MDA/GL/08

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Third Edition

# GUIDELINE FOR RE-REGISTRATION OF REGISTERED MEDICAL DEVICE

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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## 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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## 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 requirements 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 validity of a medical device registration is 5 years. Upon the expiry of the registration, the registration holder shall apply for re-registration of the medical device before it can be continue to import, export 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.

Note: Registered medical device includes those that has been registered previously.

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

**3.3** This document prescribes the requirements for the application to re-register a medical device.

## 4 Re-registration Stages of Registered Medical Device

The re-registration process of medical device shall undergo two stages:

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

a. The conformity assessment procedure shall be conducted by CAB for Class B, C and D medical devices. Prior to re-registration 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).

b. CAB shall also review all change notification that have 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 online application system (MeDC@St).

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

iii) If you have done any change to the registered medical device, the re-registration button can be found on the completed change notification Submission ID. 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.

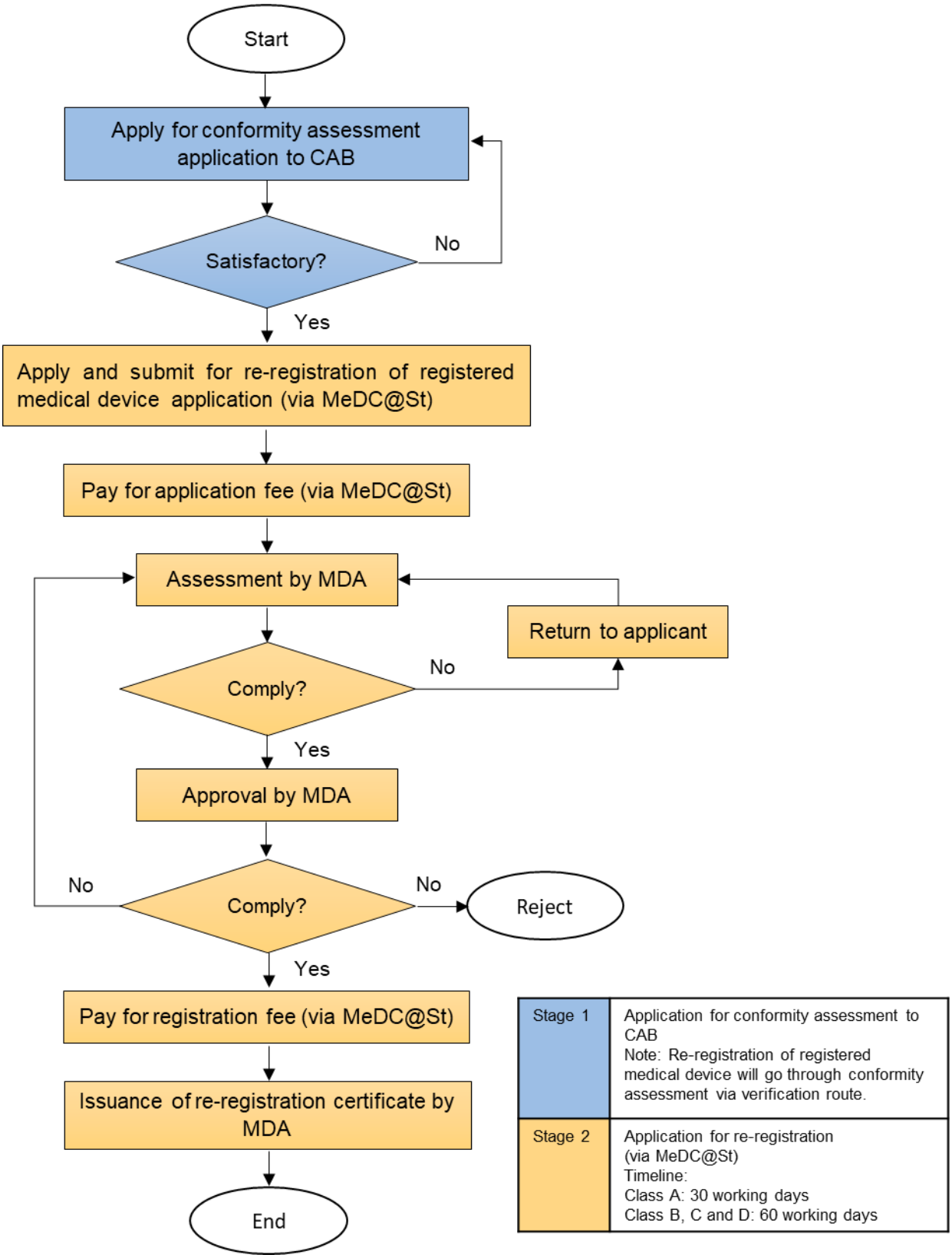
iv) Applicant is not allowed to submit re-registration application concurrently with change notification application.

