Establishment License : Issues and Updates

Muhd Radhuan bin Abdul Halim
Licensing and CAB Registration Unit
Medical Device Authority

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 (AR);
  - Distributor;
  - Importer.

Establishment License

- Application
  - Application for establishment licence shall only be made via MeDC@St at MDA website www.mdb.gov.my/
  - Applicant shall open an account to access MeDC@St.

Establishment License

- Fees
  - Based on category of license;
  - Fifth Schedule, MDR 2012:-

    i. Application fee: RM250.00

    ii. Licensing fee:

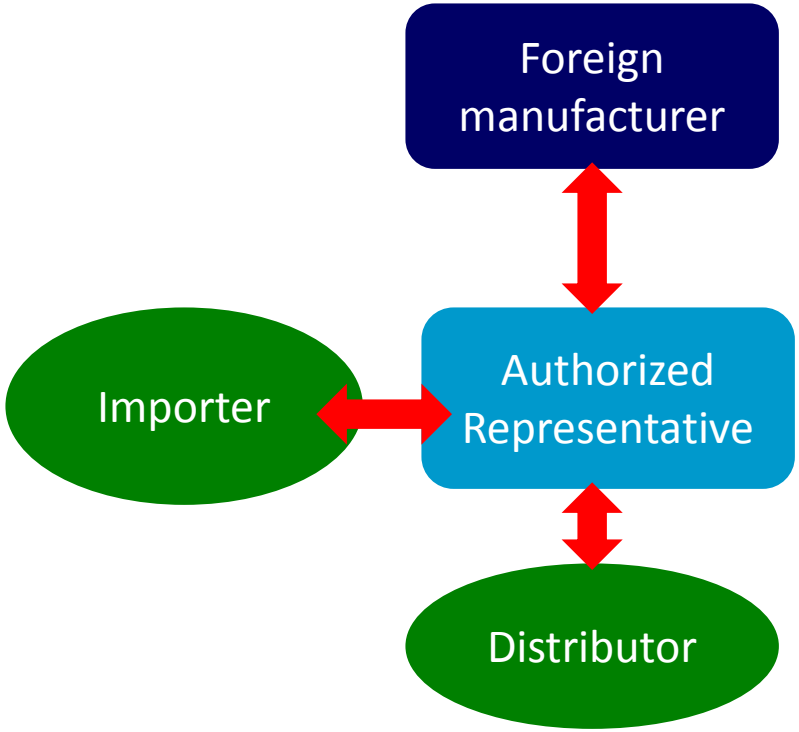
Establishment Type	Fee (RM)
Manufacturer	4,000.00
Authorized Representative (AR)	4,000.00
Distributor	2,000.00
Importer	2,000.00

Establishment License

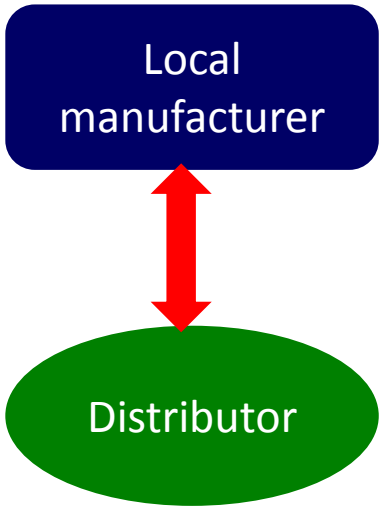
- License Issued
  - Issued for a period of 3 years

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

Issues on Authorization



Imported medical devices



Locally-made medical devices

Issues on 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 (local) / AR to distribute devices on its behalf.
- Only Manufacturer and AR can issue Letter of Authorization (LoA);
- Distributor cannot issue LoA to their sub-distributor;
- Must use the MDA template for LoA;

Template for Letter of Authorisation 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,

Issues on Authorization

- LoA for AR must from parent manufacturer not from regional office;
- Attachment 1 – need to attach the list of medical device authorized from manufacturer / AR;
- LoA for AR – sufficient for AR, Distributor and Importer.

Issues on 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.

Issues on 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.

Issues on 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*)		×	×	×

Issues on Application

- Certificate and reports of GDPMD/ISO13485
  - Must cover all clause in GDPMD/ISO13485, any exclusion need to have justification in the report;
  - Audit report must be signed by the registered auditor;
  - Particulars in the certificate issued by CAB must be in line with the audit report.

