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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; and

c) Medical Device (Duties and Obligations of Establishments) Regulations 2019; and

d) Medical Device (Advertising) Regulations 2019.

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.

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.

## 2. 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; amendment to establishment license information; and renewal of establishment license.

## 3. Terms and definition

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

### 3.1 Authority

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

### 3.2 distributor

Any natural or legal person in the supply-chain who, on his own behalf, places a medical device on the market and further the availability of the medical device to the end user including persons in the supply-chain involved in activities such as storage and transport on behalf of the authorized representative, importer or distributor.
[Source: MDA/RR/No. 1: November 2015 First Revision Good Distribution Practice for Medical Device (GDPMD)]

### 3.3 distribution

The activities of pre (release), placement (delivery) and postdelivery of medical devices conducted by the establishment.
[Source: MDA/RR/No. 1: November 2015 First Revision Good Distribution Practice for Medical Device (GDPMD)]

### 3.4 establishment

(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.
[Source: Act 737]

### 3.5 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.

### 3.6 multiple roles

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

### 3.7 licensee

Any person who obtains and holds an establishment licence under Act 737.
[Source: MDR 2012]

### 3.8 place in the market

To make available a medical device in return for payment or free of charge with a view to distributing, using, supplying or putting it into service, in Malaysia, regardless of whether it is new or reprocessed, but does not include to make available for use for clinical research or for performance evaluation of a medical device.
[Source: Act 737]

### 3.9 retailer

Any entity which sells or offers to sell medical devices directly to the general public.

### 3.10 manufacturer

(a) a person who is responsible for-
  (i) the design, production, fabrication, assembly, processing, packaging and labelling of a medical device whether or not it is the person, or a subcontractor acting on the person's behalf, who carries out these operations; and
  (ii) assigning to the finished medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement; or

(b) any other person who-
  (i) assembles, packages, processes, fully refurbishes, reprocesses or labels one or more ready-made medical devices; and
  (ii) assigning to the ready-made medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirements,

but shall not include the following persons:

(A) any person who assembles or adapts medical devices in the market that are intended for individual patients; and
(B) any person who assembles, packages or adapts medical devices in relation to which the assembling, packaging or adaptation does not change the purpose intended for the medical devices.

[Source: Act 737]

### 3.11 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 ONLY to participate in tendering process in healthcare institutions.

## 4. General requirements

### 4.1 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.

d) Importer and distributor who is also an AR for the same medical device, may use the same letter of authorization from the foreign manufacturer that appoints them as AR.

### 4.2 Establishment

Establishment shall be a firm/company registered in Malaysia.

### 4.3 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.

c) The particular details of the person responsible as below shall be uploaded in MeDC@st 2.0+ during application:

i) Appropriate identification document such as identity card or passport, and

ii) Form 49 or letter of appointment of the responsible person.

### 4.4 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.

### 4.5 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 13485:2017/ ISO 13485:2016 Medical Devices-Quality management systems-Requirements for regulatory purposes;

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

### 4.6 Post market responsibilities

a) Establishment shall:

i) Comply to Medical Devices (Duties and Obligations of Establishments) Regulations 2019 that stipulates the post marketing requirements of medical devices; and

ii) Be responsible for all medical devices that the establishment placed in the market; and

iii) Carry out responsibilities to monitor and continuously ensure the safety and performance of the medical devices in the market throughout the supply chain.

b) An AR that has been terminated by a manufacturer or closed its business with no replacement shall carry out post-market obligations for the medical devices that it has placed in the market, at least in accordance with the projected useful life of the medical device as determined by the manufacturer.

c) An AR that has closed its business after placing medical device in the market and being replaced by another AR, the newly appointed AR shall be responsible for post market issued of the medical device.

d) A local manufacturer that has closed its business after placing their medical device in the market shall be responsible to carry out post market obligations at least in accordance with the projected useful life of the medical device as determined by the manufacturer.

### 4.7 Requirement to apply for licence for retailers and tendering agents

Retailers (includes online retailers) or tendering agents who carry out manufacturing (brand owner), importation, exportation and distribution activities will be required to obtain the establishment license corresponding to the types of establishment activities being carried out and shall comply with Act 737 and its subsidiary legislations.

