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MEDICAL DEVICE GUIDANCE DOCUMENT

LICENSING FOR ESTABLISHMENT

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 the regulations under it.

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); and

b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

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 incident 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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LICENSING FOR ESTABLISHMENT

1. Introduction

The requirement for establishment license is specified under the Section 15 of the Medical Device Act 2012 (Act 737). All establishments as defined in Section 2 of the Act 737 shall obtain a license/ licenses before they can import, export or place a medical device in the market.

2. Purpose

This guidance document is prepared to provide guidance on licensing requirements for establishments dealing with medical devices in Malaysia, in complying with the Medical Device Act and regulation.

3. Scope

This guidance document applies to establishments as defined under Section 2 of the Medical Device Act 2012 (Act 737). This guidance document covers establishment licensing procedures; licensing for multiple roles; obligations of the establishment; change notification of establishment license; and renewal of establishment license.

4. Terms and definition

For the purposes of this document, the terms and definitions in Act 737, Medical Device Regulations and the following apply:

4.1 Good Distribution Practice for Medical Devices (GDPMD)

The regulatory requirement for authorised representatives, importers and distributors of medical devices on a quality management system to be established, implemented and maintained by the establishment in carrying out activities throughout the medical device supply-chain.

4.2 Multiple roles

An establishment engaging in more than one activity such as manufacturing, distributing, importing, and/or exporting of medical devices.

4.3 Person responsible

Licensee as defined in Regulation 2 of Medical Device Regulations 2012 (MDR 2012).

4.4 Tendering agent

A person or firm that participates in the tendering process to supply medical device(s) and does not carry out activities as manufacturer, AR, distributor, or importer of the medical device(s).

Tendering agent is a person or a firm authorised by any establishment to participate in tendering process in healthcare institutions.

5. General requirements

5.1 Authorisation

To apply for establishment licence, all authorised representatives (AR), importers and distributors shall obtain the letter of authorisation as follows:

a) AR shall obtain the letter of authorisation from foreign manufacturer;

b) Importer who is not an AR shall obtain a letter of authorisation from an AR; and

c) Distributor who is not a manufacturer or AR shall obtain a letter of authorisation from manufacturer or AR.

5.2 Establishment

Establishment shall be a firm/company registered in Malaysia.

5.3 Person responsible for establishment

Person responsible is the person appointed/authorised by the establishment who shall be responsible for all legal obligations and implications under Act 737 and its subsidiary legislations.

Criteria for person responsible:

a) Shall be from top management;

   i) Person responsible shall have the overall control and have the authority to make decision;

   ii) Depending on the organisational structure of the establishment, person responsible may include Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director, General Manager or Manager;

b) Domiciled in Malaysia;

   i) Malaysian citizen;

   ii) Non-Malaysian, who has an employment pass or residential address in Malaysia.

5.4 Contact person

Contact person is the person appointed/authorised by the establishment in a letter signed by the person responsible, and acts as a liaison between the Authority and the establishment relating to any regulatory issues under Act 737. The establishment may authorise contact person to make application for establishment licence.

5.5 Quality management system (QMS)

Establishment shall obtain QMS certification from a Conformity Assessment Body (CAB) registered with the Authority as follows:

a) For manufacturer, certified to MS ISO/ ISO 13485;

b) For AR, importer and distributor, certificate of conformity to GDPMD.

6. Types of licenses

6.1 Licensing of establishment is based on the activities performed by that establishment in relation to medical devices. An establishment may undertake multiple roles with regards to a specific medical device.

6.2 There are 4 types of establishment licenses:

a) Licence for manufacturer

A licence granted to an establishment who manufactures a medical device. A manufacturer is also allowed to conduct the following activities under one licence, namely:

i) manufacturing of a medical device; and

ii) distributing the medical device it manufactures; and

iii) importing the medical device from the contract manufacturer.

A manufacturer who distributes a medical device from other manufacturers is required to apply for a separate establishment licence.

b) Licence for authorised representative (AR)

A licence granted to an establishment who performs activities of an AR. An AR is also allowed to conduct the following activities under one licence:

i) representing a foreign medical device manufacturer relating to any regulatory obligations under Act 737; and

ii) importing any medical device; and/or

iii) distributing any medical device.

c) Licence for importer

A licence granted to an establishment who performs importation of medical devices. An importer shall only import registered medical device, and is authorised by the authorised representative of that medical device.