Issues on 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, GM, President;
  - Domicile in Malaysia. (residential address in Malaysia) – (employment pass/work permit or Form 49)

Issues on Application

- Contact Person
  - Authorized by Person Responsible;
  - Authorization letter signed by Person Responsible.

- Attestation
  - Using MDA template for attestation form with company letterhead;
  - Shall be signed by Person Responsible.

Issues on Tendering Agent

- Procurement issue (government)
  - Section 2, Medical Device Act 2012 (Act 737) do not mention about Tendering Agent;
  - Licensing - depends on their activities;
  - Not to be licensed - If their activities does not fall under definition of establishment in section 2, Act 737;
  - If their activities are under definition of AR, Distributor, Importer or Manufacturer – need to be licensed.

Issues on Change of AR

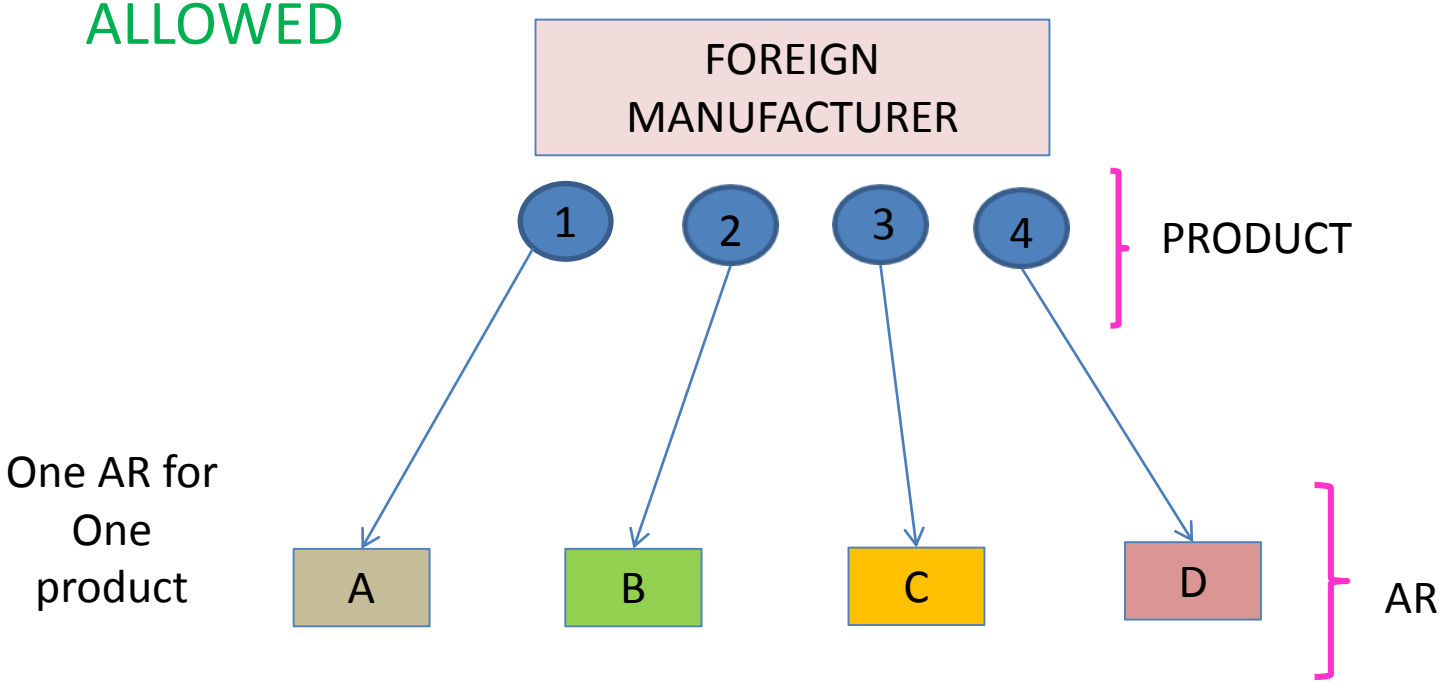
- Previous AR shall notify the MDA with the termination letter from manufacturer;
- Devices in the market sold by previous AR are still under their responsibilities until new AR is licensed;
- New AR shall apply for establishment license and comply with all requirements for establishment license;
- Establishment license for previous AR will be updated once application for new AR is approved;
- Once the new AR is licensed, devices already in the market sold by previous AR are now under New AR.

Issues on Parallel Import

- Multiple AR is not allowed for one device;
- Each medical device imported and placed in Malaysian market shall be represented by a single representative; single AR per medical device registration;
- Manufacturer outside Malaysia having many medical device products to be imported and placed in Malaysia may appoint more than one AR by fulfilling condition above.