A tendering agent shall be appointed by the establishment and obtain written agreements or Letter of Appointment from the establishment.

## 5. Types of licenses

**5.1** 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.

**5.2** Each activity will require a separate licence. For example, whenever an establishment carries out activities of a manufacturer and as a distributor, the establishment shall be required to obtain both establishment licence for manufacturer and establishment licence for distributor.

### 5.3 There are 4 types of establishment licenses:

#### a) Licence for manufacturer

A licence granted to an establishment who manufactures a medical device.

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

#### b) Licence for authorised representative (AR)

A licence granted to an establishment who representing a foreign medical device manufacturer relating to any regulatory obligations under Act 737.

Registration of medical device may be done by more than one authorized representative (AR).

#### 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

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

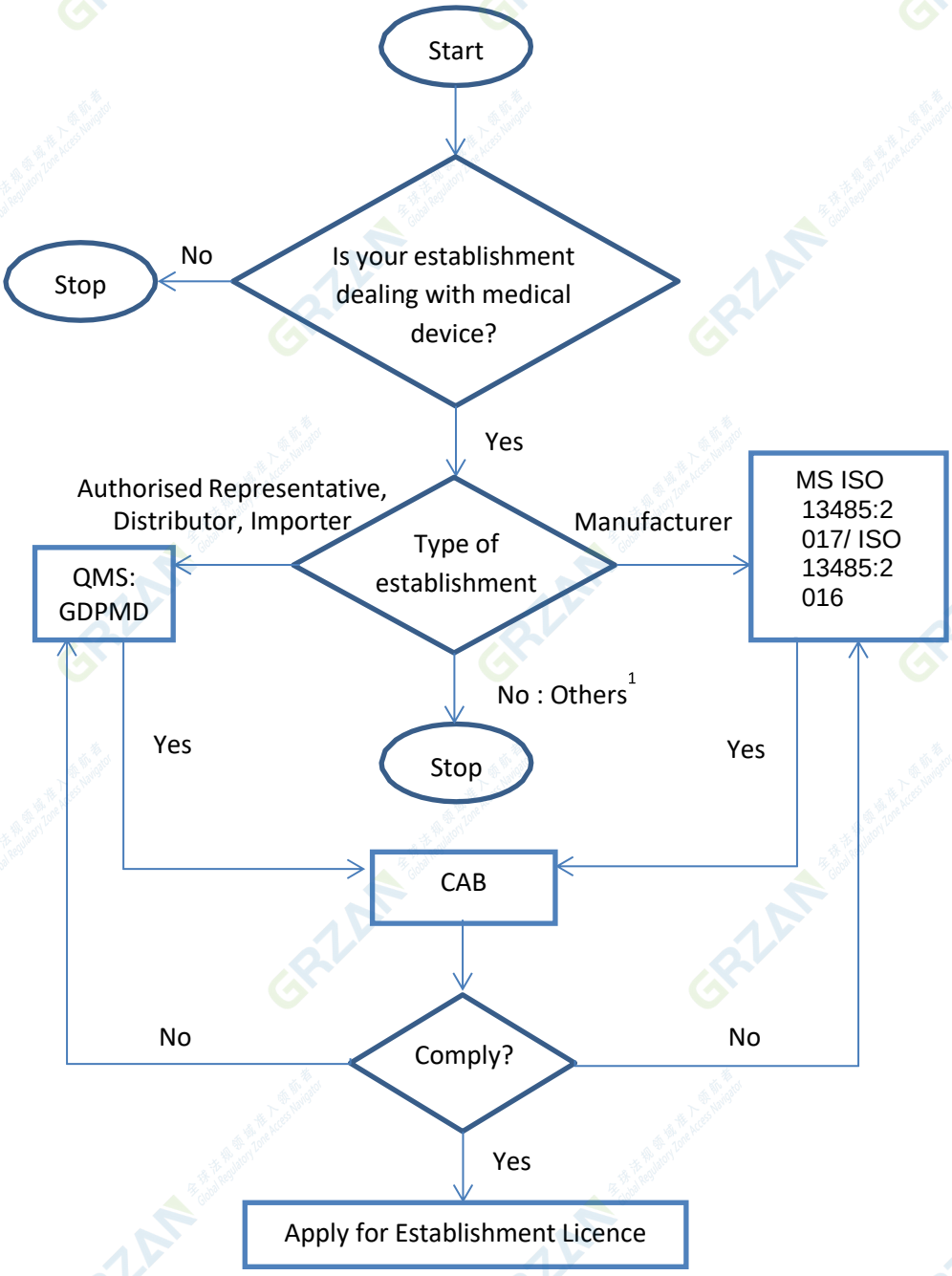
representative/manufacturer of that medical device.

