Requirements and Procedures for Establishment License

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Medical Device Authority

What is an establishment?

Establishment means (section 2, Act 737):

(a) a person who is either a manufacturer, importer, or distributor who is responsible for placing any medical device in the market but does not include a retailer; and

(b) an authorized representative appointed by a manufacturer having a principal place of business outside Malaysia,

and such person and authorized representative being :

(a) a person domiciled or resident in Malaysia; or

(b) a firm or company constituted under the laws of Malaysia,

and carrying on business or practice principally in Malaysia.

Establishment License

- 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.
- Establishment type:-

  Manufacturer, Authorized Representative, Distributor and Importer.

Establishment Type

Manufacturer

- A person/organization who places a medical device on the market under his own name, and thereby, shall hold the full responsibilities and shall make the application to register the medical device.
- If a manufacturer has a principal place of business outside Malaysia, it shall appoint an authorized representative (AR) in Malaysia to act on its behalf relating to all regulatory matters with the Authority.
- The functions of a manufacturer include one or more of the following activities related to medical devices; i.e design; assignment of the intended purpose; production/fabrication; assembly; labeling; sterilization or other processing; packaging; modification or re-labeling or refurbishment.
- When any of these functions are sub-contracted, the manufacturer remains the responsible party.

Establishment Type

Authorized Representative

- Any person designated by a foreign manufacturer, to represent it within Malaysia, in respect of matters raised by the Authority, with regard to the manufacturer's obligations under the Malaysian medical device regulatory system.
- AR must be natural or legal person with business registration in Malaysia.
- AR must maintain linkage with its foreign manufacturer and should be able to obtain the support of its foreign manufacturer whenever required.

Establishment Type

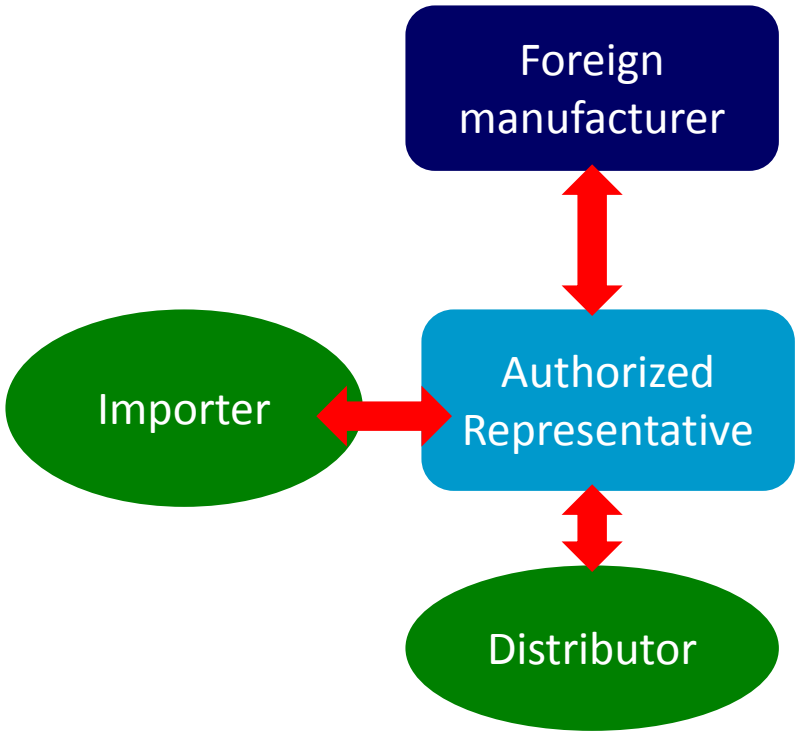
Distributor

- 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.
- In some circumstances, more than one distributor may be involved in this process

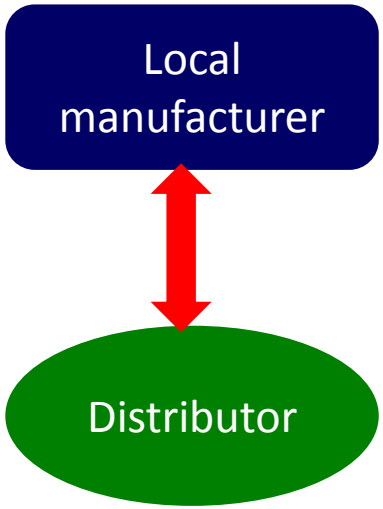
Importer

- 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.