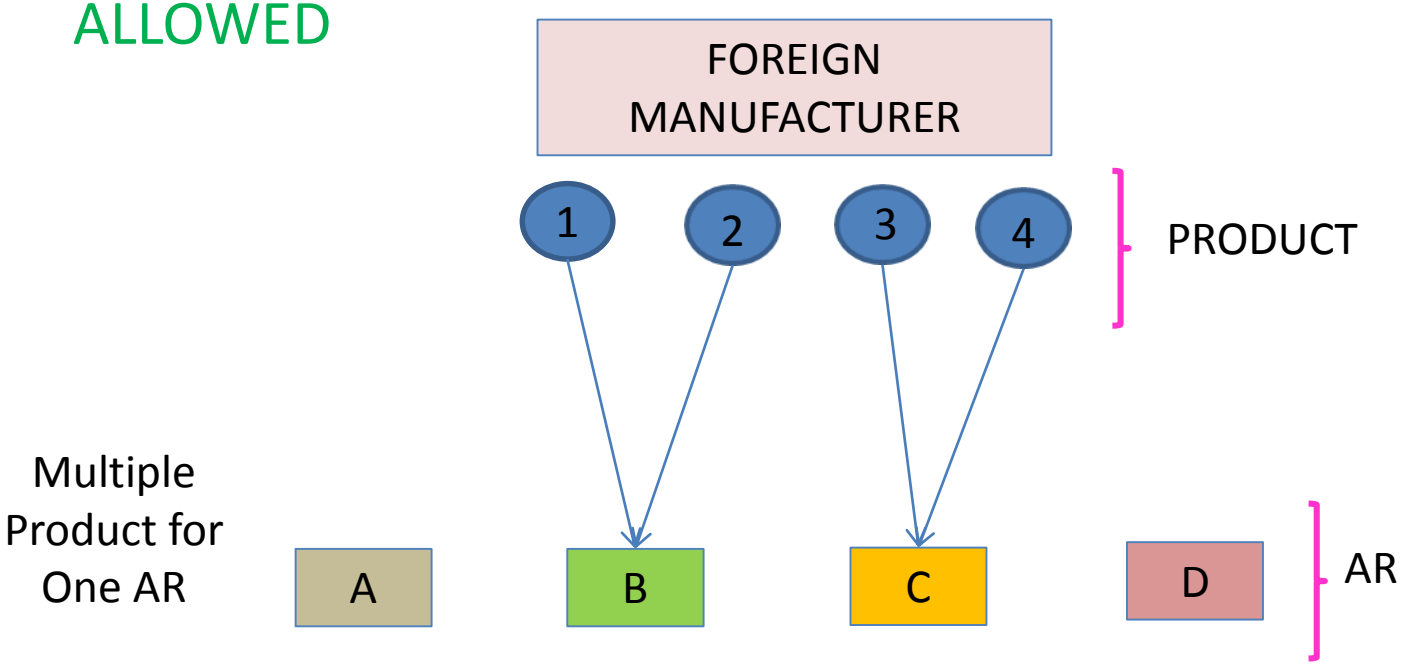
Multiple AR

ALLOWED



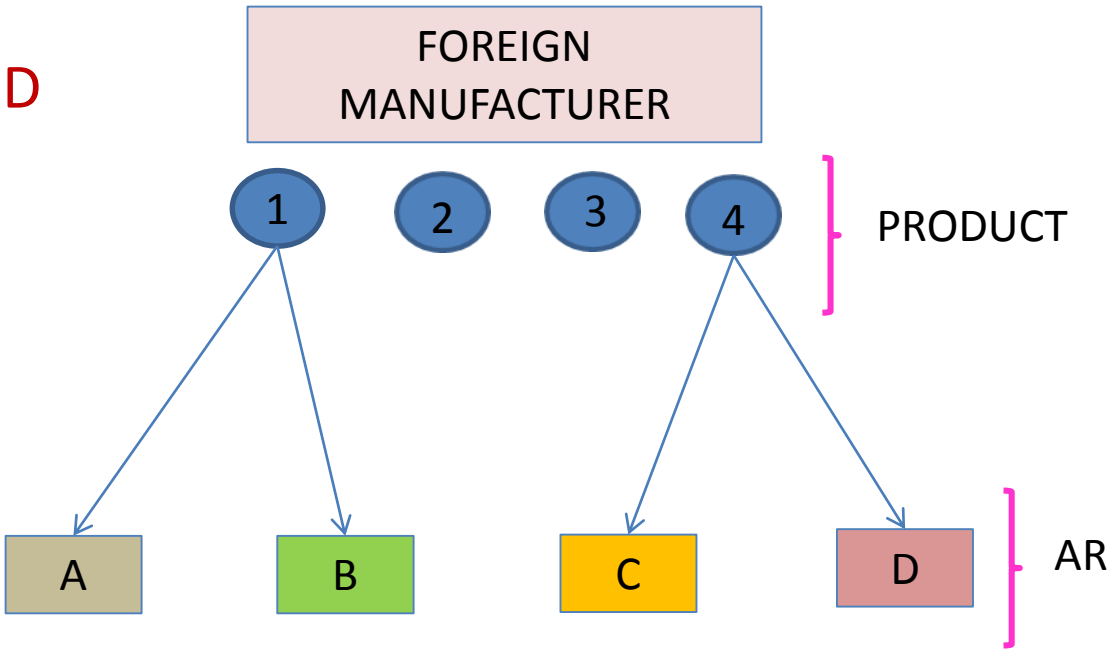
Multiple AR

ALLOWED



Multiple AR

NOT ALLOWED



Multiple AR for One product

Issue on Contract Manufacturer

- Section 2, Medical Device Act 2012 (Act 737), contract manufacturer does not fall under the definition for Manufacturer;
- Not to be licensed.

Updates on GDPMD

- Previous version, MDA/RR No.1: July 2013
- GDPMD updated version, MDA//RR No.1: November 2015 First Revision;
  - Annex 1 : Scope of Certification
  - (5) List of devices dealt with by the establishment—

No	Device Category*

Updates on GDPMD

*List of device categories:

- 01 Active implantable devices
- 02 Anesthetic and respiratory devices
- 03 Dental Devices
- 04 Electro mechanical medical devices
- 05 Hospital hardware
- 06 In vitro diagnostic devices
- 07 Non-active implantable devices
- 08 Ophthalmic and optical devices
- 09 Reusable devices
- 10 Single-use devices
- 11 Assistive products for persons with disability
- 12 Diagnostic and therapeutic radiation devices
- 13 Complementary therapy devices
- 14 Biologically-derived devices
- 15 Healthcare facility products and adaptations
- 16 Laboratory equipment
- 17 Medical software
- 18 Others: Please specify with justification for any additional categories

Updates on GDPMD

Name	Definition
