MDA/GL No 2: July 2013

Guidelines for implementation of medical device regulatory system

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

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Introduction

(1) Section 15(1) of Medical Device Act 2012 (Act 737) requires an establishment to apply for a licence under the Act before it can import, export or place in the market any registered medical device. For that purpose, an application for an establishment licence shall be made according to the requirements and in the manner determined by the Authority in Act 737 and its subsidiary legislations.

(2) Starting from 1 July 2013 when Act 737 comes into effect, all establishments dealing with medical devices shall apply for establishment licence under the Act. As provided for by Section 80 of Act 737, any person who has been importing, exporting or placing a medical device in the market prior to the effective date of the Act and intends to continue to carry out his activities shall, apply for an establishment licence under this Act within 12 months from the effective date.

Objective

(3) This Guideline is developed to provide information and explanation on how to apply for an establishment licence under Act 737.

Scope and application

(4) The scope of this Guideline covers all establishments dealing with medical devices under Act 737.

What is an establishment?

(5) An establishment can either be a manufacturer, an authorized representative (of a foreign manufacturer), an importer or a distributor of medical device.

(6) The complete definition of term "establishment" is given in Section 2 of Act 737.

What are the steps and your preparations before making an application for establishment licence?

(7) Figure 1 shows flow-chart of the steps to be taken by an applicant before making an application for establishment licence under Section 15 of Act 737.