## 6. Application process

All new and renewal applications for establishment licence are to be submitted via the online Medical Device Centralised Online Application System (MeDC@St 2.0+).

**6.1** 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 Section2, Act 737.*

**6.2** 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:<br>(a) A manufacturer shall establish, maintain and implement QMS based on MS ISO 13485:2017/ ISO 13485:2016 standard;<br>(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 2.0+ | (a) Application for establishment licence may be made after the above criteria are met and are supported with relevant information and supporting documents;<br>(b) Applicant shall create an account before making an application via MeDC@St 2.0+. |

### 6.3 Filling in the establishment licence application form

**6.3.1** After creating the MeDC@St 2.0+ account, the establishment shall fill in the Establishment Licence Application Form after logging in into the MeDC@St 2.0+ system.

**6.3.2** The primary user who created the MeDC@St 2.0+ account may create sub-account(s) wherethe 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 license can only be made by the primary user.

**6.3.3** 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.

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

**6.3.5** 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 | Descriptions | Documents to upload |
|---|---|---|
| (i) Type of establishment | Please indicate the type of your establishment:<br><br>– 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<br><br>Malaysian citizen: |

| | | |
|---|---|---|
| | | i. identity card; and<br>ii. Form 49; or letter of appointment of the person responsible signed by head of the establishment;<br><br>Non-Malaysian:<br><br>i. passport; and<br><br>ii. employment pass; and<br><br>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.<br>If the contact person is not the same person as person responsible,please provide the particulars of the contact person as required in theappropriate fields. | Letter of authorisation of the contact person signed by the person responsible.<br><br>*[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 13485:2017/ ISO 13485:2016 for manufacturer or GDPMD for other establishment types, and provide the name and registration number of the CAB. | i. Conformity assessment/ audit report; and<br><br>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;<br><br>(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.<br><br>You may check information and supporting documents that you have uploaded prior to making your submission by clicking at "preview of application form" button.<br><br>Please be advised that no change can be made on your application once you have submitted your application. | |

## 7. 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:

### 7.1 Change or add type of licence

Establishment who intends to change or add type of licence shall make a new application via MeDC@St 2.0+.

### 7.2 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 /GDPMD certificate and audit report (if applicable) | Establishment shall inform CAB pertaining to Additional LOA from Manufacturer /AR.<br><br>CAB shall audit the establishment and issue updated MS ISO 13485:2017/ ISO 13485:2016 /GDPMD certificate with new /additional medical device category in the certificate (where applicable). |

### 7.3 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;<br><br>Copy of Passport AND Working Permit | Malaysian citizen:<br>i. identity card.<br><br>Non-Malaysian:<br>i. passport; and<br>ii. employment pass. |
| 3. | Form 49 /FORM 79 (Syarikat Sdn. Bhd /Berhad) or;<br><br>Borang D (PemilikanTunggal /Perkongsian /Enterprise) or;<br><br>Borang B (Lesen perniagaan (Sabah)) or;<br><br>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.<br><br>A Director listed in Form 49 /Form 79 /Borang D /Borang B /Borang 1 shall appoint Person Responsible by issuing a Letter of Appointment. |

### 7.4 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'' |

### 7.5 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.<br><br>CAB shall audit the establishment and issue updated MS ISO 13485:2017/ ISO 13485:2016 /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.<br><br>CAB shall audit the establishment and issue updated MS ISO 13485:2017/ ISO 13485:2016 /GDPMD audit reportwith new address in the audit report. |

### 7.6 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. |

### 7.7 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.

**7.7.1** 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.

**7.7.2** 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.<br><br>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.<br><br>New AR without establishment license shall apply for establishment license application as per Clause 7. |

## 8. Renewal of licence

A licensee shall apply for renewal of its establishment licence to the Authority at least 90 days before the expiry date of the licence.