A person who imports a medical device for transit only does not require an establishment license.

d) Licence for distributor

i) A licence granted to an establishment who performs distribution of medical devices. A distributor shall only distribute registered medical device, and is authorised by the authorised representative/manufacturer of that medical device.

ii) In the same establishment licence, a distributor can also hold the scope of an importer, and vice versa.

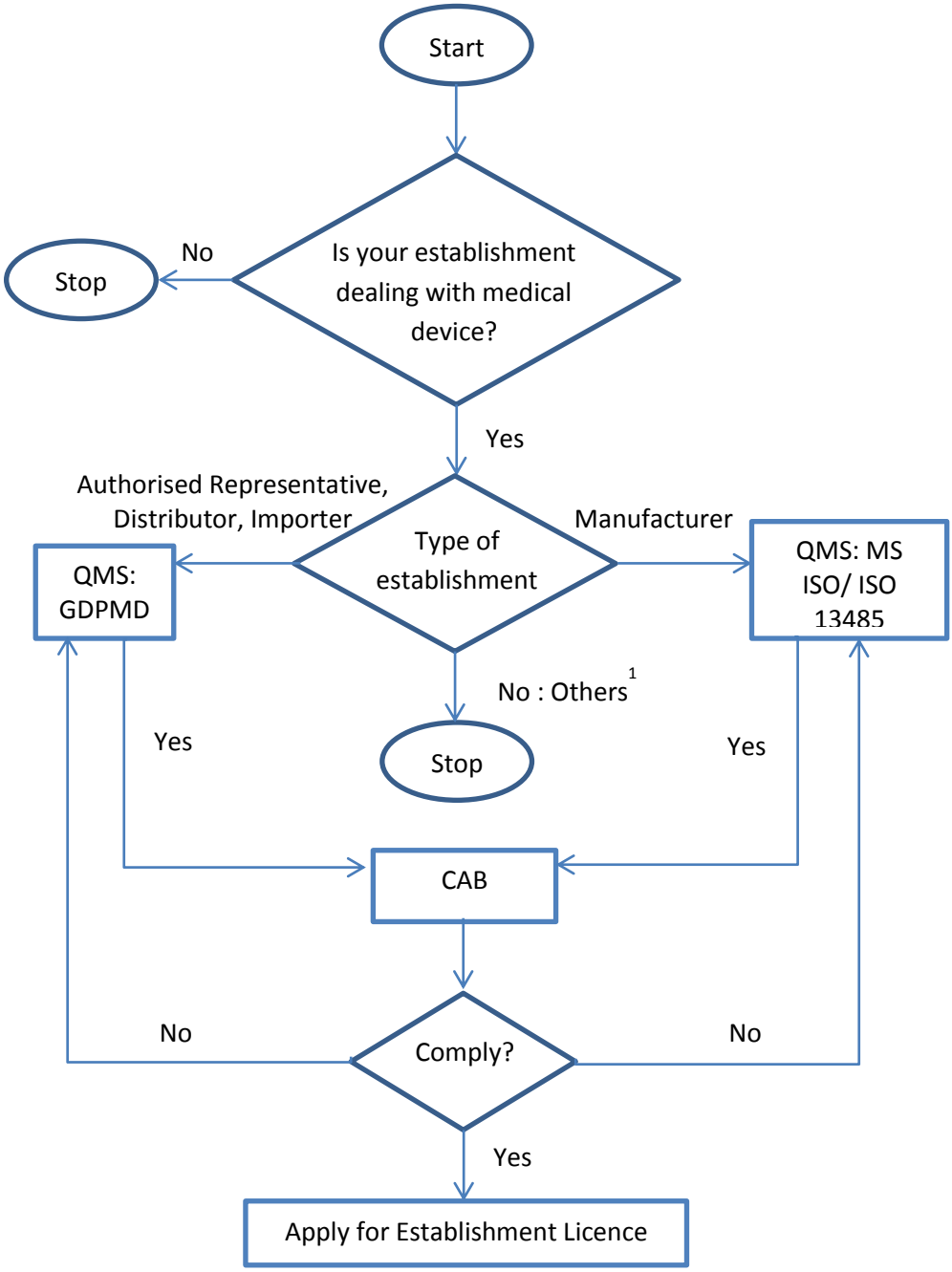
6.3 Whenever an establishment carries out activities of a manufacturer, AR, distributor and importer, the establishment shall be required to obtain both establishment licence for manufacturer and establishment licence for AR.