Authorization



Imported medical devices



Locally-made medical devices

Medical Device AUTHORITY MALAYSIA

Authorization

- Authorization from the respective establishment is required as a pre-requisite for the issuance of license
  - AR must be authorized by foreign manufacturer
  - Importer must be authorized by AR to import devices on its behalf
  - Distributor must be authorized by manufacturer/ AR to distribute devices on its behalf
- Only Manufacturer and AR can issue Letter of Authorization (LoA)

Template for Letter of Auhtorisation for AR

Template for Letter of Authorisation for Authorised Representative

[To be printed on Company Letterhead of the foreign manufacturer who is the brand owner of the medical device to be registered]

Medical Device Authority

Malaysia

[Date]

Dear Sir/Madam,

Subject: Letter of Authorisation for *[name of Authorised Representative]*

We, *[name of the foreign manufacturer]*, as the manufacturer of the medical device listed in Attachment 1, hereby authorise *[Company name (Registration Number) or Person name (IC Number) and address]*, as the Authorised Representative to prepare and submit applications for the evaluation and registration of medical devices to the Medical Devices Authority on our behalf.

We also authorise *[name of Authorised Representative]* to make declarations and to submit documents on our behalf, regarding the above medical devices, in support of this application. These declarations and submissions are made pursuant to the requirements of the Medical Device Act 2012 (Act 737), the Medical Device Regulation 2012 and any other applicable laws that may also be in force.

This authorisation shall remain in effect until our notification to the Medical Device Authority in writing (either by postal mail, e-mail or facsimile transmission) that the authorisation is revoked subject to any conditions imposed by the Authority.

We undertake to provide all the necessary support and assistance to the Authorised Representative as may be required in relation to any matter involving the medical devices listed in Attachment 1.

We acknowledge that any non-compliance with any registration condition issued by the Medical Device Authority in relation to medical devices registered under Act 737 may result in the suspension or cancellation of the medical device registration.

We agree to furnish and assist the Medical Device Authority with any request for information on the above medical devices.

Yours Sincerely,

Multiple License

- One entity may apply for multiple license
- Application fee is based on category of license
- Fifth Schedule, MDR 2012
    i. Application fee: RM250.00
    ii. Licensing fee:

Establishment Type	Fee (RM)
Manufacturer	4,000.00
Authorized Representative (AR)	4,000.00
Distributor	2,000.00
Importer	2,000.00

Multiple License

- Is based on the requirements for QMS (ISO 13485 and GDPMD)

Requirements	Local manu-facturer	AR	Importer	Distri-butor
• QMS *(ISO 13485)*	×			
• Good Distribution Practice (*GDPMD*)		×	×	×