## 9. 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) Renewal fee

i) Application renewal fee: RM 200.00.

ii) Licensing renewal fee: Table 10 shows the fees for different type of licence renewal.

**Table 10: 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 |

# ANNEX A
(informative)

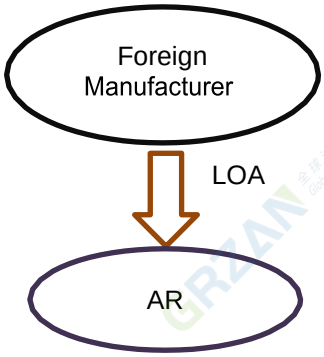
## Roles and Responsibilities of Establishment

### A.1 Scenario of Supply Chain /Business Model

**Case 1**

**Letter of Authorisation (LOA) for AR**

**Figure A.1 – LOA for AR**

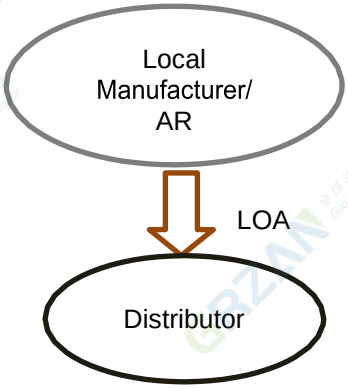



Foreign manufacturer will issue Letter of Authorisation to Authorised Representative to act on its behalf.

**Case 2**

**Letter of Authorisation for distributor**

**Figure A.2 – LOA for Distributor**

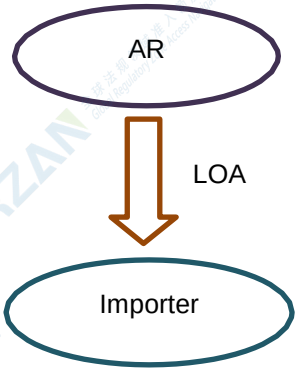



Local manufacturer or Authorised Representative will issue Letter of Authorisation to distributor to distribute or placing any registered medical device in Malaysia.

**Case 3**

**Letter of Authorisation for Importer**

**Figure A.3 – LOA for Importer**

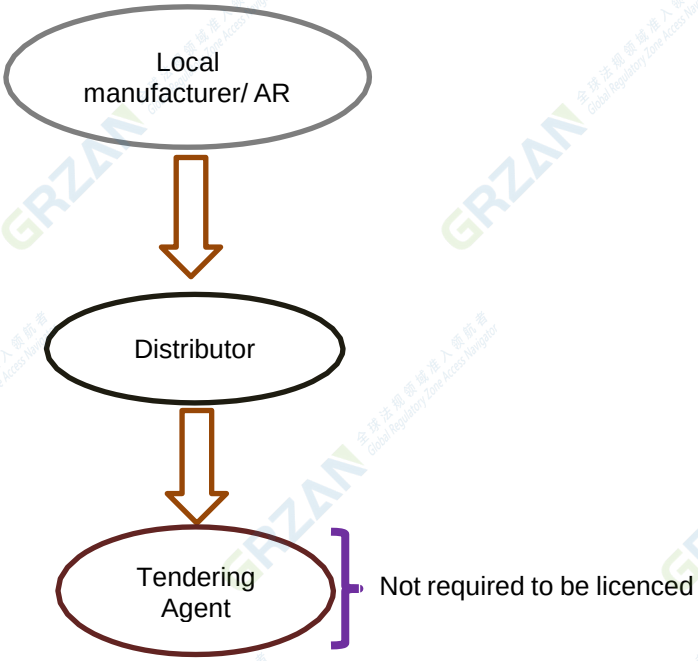



Authorised Representative will issue Letter of Authorisation to importer to import or placing the corresponding registered medical device in Malaysia.