7. Application process

All applications for establishment licence are to be submitted via the online Medical Device Centralised Online Application System (MeDC@St).

7.1 Figure 1 shows the steps to be taken by an applicant before making an application for establishment licence under Act 737.

Figure 1: Steps to be taken before making an application for an establishment licence



Note 1: Others - for company which does not fall under the definition of "establishment" in Section 2, Act 737.

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

Table 1: Requirements for establishment licence application

Step	Preparation/criteria
(i) Determine whether your establishment is dealing with medical device	The product that you are dealing with shall fit into the definition of "medical device" in Section 2 of Act 737.
(ii) Determine the type of your establishment	As according to the definition of "establishment" in Section 2 of Act 737.
(iii) Establish, maintain and implement quality management system (QMS)	According to the Third Schedule of MDR 2012: (a) A manufacturer shall establish, maintain and implement QMS based on MS ISO/ ISO 13485 standard; (b) An authorised representative, an importer and a distributor shall establish, maintain and implement an appropriate QMS based on GDPMD.
(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 MDR 2012.
(v) CAB issues report and certificate of conformity	Upon completion of conformity assessment and satisfactory fulfilment of the requirements, CAB shall issue a report and certificate of conformity according to the Third Schedule of MDR 2012.
(vi) Apply for establishment licence via MeDC@St	(a) Application for establishment licence may be made after the above criteria are met and are supported with relevant information and supporting documents; (b) Applicant shall create an account before making an application via MeDC@St.

7.3 Filling in the establishment licence application form

7.3.1 After creating the MeDC@St account, the establishment shall fill in the Establishment Licence Application Form after logging in into the MeDC@St system.

7.3.2 The primary user who created the MeDC@St account may create sub-account(s) where the sub-accounts user(s) may assist the primary user in keying in information and uploading

necessary documents into the application form. However, submission of the application for licence can only be made by the primary user.

7.3.3 The following information and documents shall be furnished by the establishment in its application:

a) establishment details;

b) person responsible for establishment;

c) contact person;

d) quality management system (QMS);

e) attestation for establishment licensing application; and

f) application submission.

7.3.4 Applicant shall furnish all information and upload relevant supporting documents as required in the form.

7.3.5 The details on how to complete the Establishment Licence Application Form and information/documents to be furnished are explained in Table 2.

Table 2: How to complete Establishment Licence Application Form

(a) Establishment details	Desriptions	Documents to upload
(i) Type of establishment	Please indicate the type of your establishment: – Manufacturer/ AR/ Distributor/ Importer	Letter of Authorisation
(ii) Business registration number	Please provide business registration number of your company as issued by the Registrar of Company (ROC), Lesen perniagaan (Sabah) or Sijil Pendaftaran Ordinan Nama-nama Perniagaan (CAP64) (Sarawak)	Form 9 /Form 13 /Borang D /Borang B /Borang 1
(iii) Establishment name	Please provide particulars and contact information of your establishment as required in the appropriate fields.	
(b) Person responsible		
Details of person responsible	Please provide the particulars of the person responsible as required in the appropriate fields.	Appropriate identification document

		Malaysian citizen: i. identity card; and ii. Form 49; or letter of appointment of the person responsible signed by head of the establishment; Non-Malaysian: i. passport; and ii. employment pass; and iii. Form 49; or letter of appointment of the person responsible signed by head of the establishment.
(c) Contact person		
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 person responsible, please provide the particulars of the contact person as required in the appropriate fields.	Letter of authorisation of the contact person signed by the person responsible. *[If contact person is not the same person as the person responsible]*
(d) Quality management system (QMS)		
Details on QMS	If your QMS have been certified by registered CAB, please indicate the QMS that you have established in the appropriate box, i.e. MS ISO/ ISO 13485 for manufacturer or GDPMD for other establishment types, and provide the name and registration number of the CAB.	i. Conformity assessment/ audit report; and ii. Certificate of conformity issued by the CAB.
(e) Attestation for establishment licensing application		
Submission of attestation	(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 by person responsible and print on company letterhead;	Completed attestation form

	(iii) Step 3: Upload the completed attestation form	
(f) 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 once you have submitted your application.	

8. Request for amendment

If an establishment intends to amend the details of establishment licence, establishment shall submit the request application to the Medical Device Authority through an official letter. There are 6 types of amendment:

8.1 Change or add type of licence

Establishment who intends to change or add type of licence shall make a new application via MeDC@St.

