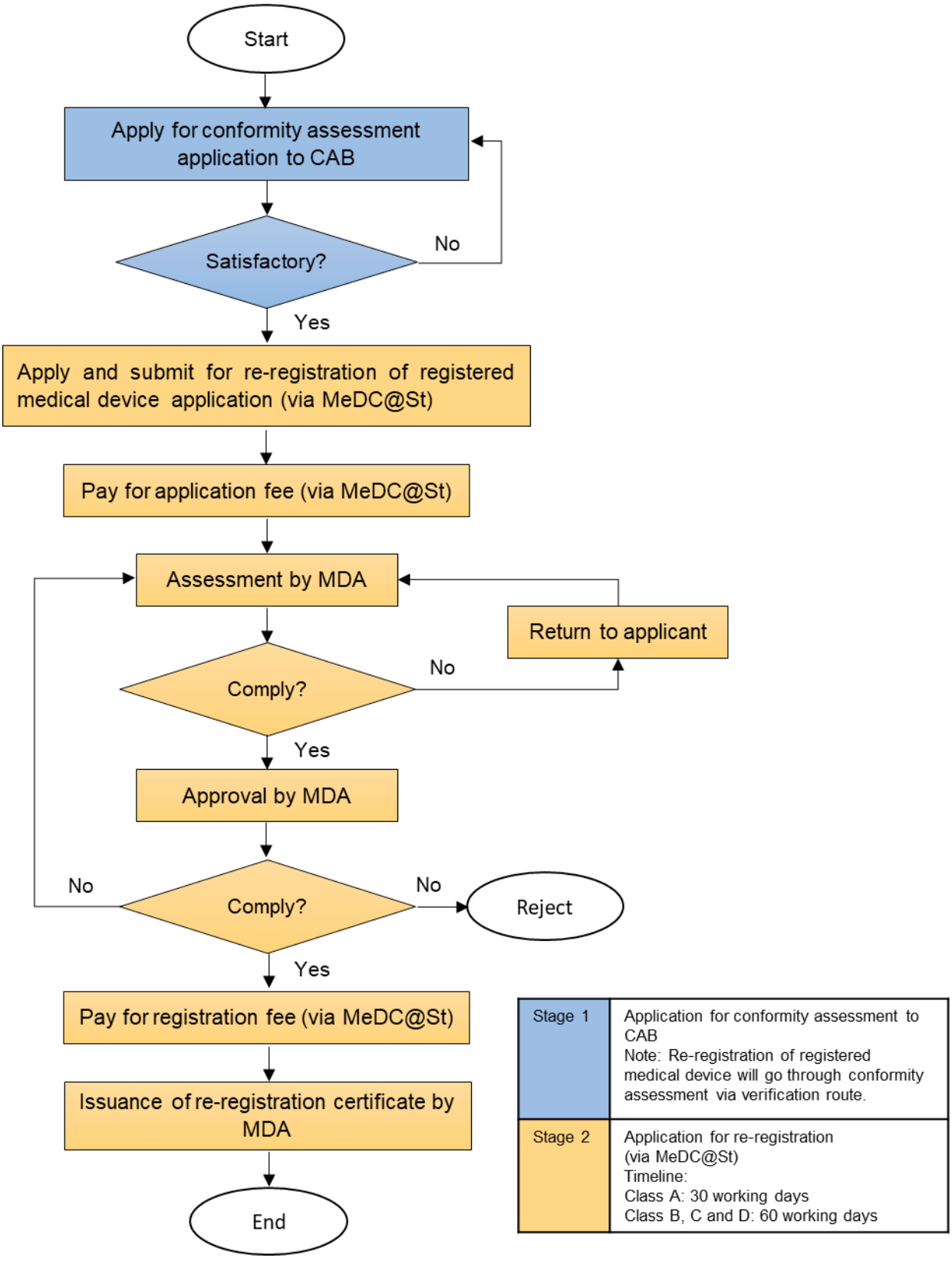
Please notify through MeDC@St Helpdesk if the button does not appear within the 1 year of expiry.

iv) No changes can be made on the application of re-registration unless it has been approved under Change Notification application as per prescribe in the guidance document MDA/GD/0020 Change Notification for Registered Medical Device.