01 Active implantable devices	Devices that operate with an integral power source (i.e., independent of energy from the human body or gravity), that are totally or partially introduced, surgically or medically, into the human body or body-orifice, where they are intended to remain temporarily or permanently. Examples of devices in this category include cochlear implants, implantable defibrillators, implantable infusion pumps, implantable stimulators, pacemakers, and their accessories.
02 Anaesthetic and respiratory devices	Devices used to supply, condition, monitor, dispense, or deliver respiratory or anaesthetic gases, vapours or other substances to provide and/or control respiration and/or anaesthesia. Examples of devices in this category include airways, anaesthesia systems, breathing circuits, humidifiers, tracheal tubes, ventilators, and their accessories.
03 Dental devices	Devices used to diagnose, prevent, monitor, treat, or alleviate oral, maxillo-facial, and dental disease/disorders. Examples of devices in this category include dental amalgam, dental cements, dental hand instruments, dental implants, dental materials, dental tools/laboratory devices, and their accessories.
04 Electro mechanical medical devices	Devices that operate on electrical energy (electromedical) and/or through some integrated physical mechanism or machinery (mechanical). Examples of devices in this category include specialized beds, defibrillators, dialysis systems, electrocardiographs (ECG), electroencephalographs (EEG), endoscopes, infusion pumps, lasers, operation/examination tables/lights, suction systems, and their accessories.