8.2 Inclusion of additional Letter of Authorisation (LOA)

Establishment who obtains additional LOA from Manufacturer /AR is required to submit the following documents as per Table 3.

Table 3: Documents required for inclusion of an additional LOA

No.	Documents required	Details
1.	Official letter	To be signed by Person Responsible on the company letterhead.
2.	Letter of Authorisation	LOA from new Manufacturer /AR has to be submitted together with list of devices using the template in Annex B.
3.	Updated MS ISO/ISO 13485	Establishment shall inform CAB pertaining to

	/GDPMD certificate and audit report (if applicable)	Additional LOA from Manufacturer /AR. CAB shall audit the establishment and issue updated MS ISO/ ISO 13485 /GDPMD certificate with new /additional medical device category in the certificate (where applicable).

8.3 Change of Person Responsible

Establishment who intends to change Person Responsible is required to submit the following documents as per Table 4.

Table 4: Documents required for change of Person Responsible

No.	Documents required	Details
1.	Official letter	To be signed by Person Responsible on the company letterhead.
2.	Copy of NRIC or; Copy of Passport AND Working Permit	Malaysian citizen: i. identity card. Non-Malaysian: i. passport; and ii. employment pass.
3.	Form 49 /FORM 79 (Syarikat Sdn. Bhd /Berhad) or; Borang D (PemilikanTunggal /Perkongsian /Enterprise) or; Borang B (Lesen perniagaan (Sabah)) or; Borang 1 (Sijil Pendaftaran Ordinan Nama-nama Perniagaan (CAP64) (Sarawak))	To show the designation of Person Responsible
4.	Letter of Appointment (if in the absence of item 3)	This letter is only required if Person Responsible is not listed in Form 49 /Form 79 /Borang D /Borang B /Borang 1. A Director listed in Form 49 /Form 79 /Borang D /Borang B /Borang 1 shall appoint Person Responsible by issuing a Letter of Appointment.

8.4 Change of establishment name

Establishment who intends to change establishment name is required to submit the following documents as per Table 5. Establishment shall inform CAB pertaining to change of establishment name.

Table 5: Documents required for change of establishment name

No.	Documents required	Details
1.	Official letter	To be signed by Person Responsible on the company letterhead.
2.	Form 13 (Akta Syarikat 1965) or equivalent.	To indicate changes of establishment name.
3.	Form 9 (Akta Syarikat 1965)	This document is ONLY required if the establishment name is changed from ''Enterprise'' to ''Sendirian Berhad''

8.5 Change of establishment address

Establishment who intends to change establishment address is required to submit the following documents as per Table 6.

Table 6: Documents required for change of establishment address

No.	Documents required	Details
1.	Official letter	To be signed by Person Responsible on the company letterhead.
2.	Updated MS ISO/ ISO 13485 /GDPMD certificate (if premise address changed)	Establishment shall inform CAB pertaining to change of establishment address. CAB shall audit the establishment and issue updated MS ISO/ ISO 13485 /GDPMD certificate with new address in the certificate.
3.	Updated MS ISO/ ISO 13485 /GDPMD audit report (if premise address changed)	Establishment shall inform CAB pertaining to change of establishment address. CAB shall audit the establishment and issue updated MS ISO/ ISO 13485 /GDPMD audit report with new address in the audit report.

8.6 Change of contact person

Establishment who intends to change Contact Person is required to submit the following

documents as per Table 7.

Table 7: Documents required for change of contact person

No.	Documents required	Details
1.	Official letter	To be signed by Person Responsible on the company letterhead.
2.	Letter of Authorisation	Only Person Responsible is allowed to issue a Letter of Authorisation for change of contact person.

8.7 Change or termination of authorised representative (AR)

There were instances where the current AR of a particular medical device has to be terminated and/or replaced with a new AR. The following are requirements to be fulfilled for this purpose.

8.7.1 Termination of AR (without replacement of the AR)

AR who intends to terminate authorization from Manufacturer for a particular medical device is required to submit an official letter informing of the termination, to be signed by Person Responsible on the company letterhead of the authorised representative. This letter shall be submitted together with the manufacturer's letter of termination, to be signed by top management on the company letterhead of the manufacturer of the medical device.

8.7.2 Termination of AR (with replacement of the AR)

When an AR is to be replaced with a new AR, the following actions are required as stipulated in Table 8.

