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MEDICAL DEVICE GUIDANCE DOCUMENT

FAST TRACK MEDICAL DEVICE REGISTRATION DURING TRANSITION PERIOD

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and its subsidiary legislations.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737);

b) Medical Device Regulations 2012; and

c) Medical Device Regulations 2015.

Irrespective of the requirements of this Guidance 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 has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.
MDA reserves the right to amend any part of the guidance document from time to time.

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FAST TRACK MEDICAL DEVICE REGISTRATION DURING TRANSITION PERIOD

1 Introduction

1.1 Section 5 (1) of Medical Device Act 2012 (Act 737) requires all medical devices to be registered prior to their importation, exportation or placement on the Malaysian market. Section 80(1) requires all medical devices to be registered within twenty four (24) months from the appointed date which is 1 July 2013. Therefore, the transition period to register medical device is until 30 June 2015.

1.2 However, as an effort to facilitate the industry, the Authority through its Circular Letter No. 7 Year 2015 dated 6 April 2015 has decided to implement *'fast track'* medical device registration during transition period. Even though *'fast track'* medical device registration is implemented, establishments are still required to comply with all relevant requirements of the Act.

1.3 Fast track registration is a registration route undertaken by an establishment to register medical device during transition period where the requirement of conformity assessment in third schedule of Medical Device Regulation 2012 by Conformity Assessment Body (CAB) is waived. However, the establishment shall comply with other requirements for medical device registration as stipulated by the Act.

2 Purpose

This document is intended to provide guidance on fast track medical devices registration during transition period and the requirements that need to be complied with for the purpose of placement of the medical device in the market.

3 Scope and application

This document specifies requirements for fast track medical device registration and shall be effective during transition period until 30 June 2015.

It is applicable to all medical device categories described in Circular Letter No. 7 Year 2015 which includes:

a) Medical device in the market that has obtained approval from at least one of five reference countries (United States, Europe, Canada, Japan and Australia); or

b) Medical device that has obtained approval from non-reference countries other than specified in 3 (a); or

c) Class A medical device (sterile, active and has measuring function) which has not been registered in any country as specified in 3(a) and (b).

Class B, C or D medical device which has not been registered in any country is not eligible for fast track registration as prescribed in this document.

Fast track registration does not exempt the establishment to comply with other relevant requirements of Act 737 and its subsidiary legislation.

4 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, its subsidiary legislations and the following terms and definitions apply.

4.1 Authority

The Medical Device Authority established under Medical Device Authority Act 2012 (Act 738).

4.2 place in the market

An activity as defined in Section 2 of Medical Device Act 2012 (Act 737).

4.3 authorized representative

An authorized representative as defined in Section 2 of Act 737.

4.4 manufacturer

A manufacturer as defined in Section 2 of Act 737.

4.5 establishment

An establishment as defined in Section 2 of Act 737.

5 Requirements

5.1 Application for fast track medical device registration is only applicable for the medical device categories as specified in paragraph 3.

5.2 Establishments shall fulfil the following conditions-

a) Conformity assessment under Part II Regulation 4 of Medical Device Regulation 2012 shall be conducted by a CAB and the

establishment shall obtain the certificate of conformity within five (5) years from 1 July 2015.

b) Establishment who has not obtained conformity assessment for medical device shall appoint a CAB within three (3) years from 1 July 2015.

c) The adequacy of the Declaration of Conformity shall be reviewed and confirmed by the CAB within five (5) years in accordance with Item 9 Part III of Third Schedule of Medical Device Regulation 2012.

d) The establishment shall report to the Authority any on-going incident related to medical device during application for registration.

6 Cancellation of registration and suspension/ revocation of certificate

6.1 Registration of medical device will be cancelled / registration certificate shall be suspended and/ or revoked if there is any breach of the conditions in 5.2.

6.2 If conformity assessment is not completed or done and the certificate of conformity is not obtained within the five (5) years period, the registration shall be revoked. New application will have to be made according to Section 5 of Act 737.

7 In the case of incident during application of registration

Registration of medical device will be put on-hold for further review by the Authority if any incident occurs related to the medical device. Registration will only be reviewed after the establishment has undertaken appropriate corrective or preventive actions and has complied with additional requirements set by the Authority.

8 Fast track medical device registration procedure

8.1 The application for fast track medical device registration shall be made to the Authority through the online system, “Medical Device Centralized Online Application System (MeDC@St)”. Figure 1 shows the steps to be taken by applicant for fast track medical device registration.