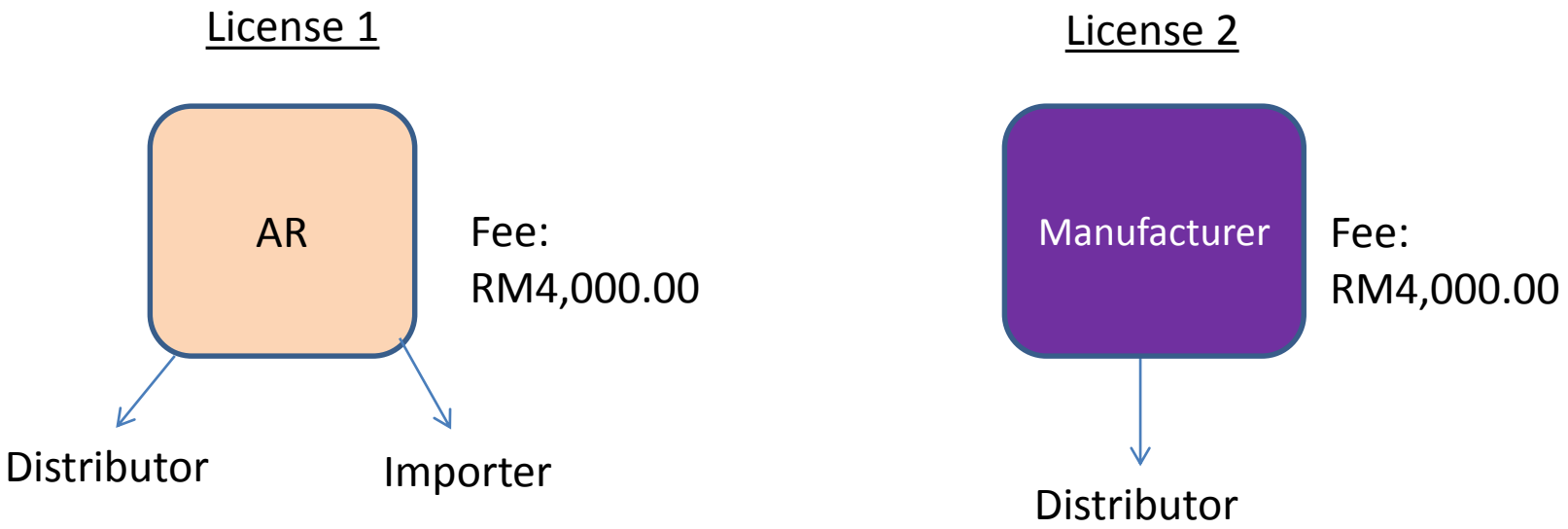
Multiple License

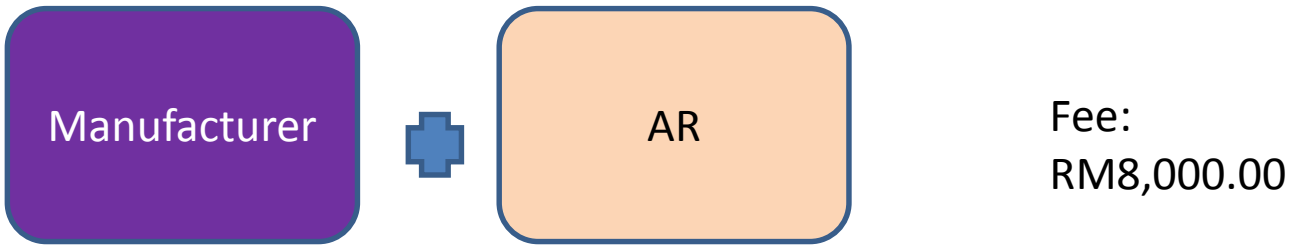
- A license granted to establishment who perform the activities of a manufacturer. A manufacturer is allowed to conduct the following activities under a same licence —
  - manufacturing a medical device; and
  - distributing the medical device.

Multiple License

- A license granted to an establishment who perform activities of AR. An AR is allowed to conduct the following activities under a same licence —
  - representing a foreign medical device manufacturer relating to any regulatory obligations under Act 737;
  - importing the medical device; and
  - distributing the medical device.