Table 8: Actions required for change of authorised representative

No.	AR	Actions
1.	Current AR	Official letter from current AR informing on the termination, to be signed by Person Responsible on the company letterhead of the authorised representative shall be submitted to the Authority. This letter shall be submitted together with the manufacturer's letter of termination, to be signed by top management on the company letterhead of the manufacturer of the medical device.
2.	New AR	New AR already licensed shall submit an official letter informing of the new authorisation, together with the LOA.

		New AR without establishment license shall apply for establishment license application as per Clause 7.

9. Renewal of licence

Licensee(s) are required to submit their renewal applications via MeDC@St not later than one year before its expiry.

10. Licence fee

Licensing fee is based on type of licence. An establishment may apply for multiple licences. With reference to the Fifth Schedule, MDR 2012, fees are as per below:

a) application fee: RM 250.00.

b) licensing fee: Table 9 shows the fees for different type of licence.

Table 9: Type of licence and fees

Type of licence	Fee (MYR)
Manufacturer	4,000.00
Authorised Representative (AR)	4,000.00
Importer	2,000.00
Distributor	2,000.00

c) Table 10 shows the fees for multiple licence

Table 10: Multiple roles licence and fees

Type of licence	Fee (MYR)
Manufacturer + distributor	4,000.00
Manufacturer + AR	8,000.00
AR + Distributor + Importer	4,000.00
Importer + Distributor	2,000.00

d) Renewal fee

i) application renewal fee: RM 200.00.

ii) licensing renewal fee: Table 11 shows the fees for different type of licence renewal.

Table 11: Fees for renewal of licence

Type of licence	Renewal Fee (MYR)
Manufacturer	2,000.00
Authorised Representative (AR)	2,000.00
Importer	1,000.00
Distributor	1,000.00

iii) Table 12 shows the fees for renewal of multiple licences

Table 12: Fees for renewal of multiple licences

Type of licence	Renewal Fee (MYR)
Manufacturer + distributor	2,000.00
Manufacturer + AR	4,000.00
AR + Distributor + Importer	2,000.00
Importer + Distributor	1,000.00

ANNEX A
(informative)

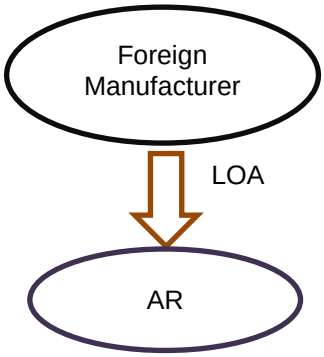
Roles and Responsibilities of establishment

A.1 Scenario of Supply Chain /Business Model

Case 1

Letter of Authorisation (LOA) for AR

Figure A.1 – LOA for AR

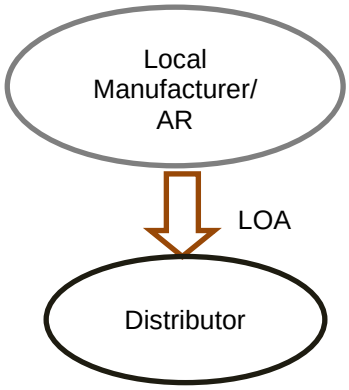


Foreign manufacturer will issue Letter of Authorisation to Authorised Representative to act on its behalf.

Case 2

Letter of Authorisation for distributor

Figure A.2 – LOA for Distributor

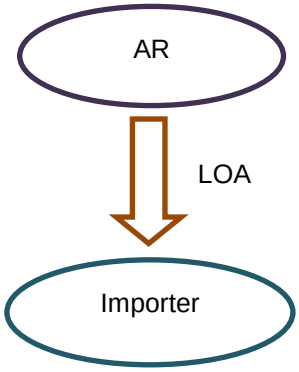


Local manufacturer or Authorised Representative will issue Letter of Authorisation to distributor in order for distributor to distribute or placing any registered medical device in Malaysia.

