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Malaysia Medical Device Regulations

Passed in 2012, the Medical Device Act (Act 737) and the Medical Device Authority Act 2012 (Act 738) represent the first efforts by Malaysia to implement mandatory safety requirements for the medical device market in Malaysia. Regulations under the Medical Device Act (Act 737) replaced the country's voluntary product registration scheme, originally established in 2006. Now all medical devices manufactured, imported, or distributed in Malaysia require a registration.

The Medical Device Authority (MDA) is a division of the Ministry of Health Malaysia (MOH) in charge of regulating medical device and its industry players in Malaysia.

MDA guidelines related to establishment license and medical device registration

The MDA has taken into account concerns from various stakeholders and has made efforts to facilitate the implementation of Medical Device Regulations. In this context, the circular letters below have been issued:

Circular letter No. 1, 2014	Establishment as Authorized Representative and establishment undertaking multiple activities
Circular letter No. 2, 2014	Conformity assessment procedures for medical device approved by recognized countries
Circular letter No. 4, 2014	Medical device for the purpose of export and transit, and medical device for import/export from/to countries without diplomatic ties with Malaysia
Circular letter No. 5, 2014	Certification of Good Manufacturing Practice (GMP) for the purpose of obtaining establishment license
Circular letter No. 1, Year 2016	Refurbishment of medical devices
Medical Device Act 2012 [Act 737] Order	Medical Device Exemption Order 2016 (gazetted on April 18, 2016)

Establishment license

Definitions of "establishment" under Act 737, section 2:

1) 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
2) An Authorized Representative appointed by a manufacturer having a principal place of business outside Malaysia. An Authorized Representative is a person domiciled or resident in Malaysia or a firm/company constituted under the laws of Malaysia.

For the purpose of placing a medical device in the market: manufacturer, Authorized Representative of foreign manufacturer, importer, and distributor shall establish, maintain and implement an appropriate quality management system that is commensurate with the role and function of the establishment and in compliance with the requirements below:

Type of establishment	Quality management system
Manufacturer	ISO 13485
Authorized Representative	Good Distribution Practice of Medical Devices (GDPMD)
Importer	Good Distribution Practice of Medical Devices (GDPMD)
Distributor	Good Distribution Practice of Medical Devices (GDPMD)

Requirement of quality management system

Upon completion of the conformity assessment procedure, an establishment may apply for:

1) Establishment license
2) Registration of medical devices

To register a medical device, a manufacturer must retain the services of a Conformity Assessment Body (CAB) licensed by the Medical Device Authority.

As part of the conformity assessment process, the CAB will conduct a technical file review, a product verification, and an audit of the manufacturer's/Authorized Representative's/importer's/distributor's quality management system (ISO 13485 or GDPMD). Certified applications are then submitted to the Medical Device Authority through an online registration system called MeDC@St for final review and approval.