**Case 4**

**Tendering Agent**

**Figure A.4. Tendering agent**

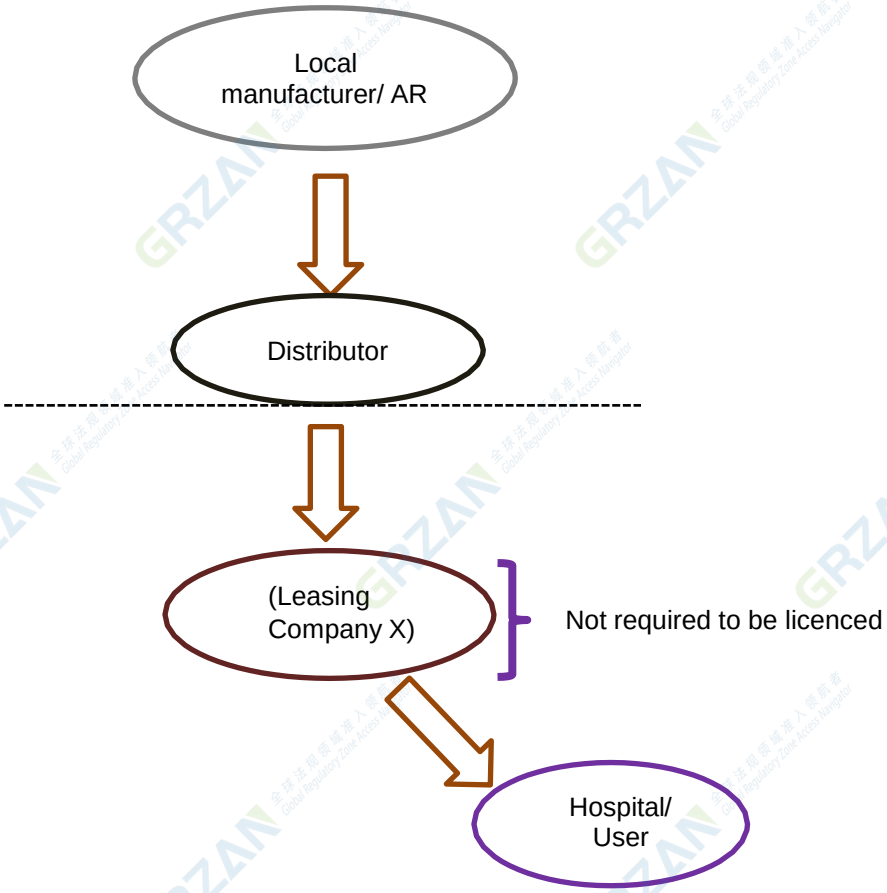



Tendering Agent is not required to be licenced.

**Case 5**

**Leasing company**

**Figure A.5 – Leasing company**

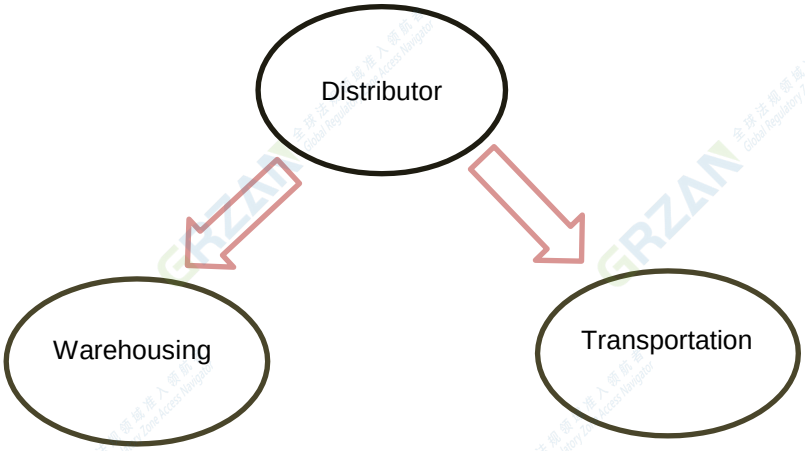



Company X which is carries out activity of leasing is not required to obtain Establishment Licence.