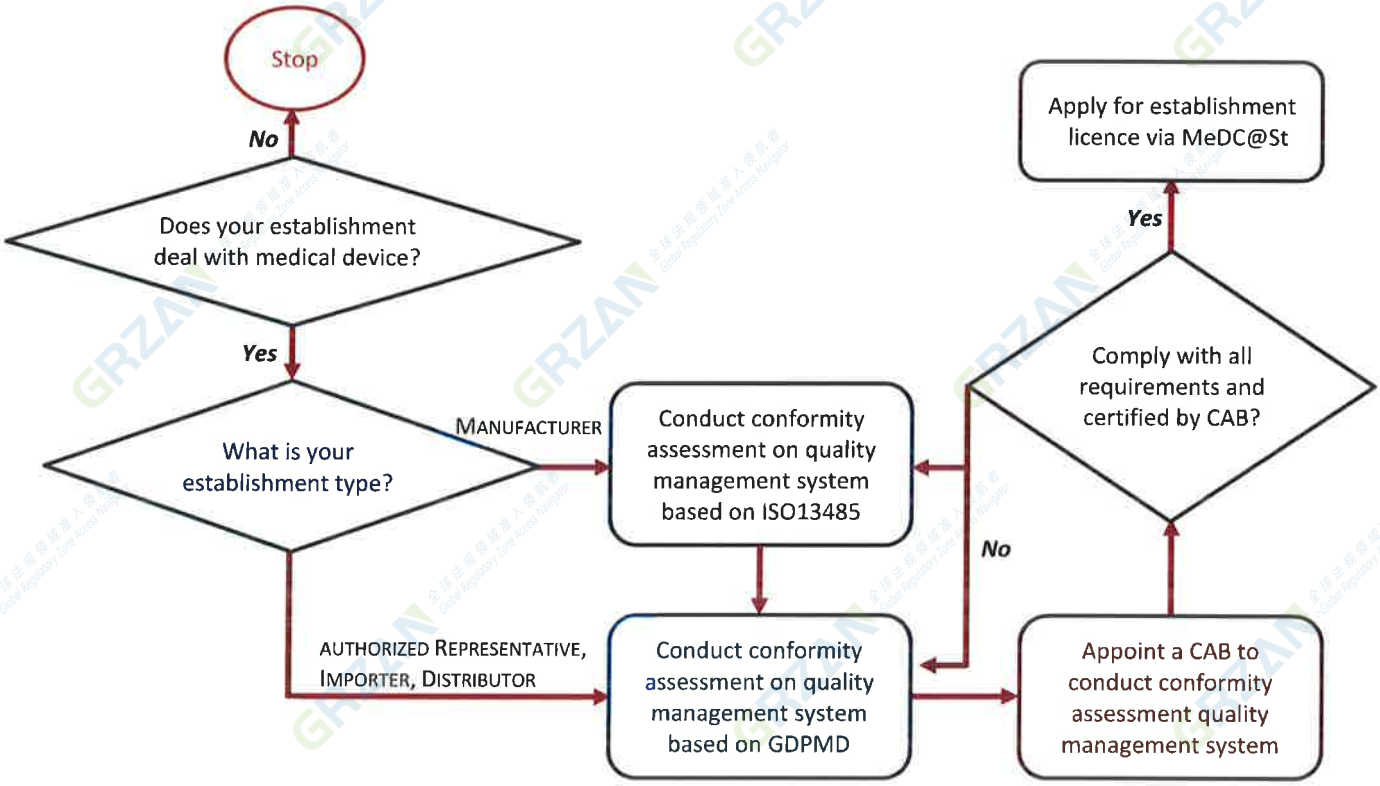


Figure 1: Flow-chart that shows the steps to be taken before making an application for an establishment licence

(8) Table 1 shows necessary preparations before making an application for establishment licence. It also shows certain criteria to be met for each step of the preparation.

Step	Preparation/criteria
(i) Determine whether your establishment is dealing with medical device	The product that you are dealing with must fit the definition of "medical device" in Section 2 of Act 737
(ii) Determine the type of your establishment	According to the definition of "establishment" in Section 2 of Act 737
(iii) Conduct conformity assessment on quality management system (QMS)	Conformity assessment shall be done according to Third Schedule of Medical Device Regulation 2012: (a) A manufacturer shall establish, maintain and implement QMS based on ISO13485 standard (b) An authorized representative, an importer and a distributor shall establish, maintain and implement

Step	Preparation/criteria
	an appropriate QMS based on GDPMD (c) Establishment shall establish, maintain and implement a post-market surveillance (PMS) system
(iv) Appoint CAB to conduct conformity assessment on QMS	Establishment shall appoint CAB registered under Section 10 of Act 737 to conduct conformity assessment according to Third Schedule of Medical Device Regulation 2012
(v) CAB issues report and certificate of conformity	Upon completion of conformity assessment on QMS and satisfactory fulfilment of the requirements, CAB shall issue report and certificate of conformity according to Third Schedule of Medical Device Regulation 2012
(vi) Apply for establishment licence via MeDC@St	(a) Application for establishment licence may be made after the criteria are met and are supported with relevant information and supporting documents (b) Application for establishment licence shall be made via MeDC@St (c) Applicant must open an account before making application via MeDC@St

Table 1: Criteria to be fulfilled before making an application for registration of a medical device

Filling in the establishment licence application form

(9) Application for establishment licence shall only be made via MeDC@St at MDA website www.mdb.gov.my/ and an applicant shall open an account to access MeDC@St.

(10) To create a MeDC@ST account, click on the MeDC@St tab and you will be brought the MeDC@St page. You can find instructions on how to open MeDC@St account at this page. Please follow the instructions to open a MeDC@St account.

(11) After you have created the MeDC@St account, go to MDA website, click MeDC@St and login to MeDC@St using your username and password that you have created and validated by the system.

(12) After logging in to MeDC@St, go to "Establishment Licensing" link and click "Application Form" to retrieve Establishment Licence Application Form. The form consists of 8 parts as follows—

(i) Establishment details;

(ii) Person responsible for establishment;

(iii) Contact person;

(iv) Quality management system (QMS);

(v) Post-market surveillance system;

(vi) Medical device details;

(vii) Attestation for establishment licensing application;

(viii) Application submission.

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

(14) The details on how to complete the application form for medical device registration and information to be furnished are explained in Table 2.