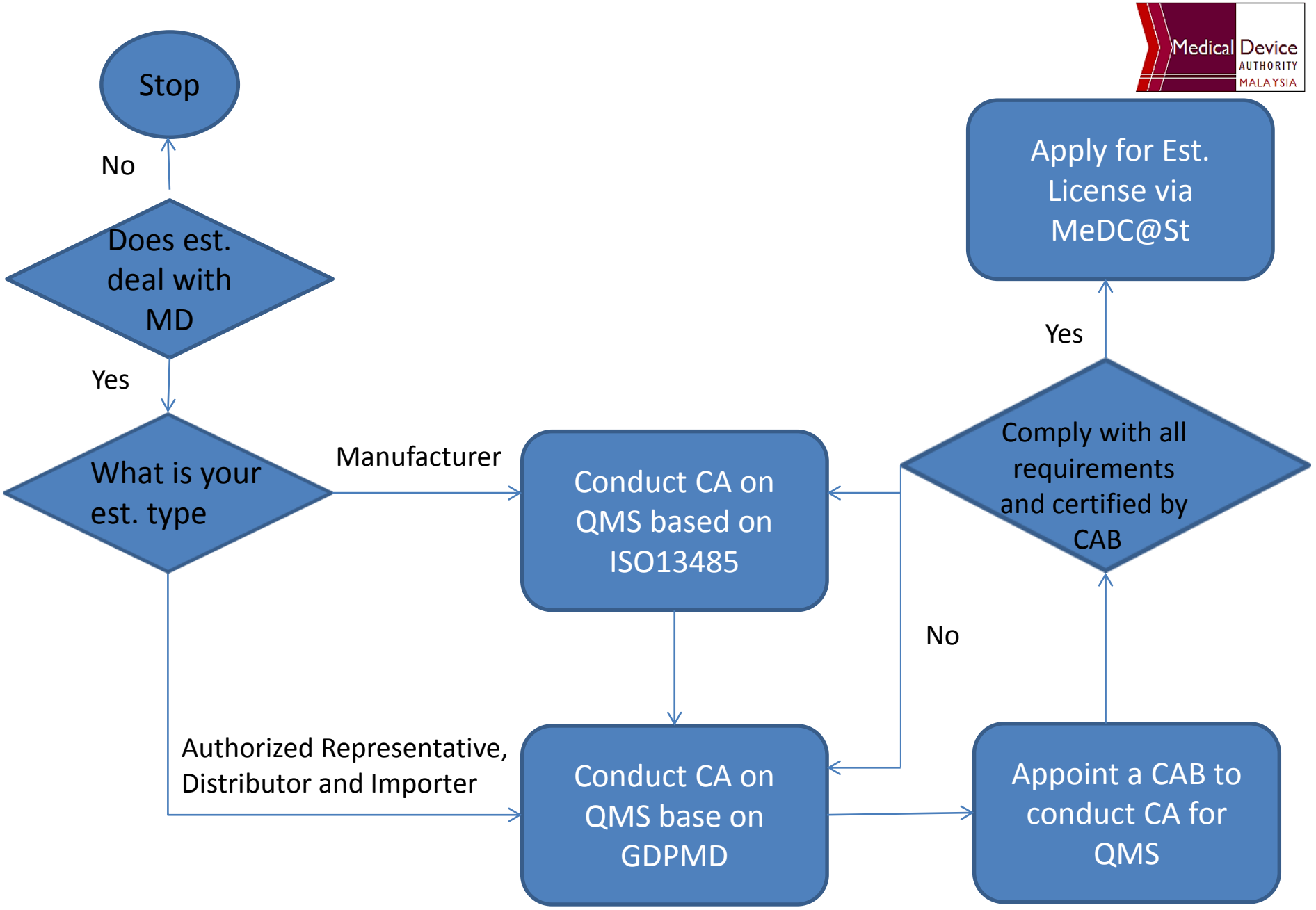
Multiple License





Multiple License

Distributor	+	Importer	Fee RM2,000.00
Distributor			Fee RM2,000.00
Importer			Fee RM2,000.00


Stop
No
Does est. deal with MD
Yes
What is your est. type
Manufacturer
Conduct CA on QMS based on ISO13485
Authorized Representative, Distributor and Importer
Conduct CA on QMS base on GDPMD
Comply with all requirements and certified by CAB
No
Yes
Apply for Est. License via MeDC@St
Appoint a CAB to conduct CA for QMS

Application

- 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.

Application

- Establishment Licence Application Form.

  The form consists of 7 parts as follows—

  (i) Establishment details;

  (ii) Person responsible for establishment;

  (iii) Contact person;

  (iv) Quality management system (QMS);

  (v) Medical device details;

  (vi) Attestation for establishment licensing application;

  (vii) Application submission.

Application

- Establishment details;

  i) Type of Establishment

  -Manufacturer, AR, Distributor, Importer

  ii) Business Registration Number

  - company registered in Malaysia
  - Issued by Registrar of Company (ROC) or other relevant authority

  iii) Establishment name

  - particulars and contact information of the establishment

Application

- Person responsible for establishment;

  - The person appointed/authorized by the establishment who shall be responsible for all legal obligations and implications under Act 737 and its subsidiary legislations;

  - Responsible person shall have the overall control and have the authority to make decision. E.g. CEO, MD or GM;

  - Domicile in Malaysia.

  - Supporting document (IC/ passport/ work permit), (Form 49/ Letter of appointment)

Application

- Contact person;

  - 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.

  - supporting document (IC/ passport/ work permit), (Letter of appointment), (Letter of Authorization to authorize the Contact Person from top management)

Application

- Quality management system (QMS); establish, maintain and implement.
- Evidence of Conformity for GDPMD/ ISO 13485
- Appoint CAB registered with MDA to do Conformity Assessment for product and QMS
- CAB satisfied that all requirements fulfilled, Certificate and reports of QMS issued.
- Certificate and reports of QMS to be submitted to MDA

Requirements	Local manu-facturer	AR	Importer	Distri-butor
• QMS *(ISO 13485)*	×			
• Good Distribution Practice (*GDPMD*)		×	×	×

Application

- Medical device details;

  - To provide information of the medical device that establishment dealing with.

MEDICAL DEVICE DETAILS	
NAME OF MEDICAL DEVICE	
NAME OF MANUFACTURER	
NAME OF AUTHORISED REPRESENTATIVE (if medical device is manufactured by foreign manufacturer)	

Application

- Attestation for establishment licensing application;
  - Download *Attestation for Establishment Licensing form* and fill in, stamp and sign and upload the complete form.

Application

- Additional information / documents
  - If not complete, MDA may request additional information/document;
  - Shall be provided by the applicant within 30 days from the date of request by the MDA;
  - Applicant may request an extension time to the MDA.

- License Issued
  - Issued for a period of 3 years

- Renewal
  - Shall be made to the MDA not later than One year before its expiry date.

Transitional

- Section 80(3), Establishment may continue their business activities pending determination of its application for an establishment license.
- Submit application before 1st July 2014
- Letter of Acknowledgement once submitted and application fee paid.

Medical Device AUTHORITY MALAYSIA

THANK YOU