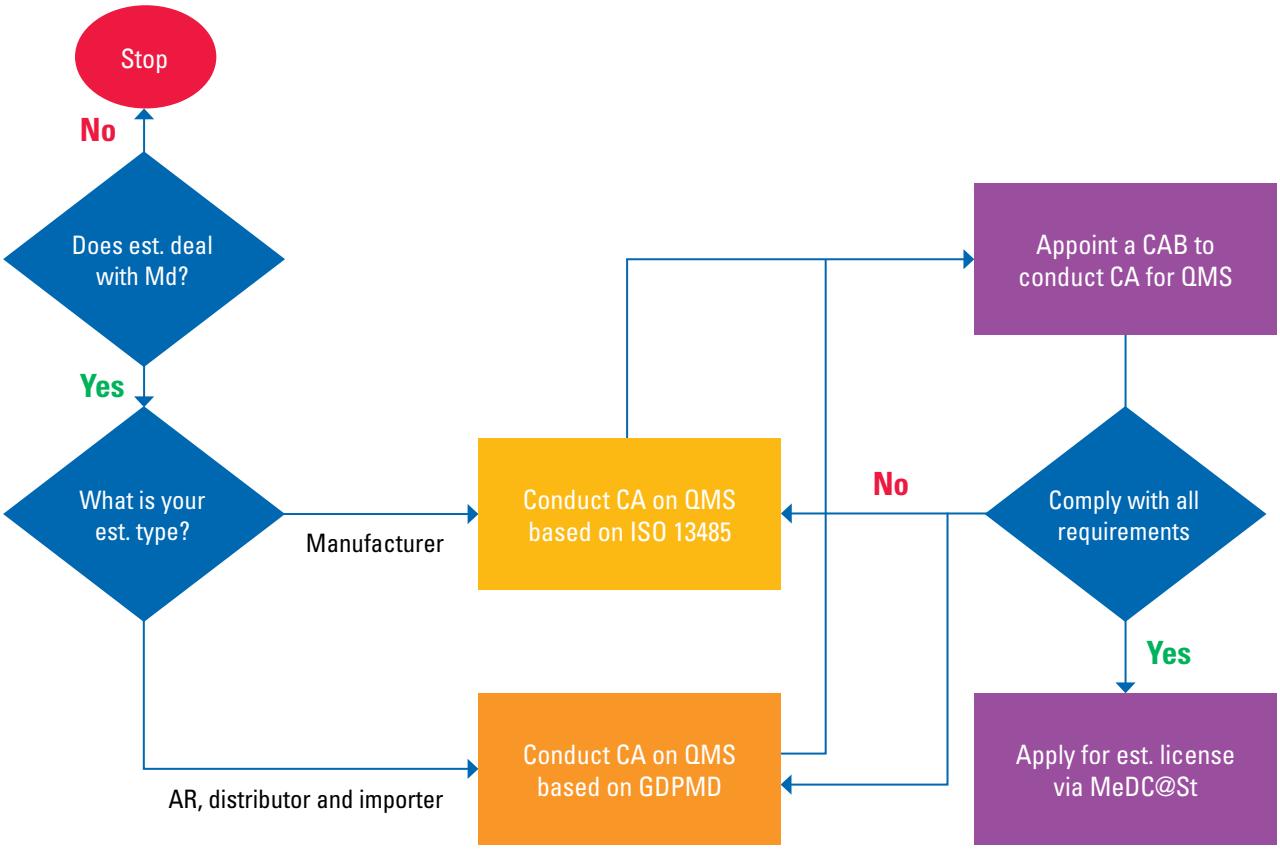

Figure 1: Conformity assessment of quality management system

Application for establishment license

Application for establishment license 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. License issued is valid for a period of three years. Renewal shall be made to the MDA not later than one year before its expiry date.

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 shall have the overall control and the authority to make decisions, e.g. CEO, MD, GM, president, and must be domiciled in Malaysia (residential address in Malaysia, work permit or Form 49).

Change of Authorized Representative (AR)

New AR must notify the MDA with Letter of Authorization (LoA) and confirmation about the change of AR from manufacturer. New AR apply for establishment license and comply with all requirements for establishment license. Establishment license for previous AR will be updated/amended once application for new AR is approved.

Multiple Authorized Representatives (AR)

Multiple AR are 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. Manufacturers outside Malaysia importing and placing many medical device products in Malaysia may appoint more than one AR by fulfilling condition above.

Contract manufacturer

Contract manufacturers do not fall under the definition for "manufacturer" of Act 737, section 2 Medical Device Act 2012; not to be licensed.

Registration of medical device

Any application for registration of medical device shall be made to MDA using MeDC@St. The application shall be accompanied with: application fee, supporting documents, any other information required by MDA. Registration of medical device is granted for five years.