Case 3

Letter of Authorisation for Importer

Figure A.3 – LOA for Importer

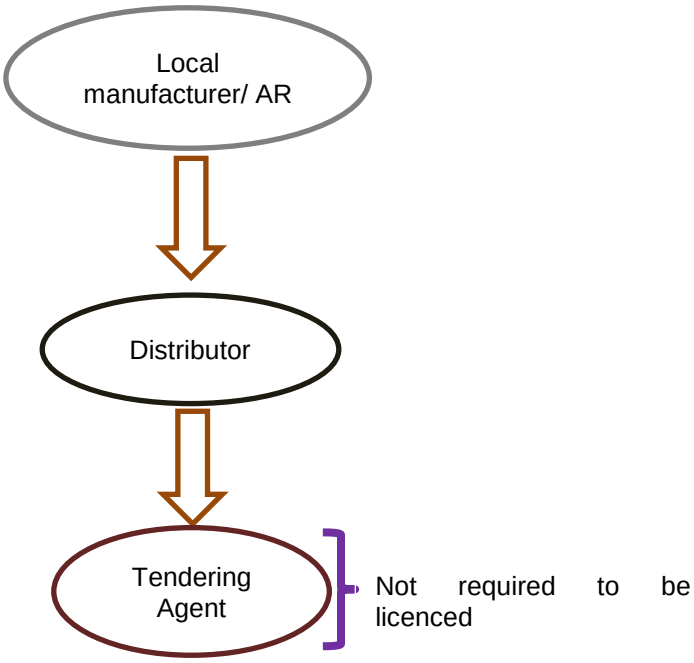


Authorised Representative will issue Letter of Authorisation to importer in order for importer to import or placing any registered medical device in Malaysia.

Case 4

Tendering Agent

Figure A.4. Tendering agent

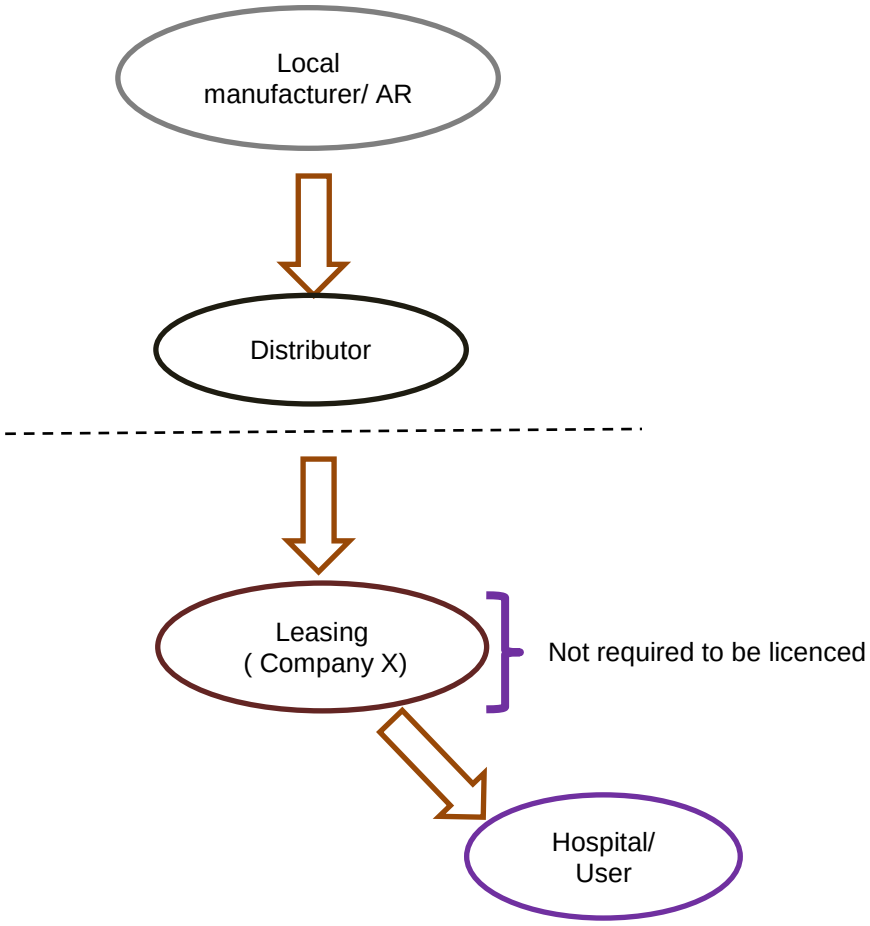


Tendering Agent is not required to be licenced.