**Case 6**

**Appointed supplier of outsourced activities/third party.**

**Figure A.6 - Appointed supplier of outsourced activities/third party.**




A distributor may outsource their activities such as warehousing, storage and handling and transportation to the supplier of outsourced activities /third-party.

However, the distributor shall have control over the outsourced activities of the appointed supplier of outsourced activities / third-party within their scope of the GDPMD and shall ensure the compliance of all requirements by having in place an established procedure and contractual agreements with the outsource parties.

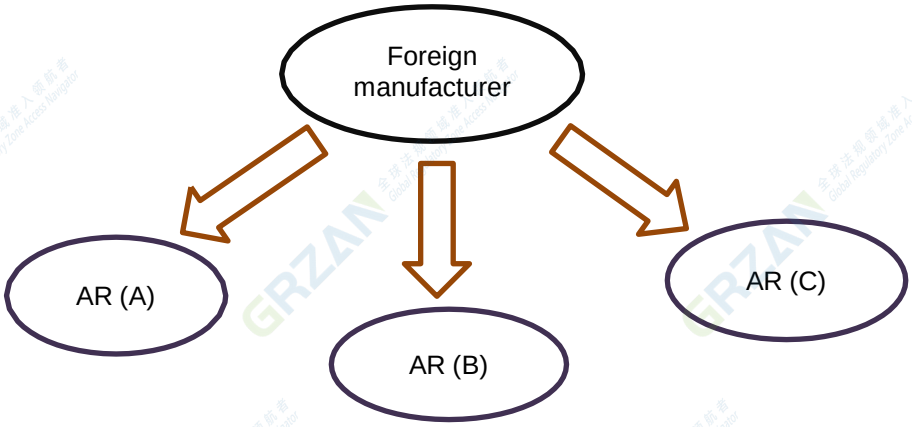
The appointed supplier/ third-party may apply for GDPMD certification but is not required to apply for establishment licence. Also refer to 5.2.

The distributor shall declare their outsourced partners in their quality manual for the purpose GDPMD certification.

**Case 7**

**Multiple AR**

**Figure A.7 – Example of multiple AR**




Foreign Manufacturers are allowed to appoint multiple AR to act on its behalf.

AR (A), AR (B) and AR (C) are allowed to register and place the same medical devices in the market.

However, the establishment shall: -

i. comply with medical device regulatory requirements as stipulated in Act 737 and its subsidiary legislations**;** and
ii. obtain an authorization from the foreign manufacturer.

# ANNEX B
(normative)

## Template for Letter of Authorisation

### B.1 Authorised Representative only

The template for Letter of Authorisation from foreign Manufacturer as presented below shall be used.

[To be printed on Company Letterhead of the foreign 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 or e-mail) 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 appointed by AR

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

[To be printed on Company Letterhead of the AR]

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 or e-mail) 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

### B.3 Distributor appointed by a local Manufacturer

The template for Letter of Authorisation for Distributor appointed by a local manufacturer as presented below shall be used.

[To be printed on Company Letterhead of the Local Manufacturer]

Medical Device Authority
Malaysia

[Date]

Dear Sir/Madam,

Subject: Letter of Authorisation for [name of Distributor]

We, [name of the local 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 Distributor to distribute 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 or e-mail) 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 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]

## ANNEX C
## (informative)

## Template for Attachment 1 in Letter of Authorization

The list of medical devices imported/ distributed shall be provided in Attachment 1 of Letter of Authorization. The template for Attachment 1 of Letter of Authorization shall be used as below:

| No. | Name of Medical Device | Identifier |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

[Signature]

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

# MEDICAL DEVICE AUTHORITY

## MINISTRY OF HEALTH, MALAYSIA

**Contact Information:**

**Medical Device Authority**
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II, Block 3547, Persiaran APEC, 63000 Cyberjaya, Selangor, MALAYSIA
**T**: (03) 8230 0300
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