(1) Establishment details	
(i) Type of establishment	Please indicate the type of your establishment— - **Manufacturer** as defined in Section 2 of Act 737. - **Authorized representative** (AR) as defined in Section 2 of Act 737. *[An AR is required to upload the authorization letter from foreign manufacturer of the medical device]* - **Importer** is a person or company appointed by an AR to bring in registered medical device under the latter's control from foreign country. An importer shall only import registered medical device that is authorized by the authorized representative of that medical device. *[An importer is required to upload the authorization letter from the AR that authorizes for the medical device to be imported]* - **Distributor** is a person or company appointed by an authorized representative or a manufacturer to distribute/further in the market any registered medical device under the latter's control. A distributor shall only distribute/further in the market registered medical device that is authorized by the authorized representative/manufacturer of that medical device. *[A distributor is required to upload the authorization letter by the AR/manufacturer for the medical device to be distributed]*
(ii) Business registration number	Please provide business registration number of your company as issued by the Registrar of Company (ROC) *[ROC certificate for your business shall be uploaded]*
(iii) Establishment name	Please provide particulars and contact information of your establishment as required in the appropriate fields.

(2) **Person responsible for establishment** Person responsible is the person appointed by the establishment who shall be responsible for all legal obligations and implications under Act 737 and its subsidiary legislations - including making submission for application for establishment licensing and medical device registration. Responsible person shall have the overall control and have the authority to make decision. Depending on the setup of an establishment, example of person responsible may include chief executive officer, managing director or general manager for an enterprise.	
Person responsible	Person Responsible will be super user and responsible for submission of application. Please provide the particulars of the person responsible as required in the appropriate fields.
Details of person responsible	[Appropriate identification document, such as identity card or passport, Form 49 or letter of appointment of the responsible person shall be uploaded]
(3) **Contact person details** Contact person is the person appointed/authorized by the establishment as a liaison between the Authority and the establishment relating to any regulatory issues under Act 737. The establishment may authorize contact person to make submission for application for establishment licensing and medical device registration.	
Same as person responsible for establishment	Contact Person will be sub user and will be appointed by super user. Contact Person will fill up the application form. However, Contact Person is not allowed to submit the application.
Details of contact person	Please indicate whether contact person is the same person as the responsible person. If the contact person is not the same person as responsible person, please provide the particulars of the person responsible as required in the appropriate fields. [An appropriate appointment/authorization letter for contact person shall be shall be uploaded if contact person is not the same person as the person responsible]
(4) **Quality management system (QMS)**	
(i) Have your QMS been certified? - ISO 13485 - GDPMD	If your QMS have been certified by registered CAB, please indicate the QMS that you have established in the appropriate box, ie ISO 13485 for manufacturer or GDPMD for other establishment types. Please upload a copy of the report and certificate of conformity issued by the CAB and provide the name and registration number of the CAB.

(ii) Please provide report and certificate issued by Conformity Assessment Body (CAB) - Name of CAB - CAB registration number	
(5) Attestation for establishment licensing application	
(i) Step 1: Click the "Download" button to download the attestation for establishment licensing form (ii) Step 2: Fill in, stamp and sign the form (iii) Step 3: Upload the completed form	Attestation for establishment licensing application shall be uploaded following the steps and instructions.
(6) Application submission	
Preview of application form	The application may be submitted after all the applicable fields have been filled and appropriate supporting documents have been uploaded. You may check information and supporting documents that you have uploaded prior to making your submission by clicking at "preview of application form" button. Please be advised that no change can be made on your application form once you have submitted your application.

Table 2: How to complete application form for establishment licence

Further queries

(1) Any queries and further information on establishment licensing shall be directed to—

Licensing, Registration & Enforcement Division, Medical Device Authority, Ministry of Health Malaysia, Level 5, Menara Prisma, Plot 3C4, No 26, Jalan Persiaran Perdana, 62675 Putrajaya, Malaysia. email: mdb@mdb.gov.my/ or telephone: 603- 88922400 and fax: 603-88922500