Case 5

Leasing company

Figure A.5 – Leasing company

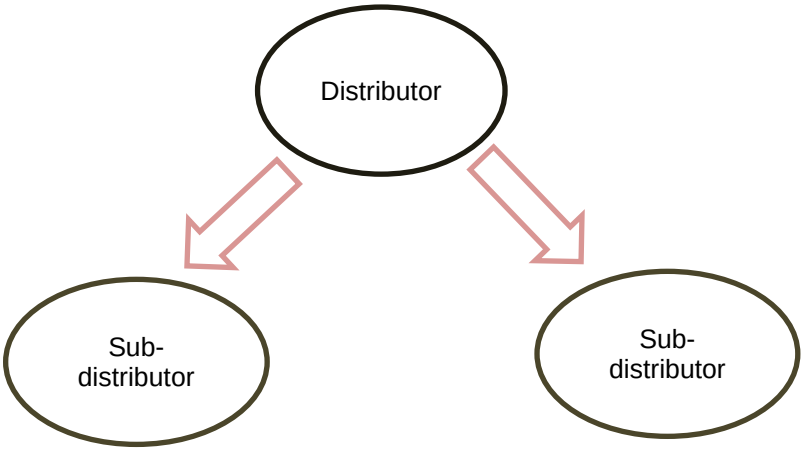


Company X which is carries out activity of leasing is not required to obtain Establishment Licence.

Case 6

Sub-Distributor

Figure A.6 – Sub-distributor



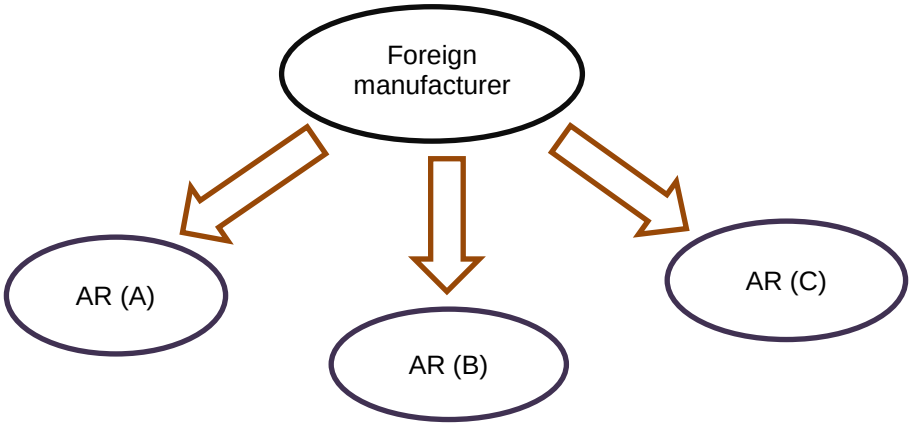
Distributor is required to apply for GDPMD certificate which is to be conducted by the registered conformity assessment body. Distributor is outsourcing their activities i.e. warehouse, transportation to sub-distributor(s).

Sub-distributor(s) can be certified to GDPMD covering the scope of the outsourced activity. Sub-distributor(s) may apply GDPMD certificate which is conducted by registered CAB but is not required to obtain Establishment Licence.

Case 7

Multiple AR

Figure A.7 – Example of multiple AR



Foreign Manufacturer is allowed to appoint multiple AR to act on its behalf.

AR (A), AR (B), and AR (C) **are not allowed** to register and place **the same model of medical device** in the market.

ANNEX B
(normative)

Template for Letter of Authorisation

B.1 Authorised Representative only

The template for Letter of Authorisation for Authorised Representative as presented below shall be used.

[To be printed on Company Letterhead of the Manufacturer]

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 Regulations 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 condition imposed by the Authority.

We undertake to provide all the necessary support and assistance to the distributor/importer 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 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,

[Signature]
[Full Name]
[Designation of Senior Company Official]
[Company stamp]

B.2 Distributor/Importer

The template for Letter of Authorisation for Distributor /Importer as presented below shall be used.

[To be printed on Company Letterhead of the AR/Manufacturer]

Medical Device Authority
Malaysia

[Date]

Dear Sir/Madam,

Subject: Letter of Authorisation for [name of **Distributor/ Importer]**

We, [name of the AR/Manufacturer*], as the Authorised Representative/Manufacturer* of the medical device listed in Attachment 1, hereby authorise [Company name (Registration Number) or Person name (IC Number) and address], as the **Distributor/ Importer to distribute / import the listed medical device on our behalf.**

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 condition imposed by the Authority.

We undertake to provide all the necessary support and assistance to the distributor/importer 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 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,
[Signature]

[Full Name]
[Designation of Senior Company Official]
[Company stamp]
* Choose one

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

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