**Legal**

**Legal framework:** Yes

**Authorizing legislation:** Medical Device Act 2012


Medical Device Authority Act 2012

http://www.federalgazette.agc.gov.my/outputaktap/20120209_738_BI_JW001759%20Act%20738(BI).pdf - establishes the Medical Device Authority

Medical Device Regulations, 2012


**Guidelines:** Medical Device (Exemption) Order 2015


**National Regulatory Authority**

**National Regulatory Authority present:** Yes

**Name:** Medical Device Authority, Ministry of Health Malaysia http://www.mdb.gov.my/mdb/

**Responsibilities of the NRA:** The MDA’s core competencies include:

- registering medical devices (all classes)
- issuing licenses to manufacturer, distributor, importer, exporter,
- inspecting facilities (establishments)
- monitoring medical devices already on the market
- monitoring operation and usage of medical devices, including disposal
- (laboratory testing)
- drafting laws and standards


**Medical device definition**

**Medical device defined:** Yes

**Text:** A medical device means

(a) any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of--

(i) diagnosis, prevention, monitoring, treatment, or alleviation of disease;
(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(iii) investigation, replacement or modification, or support of the anatomy or of a physiological process;
(iv) support or sustaining life;
(v) control of conception;
(vi) disinfection of medical device; or
(vii) providing information for medical or diagnosis purpose by means of in-vitro examination of specimens derived from the human body which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means; and

(b) any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related articles, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, public health or public risk, declare to be a medical device by order published in the Gazette. Medical Device Act of 2012, § 2.

**In vitro diagnostic medical device (IVD) defined:** Yes

**Text:** Defined, Included in Medical Device definition.

**Medical device classification**

**Classification:** Yes

**Categories:** A, B, C, D Medical Device Regulations 2012, First Schedule Part II: Medical Device Classification

**Classification rules:** Yes

**Classification rules details:** Medical devices are classified based on the level of risk, intended use, and its interaction with the body. Medical Device Act 2012, § 3.

See First Schedule Part I: Rules of Classification of Medical Device. Medical Device Regulations, p.148-151
Essential principles
Essential principles: Yes
Details: A manufacturer shall ensure that a medical device conforms to the prescribed essential principles of safety and performance. Medical Device Act 2012, § 4; 79.2c.

Conformity assessment
Conformity assessment bodies: Yes
Pre-marketing / procedure: Medical Device Regulations, 2012, Third Schedule: Conformity Assessment Procedure

Reliance
Reliance: N/A
Details: N/A
Jurisdictions: N/A

Clinical investigation
Clinical investigation controls: N/A
Details: N/A

Registration and listing
Registration of establishment: Yes
Details: An establishment must have a license before it imports, exports, or places a device in the market. Medical Device Act of 2012, § 15.
Listing of medical devices: Yes
Details: No medical device may be imported, exported, or placed on the market unless it is registered. Medical Device Act 2012, § 5.

Import controls
Import controls: N/A
Details: N/A

Post market controls
Post Market Surveillance: Yes
Details: An establishment entity must monitor safety and performance of the medical device with a post-market surveillance system. Medical Devices Act of 2012, § 38.
Inspection (QMS): Yes
Details: Once the Authority is satisfied that the medical device is manufactured in a proper facility following inspection, then the Authority may register the device. Medical Device Act of 2012, § 7.
Enforcement: Yes
Details: An authorized officer may investigate any potential violations of the Medical Devices Act of 2012. § 50. A Magistrate may issue a warrant to permit an authorized officer to search premises for reasonable cause. Id. § 51. An authorized officer may also investigate without a warrant for reasonable cause. Id. § 52. An authorized officer may also take samples for analysis. Id. § 65. As a general penalty, anyone who violates the Medical Devices Act of 2012 may be liable for a fine and/or a term or imprisonment. § 78.
Adverse event reporting: Yes
Details: An establishment entity must assure that any adverse incident is recorded and evaluated. Medical Device Act, § 38. And, it must report to the NRA any incident anywhere in the world that has led to some level of patient or user harm within specified time periods. Id. § 40.
Field safety corrective action monitoring: Yes
Details: An establishment must undertake corrective or preventive action as to a medical device imported and placed on the market, which may include return, modification, exchange, or destruction of a medical device or the issuance of advice. Medical Device Act of 2012, § 41. An establishment may also recall a defective device but must first provide information to the Authority. Id. § 42.
Advertising: Yes
Details: No person may advertise a medical device unless it has been registered and it complies with other requirements. Advertisements may not be misleading or fraudulent. Medical Device Act of 2012, § 44.
Labelling: N/A
Details: N/A

Limitations: these data reflect a limited view and do not capture what may currently occur within Member States or how they implemented the data. Complete verification of the data may not be immediately possible and inaccuracies may linger. Mis-categorization or non-capture of a country's regulatory framework is possible due to translation and interpretation.