Exemption from registration of medical devices:

Medical Device Exemption Order 2016 gazetted on April 18, 2016: The minister exempts any medical device from section 5 of the Act (Act 737) if the medical device is:

1. For the purpose of personal use
2. For the purpose of marketing demonstration
3. For the educational purposes
4. For the purpose of clinical research or performance evaluation of the medical device
5. A custom-made medical device
6. A special access medical device

This exemption is given subject to the Medical Device Authority (MDA) being notified in writing "Exemption From Registration of Medical Devices" form available at www.mdb.gov.my).

All class A medical devices are exempted from conformity assessment procedures by a conformity assessment body under section 7 of the Act.

Steps in Medical Device Registration

Step 1:

- Determine the classification of the medical device according to Appendix I of the Medical Device Regulations 2012 (classification rules are similar to the regulations of the European Medical Devices Directive (MDD) 93/42/EEC). All class A devices are exempted.

Step 2:

- Select a Malaysian Authorized Representative (AR) to manage your medical device registration.

Step 3:

- Prepare the technical file using the Common Submission Dossier Template (CSDT).

Step 4:

Select a registered Conformity Assessment Body (CAB) to perform conformity assessment. Prepare the documentation for the CAB as per requirement stated in Circular #2, including:

- Basic information on the medical device: intended use as described in the CSDT, classification rule as per Appendix 1 of the First Schedule the Medical Device Regulations 2012, Grouping Rule in the Second Schedule of the Medical Device Regulations 2012
- ISO 13485 certificate or other equivalent QMS certificate issued by a recognized Notified Body or regulatory authority granting the certificates
- CE mark certificate and/or certificate of approval by recognized foreign regulatory authority (US, Canada, Japan, Australia, and Europe)
- Post-market surveillance – list of globally reported ongoing incidents (if applicable), list of incidents that have been resolved over the past three years (if applicable), date of last audit
- Common Submission Dossier Template (CSDT); labeling in accordance with the Sixth Schedule of the Medical Device Regulations 2012
- Declaration of conformity

Step 5:
- CAB reviews the documentation and issues certification upon favorable review.

Step 6:
- Prepare submission application according to the requirements of the Medical Device Regulations 2012 and applicable guidance documents.

Step 7:
- Establishment: Authorized Representative (AR), importers, distributors/manufacturers submit application electronically via MeDC@St. Pay fee. All documents can be submitted in English. Devices for home use must have IFU and labeling in Malay language.

Step 8:
- MDA verifies classification. Evaluation of application: approval or rejection.

Step 9:
- Upon approval, your product is added to the MDA's list of registered medical devices. Registrations must be renewed every five years. Registration completed.

For more information

Malaysia Medical Device Authority: **www.mdb.gov.my**

Services offered by TÜV SÜD Malaysia

As a registered Conformity Assessment Body (CAB) with the Malaysia Medical Device Authority (MDA), with CAB number MDA/CAB-001, TÜV SÜD Malaysia carries out conformity assessments including:

Quality system audit services (GDPMD and ISO 13485) for establishment licensing

TÜV SÜD Malaysia is qualified to conduct audits of a manufacturer's quality management system as required by the provisions of the MDA, including Good Distribution Practice of Medical Device (GDPMD) and ISO 13485.

Product verification and CSDT file review for Medical Device Registration

TÜV SÜD Malaysia is authorized to evaluate and certify registration applications for medical devices which include CSDT file review for product registration. For medical devices already approved in a recognized country (Europe, USA, Canada, Japan, and Australia), TÜV SÜD Malaysia is able to perform product verifications as stated in circular letter No. 2, 2014: Conformity assessment procedures for medical device approved by recognized countries.

Other testing and certification services

In addition to performing conformity assessments of medical devices to MDA requirements, TÜV SÜD Malaysia can also provide biocompatibility testing, electrical safety testing, EMC testing, mechanical/physical testing, and chemical testing for a wide range of medical devices according to relevant standards. In addition, TÜV SÜD as a Notified Body can provide various medical device certifications including EN ISO 13485, CE marking of medical devices, JPAL, CMDCAS, and others.

Your contact partner at TÜV SÜD Product Service can provide further information.

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