Updates on GDPMD

Name	Definition
05 Hospital hardware	Treatment-related devices that typically are not directly or actively involved in the diagnosis or treatment of patients, but that support or facilitate such activities. Examples of devices in this category include air cleaners, baths, detergents, disinfectants, removable floor coverings/mats, portable incinerators, patient beds, patient transfer equipment, sterilizers, and their accessories.
06 In vitro diagnostic devices	Devices used to examine clinical samples taken from the human body to evaluate physiological or pathological conditions. Examples of devices in this category include analysers, blood glucose monitoring devices, in vitro diagnostic (IVD) test kits/calibrators/controls, dedicated laboratory equipment, microbial sensitivity systems, and their accessories.
07 Non-active implantable devices	Devices without an integral power source that are totally or partially introduced, surgically or medically, into the human body or body-orifice, where they are intended to remain for longer than 30 days. Examples of devices in this category include cardiovascular clips, embolization implants, orthopaedic fixation systems, intrauterine devices, heart valves, bone prostheses, and their accessories.
08 Ophthalmic and optical devices	Devices used to diagnose, prevent, monitor, treat, correct, or alleviate diseases or disorders related to the eye. Examples of devices in this category include contact lenses, keratomes, intraocular lenses, slit lamps, ophthalmic test instruments, phacoemulsification systems, tonometers, and their accessories.

Updates on GDPMD

Name	Definition
09 Reusable devices	Devices that can be used for more than one application period, often involving cleaning and/or sterilization between the periods (excluding capital equipment). Examples of devices in this category include drills, elastic bandages, haemostats, medicine administration kits, saws, scar management garments, reusable surgical instruments (chisels, scissors, retractors, scalpels), and their accessories.
10 Single-use devices	Devices intended to be used only once, or for only one patient during one medical procedure or short term, and then discarded if not already rapidly absorbed. Examples of devices in this category include adhesive tapes, bandages, blood collection devices, catheters, condoms, dressings, electrodes, kits/sets (biopsy, intravenous infusion), needles, single-use surgical instruments/products (cannulae, scalpels, absorbents), and disposable bedding.
11 Assistive products for persons with disability	Devices specially produced or adapted which compensate for, relieve, prevent, or neutralize an impairment, disability, or handicap. Examples of devices in this category include artificial limbs, audiometers, crutches, hearing aids, lifts, orientation aids, rehabilitation devices, wheelchairs, and their accessories.
12 Diagnostic and therapeutic radiation devices	Devices that use radiation energy including in vivo isotopes, excited particle energy, magnetic resonance imaging, nuclear energy, ultrasound, and x-ray for the purpose of providing diagnostic imaging and/or therapeutic radiation treatment. Examples of devices in this category include accelerator systems, bone absorptiometric systems, computed tomography (CT) systems, magnetic resonance imaging (MRI) systems, positron emission tomography (PET) systems, X-ray systems, and their accessories. Radiant warming and phototherapy devices are excluded.

Updates on GDPMD

Name	Definition
13 Complementary therapy devices	Devices that use traditional or alternative methods to diagnose or treat illness. These devices may be used alone or to complement allopathic medicine. Commonly their use is related to the body's innate energy system. Examples of devices in this category include acupuncture needles/devices, bio-energy mapping systems/software, magnets, moxibustion devices, and suction cups.
14 Biologically-derived devices	Devices incorporating human and/or animal tissues or cells, or tissue-derived products (excluding in vitro diagnostic products). Examples of devices in this category include tissue heart valves, biological products for tissue regeneration, and natural grafts.
15 Healthcare facility products and adaptations	Building-related products and furnishings for the function and utilization of healthcare facilities, or for home healthcare, which are not involved in patient diagnosis or disease-related treatment. Examples of products in this category include electrical outlets, safety systems (e.g., electrical fail-safe systems, personnel assistance warning systems), fixed generators, sanitation products (e.g., special toilets and baths for routine hygiene), permanent floor/wall coverings, goods transportation systems, adapted and standard furniture, and their accessories.

Updates on GDPMD

Name	Definition
16 Laboratory equipment	Devices used to contain, handle, process, measure, examine, and identify clinical specimens or other substances typically in the evaluation of physiological and pathological conditions. Examples of devices in this category include analysers, microscopes, microtomes, centrifuges, scales and balances, test tubes, pipettes, cabinets, containers, and the equipment necessary to manage a laboratory.
17 Medical software	Computer programs and related data designed for use in a parent medical device, or as a stand-alone medical device, intended to provide a variety of functions such as: to help drive and/or influence a process or procedure, receive, collect, store, manage [data manipulation (e.g., calculations)], assist in analysis of, display, output, and distribute data within the parent device or between other medical or non-medical devices and/or healthcare facilities. It is typically supplied pre-installed in a parent device, or as an update, or is installed on an electronic medium for installation into an existing computer(s)/network or Internet-based software. Examples of devices in this category include operating system software, application program software (e.g., blood bank information systems, clinical-coding information systems), diagnostic digital imaging systems, IVD software, and web-based software.

Medical Device AUTHORITY MALAYSIA

THANK YOU