8.2 Detailed explanation on medical device registration is available in MDA guidelines, MDA/GL/MD-01 and MDA/GL/IVD-1. As stipulated in the guidelines, all relevant documents need to be submitted via MeDC@St except for the following-

a) Details of CAB
b) Conformity assessment certificate
c) Conformity assessment report

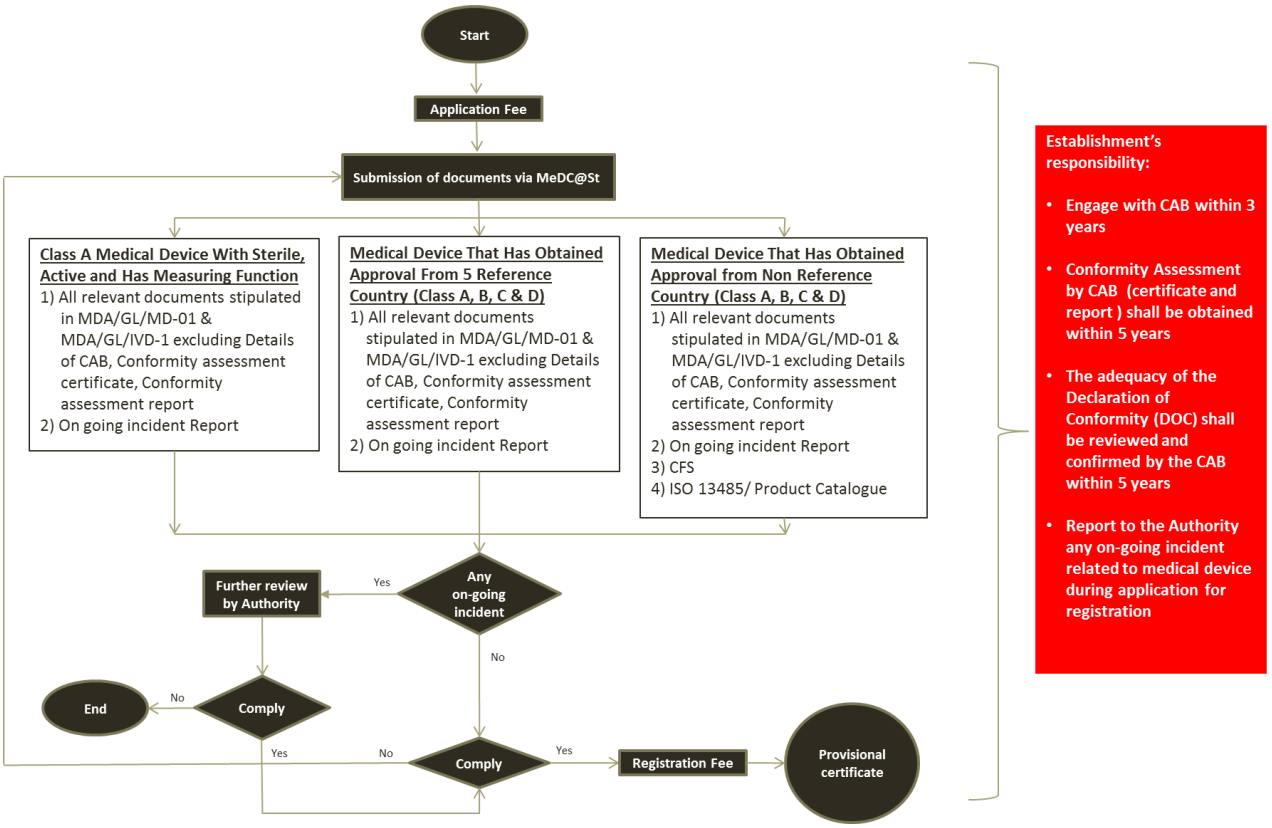

Figure 1: Flow chart for fast track medical device registration

Step	Criteria
(1) Apply to register medical device using MeDC@St system (refer to MDA/GL/MD-01 & MDA/GL/IVD-1)	(i) Application for registration of medical device may be made after the information and documents to support the criteria are available; (ii) Applicant must create an account before making application via MeDC@St; (iii) Application for medical device registration shall be made via MeDC@St.
(2) Submission of documents	(i) Class A medical device (sterile, active and has measuring function) a) All relevant documents stipulated in MDA/GL/MD-01 & MDA/GL/IVD-1 excluding details of CAB, conformity assessment certificate, conformity assessment report b) On-going incident Report
	(ii) Medical device that has obtained approval From 5 Reference Country (Class A, B, C & D) a) All relevant documents stipulated in MDA/GL/MD-01 & MDA/GL/IVD-1 excluding details of CAB, conformity assessment certificate, conformity assessment report b) On-going incident Report

	(iii) Medical device that has obtained approval form non Reference Country (Class A, B, C & D) a) All relevant documents stipulated in MDA/GL/MD-01 & MDA/GL/IVD-1 excluding details of CAB, conformity assessment certificate, conformity assessment report b) On-going incident Report c) CFS d) ISO 13485/ Product Catalogue
(3) Any on-going incident	The application will be put on hold for further review by Authority and will only be reviewed after the establishment has undertaken appropriate corrective or preventive actions and has complied with additional requirements set by the Authority
(4) Provisional Certificate	The provisional certificate is valid for 5 years effective from 1 July 2015 if the application is submitted before 30 June 2015

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