v) 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

5.1 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**



5.2 Table 1 below 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** | | |
| **5.2.1** | 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). |
| **5.2.2** | 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** | | |
| **5.2.3** | Apply for conformity assessment application to CAB<br><br>For Class B, C and D.<br>Not included Class A. | The registration holder shall apply for conformity assessment from a registered CAB.<br><br>According to 3rd Schedule of Medical Device Regulations 2012:<br>a. the evidence of conformity has to be verified or validated by the registered CAB;<br>b. 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)** | | |
| • 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.<br>• Application for medical device registration shall be made via MeDC@St. | | |
| **5.2.4** | Intended use of medical device | a. The intended use/ indication for use shall be the same as what has been approved by the recognized country.<br><br>b. The intended use/ indication for use of medical device shall be remained with no change with existing registered medical device. |
| **5.2.5** | Medical device grouping | a. 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);<br><br>b. The list of configurations shall be same with existing registered medical device; and |

| No | Element | Requirement/ Documents to be submitted |
|---|---|---|
| | | c. 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)** | | |
| **5.2.6** | Please upload your validation report | Please upload the validation report on the sterility or measuring function.<br><br>To provide biocompatibility testing report (if applicable). |
| **Conformity assessment of technical documentation** | | |
| **5.2.7** | 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). |
| **5.2.8** | Supporting Documents for Common Submission Dossier Template | Please provide supporting documents to support the information written in the CSDT. |
| **5.2.9** | Pre-market Clearance/ Approval | All application shall undergo conformity assessment via verification route for registered medical devices:<br><br>a. Valid CE marking or pre-market approval as per circular 2/2014 conformity assessment procedures for medical device approved by recognized countries shall be submitted.<br><br>b. Removal of CE marking shall be notified to MDA via change notification. This letter shall be submitted to CAB in order to do conformity assessment via verification route.<br><br>c. All the registered application that was approved under full conformity assessment also will undergo verification route with CAB for re-registration. |
| **5.2.10** | 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). |
| **5.2.11** | Combination Product (Device-drug)<br>(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. |
| **5.2.12** | 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. |

| No | Element | Requirement/ Documents to be submitted |
|---|---|---|
| **5.2.13** | Medical device registration certificate | A copy of medical device registration certificate shall be submitted. |
| **Conformity assessment of quality management system (QMS)** | | |
| **5.2.14** | Manufacturer information | a. 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;<br><br>b. Scope of QMS of the manufacturer of medical device as required by Third Schedule of MDR 2012; and<br><br>c. All certificates submitted shall be within validity period. |
| **Conformity assessment** | | |
| **5.2.15** | Conformity assessment | The new conformity assessment certificate and report issued by registered CAB shall be submitted. |
| **Post market surveillance system** | | |
| **5.2.16** | Post-market surveillance and vigilance | a. List of reported ongoing incidents globally (if applicable);<br><br>b. List of incidents that have been resolved for the past 3 years (if applicable); and<br><br>c. Date of last audit<br><br>d. General Medical Devices (GMD): Updated Clinical Evaluation Report (CER) which includes the latest Post Market Surveillance and Vigilance report for the past 3 to 5 years.<br><br>e. In Vitro Diagnostic Devices (IVD): Updated Clinical Performance Report (CPR) **AND** Post Market Surveillance and Vigilance report for the past 3 to 5 years.<br><br>If there is no PMSV adverse events thus declaration letter shall be provided. |
| **Declaration of Conformity (DoC)** | | |
| **5.2.17** | 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 online (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 via MeDC@St system must be made within **60 days from the date of invoice,** failing to do so, 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 fee 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 |

# MEDICAL DEVICE AUTHORITY

## MINISTRY OF HEALTH, MALAYSIA

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