5 Re-registration Requirement and Process Flow

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

Figure 1 Flowchart on Re-Registration Process of Registered Medical Device



Explanation of the steps

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

Table 1 explanation on the re-registration requirement

No	Element	Requirement/ Documents to be submitted
Application requirement		
1.	Determine whether the product is a medical device	The determination of the product will be based on the definition of "medical device" 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 Regulations 2012 and further elaborated in the Guidance Document on The Rules of Classification for General Medical Devices (MDA/GD/0009) or In-Vitro Diagnostic (IVD) Medical Device Classification System (MDA/GD/0001).
STAGE 1: APPLICATION FOR CONFORMITY ASSESSMENT CONDUCTED BY CAB		
3.	Apply for conformity assessment application to CAB For Class B, C and D. Not included Class A.	The registration holder shall apply for conformity assessment from a registered CAB. According to 3rd Schedule of Medical Device Regulations 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.
STAGE 2: APPLICATION FOR RE-REGISTRATION OF MEDICAL DEVICE (VIA MeDC@St)		
(i) Application for re-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.		
4.	Intended use of medical device	i) The intended use/ indication for use shall be the same as what has been approved by the recognized country. ii) The intended use/ indication for use of medical device shall be remained with no change with existing registered medical device.
5.	Medical device grouping	i) The grouping of medical device shall be done according to the rules of medical device grouping as specified in Second Schedule of Medical Device Regulations 2012 and further elaborated in the Guidance Document on Product Grouping of Medical Device (MDA/GD/0005); ii) The list of configurations shall be same with existing registered medical device; and

No	Element	Requirement/ Documents to be submitted
		iii) The medical device list in grouping shall be in accordance with Medical device registration certificate and change notification approval letter issued by MDA (if applicable).
Information on Validation (applicable for Class A Sterile or with Measuring Function)		
6.	Please upload your validation report	Please upload the validation report on the sterility or measuring function. To provide biocompatibility testing report (if applicable).
Conformity assessment of technical documentation		
7.	CSDT	The updated CSDT shall be in accordance with Appendix 2 of Medical Device Regulations 2012 or Guidance Document on Common Submission Dossier Template (CSDT) (MDA/GD/0008) or Guidance Document Common Submission Dossier Template (CSDT) of In- Vitro Diagnostic (IVD) Medical Device (MDA/GD/004).
8.	Supporting Documents for Common Submission Dossier Template	Please provide supporting documents to support the information written in the CSDT.
9.	Labelling	The labelling of medical device shall be in accordance with labelling requirement as specified in First Schedule of Medical Device Regulations 2012 and further elaborated in the Guidance Document on Requirements for Labelling of Medical Devices (MDA/GD/0026).
10.	Combination Product (Device-drug) (Class D Rule 13)	Endorsement letter issued by National Pharmaceutical Regulatory Agency (NPRA) for combination product in accordance with Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products Third Edition.
11.	Declaration on change of notification	Change notification letter issued by MDA (if applicable) shall be submitted. If no changes, please provide letter there is no change notification on the device.
12.	Medical device registration certificate	A copy of medical device registration certificate shall be submitted.
Conformity assessment of quality management system (QMS)		
13.	Manufacturer information	i) Authenticity of the manufacturer's QMS certificate, e.g. ISO 13485 or other equivalent QMS certificate issued by foreign recognized notified body or regulatory authority granting the certificate; ii) Scope of QMS of the manufacturer of medical device as required by Third Schedule of MDR 2012; and iii) All certificates submitted shall be within validity period.

No	Element	Requirement/ Documents to be submitted
Conformity assessment		
14.	Conformity assessment	The new conformity assessment certificate and report issued by registered CAB shall be submitted.
Post market surveillance system		
15.	Post-market surveillance and vigilance	i) List of reported ongoing incidents globally (if applicable); ii) List of incidents that have been resolved for the past 3 years (if applicable); and iii) Date of last audit
Declaration of Conformity (DoC)		
16.	Declaration of Conformity (DoC)	The updated DoC shall be submitted. The template shall be in accordance with Appendix 1A of Medical Device Regulations 2012.

6 Payment Information

The payment shall be made through online payment (via MeDC@St system) or bank draft. For the bank draft, it shall be payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN" and should be submitted to:

Chief Executive
Medical Device Authority (MDA)
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Blok 3547, Persiaran APEC 63000 Cyberjaya,
Selangor.
(Attn: Management and Service Unit)

Note: Information on reference number and phone number of the applicant must be written at the back of the bank draft, not in the table section. The payment of different application shall be made separately.

All payment in MeDC@St system must be made within **60 days from the date of invoice generated enforced on 1st February 2022**. Failing to do so, the current application will automatically be dropped from the system and a new application has to be made.

7 Fee Information

Application Fee for Medical Device Registration and Registration Fee for Medical Device Registration are referred in Table 2 and Table 3 respectively.

Table 2 Application Fee for Medical Device Re-Registration

Medical Device	Fee Payable (RM)
A Class A medical device	100
A Class B medical device	250
A Class C medical device	500
A Class D medical device	750

Table 3 Registration Fee for Medical Device Re-Registration

Medical Device	Fee Payable (RM)
A Class A medical device	-
A Class B medical device	1,000
A Class C medical device	2,000
A Class D medical device	3,000
A medical device that contains a medicinal product	5,000

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