Legal framework: Yes

Authorizing legislation: Health Products (Medical Devices) Regulations 2010b https://www.google.ch/webhp?sourceid=chrome-instant&ion=1&espv=2&ie=UTF-8#q=SFDA+National+provisions+and+requirements+for+medical+devices


National Regulatory Authority present: Yes

Name: Medical Device Branch, Health Sciences Authority http://www.hsa.gov.sg/content/hsa/en.html


Medical device definition

Medical device defined: Yes

Text: A medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of
(a) diagnosis, prevention, monitoring, treatment or alleviation of any disease;
(b) diagnosis, monitoring, treatment, alleviation or compensation for an injury;
(c) investigation, replacement, modification, or support of the anatomy or of physiological process;
(d) supporting or sustaining life;
(e) control of conception;
(f) disinfection of medical devices;
(G) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;
and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means. http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Overview/Regulatory_Framework.html.

In vitro diagnostic medical device (IVD) defined: Yes

Text: Defined Separately

Health Products Act (Medical Devices) Regulations, Third Schedule, Part II, 24.

Medical device classification

Classification: Yes

Categories: Class A, B, C, and D

Health Products Act (Medical Devices) Regulations, Third Schedule, Part I, 1.; see also http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Overview/Regulatory_Framework.html

Classification rules: Yes

Classification rules details: Classification rules are adopted from the GHTF guidance


For purposes of classifying a medical device, a medical device that may be assigned in two or more classes shall be assigned into the higher-risk class. Health Act (Medical Devices) Regulations, 24.

Essential principles

Essential principles: Yes

Details: N/A

Conformity assessment

Conformity assessment bodies: N/A

Details: N/A

Pre-marketing / procedure: The owner of a medical device or its authorized representative is responsible for preparing a declaration of conformity. See Guidance on the Declaration of Conformity, p. 5.

Reliance

Reliance: Yes

Details: N/A

Jurisdictions: USA, Japan
Clinical investigation
Clinical investigation controls: Yes
Details: A person may not supply a registered medical device unless samples are taken and tested, and the Authority is satisfied by the results of the analysis. Health Products Act (Medical Devices) Regulations 2010, 12.

Registration and listing
Registration of establishment: N/A
Details: N/A
Listing of medical devices: Yes
Details: All medical devices used in humans in Singapore must be registered with the Singapore Medical Device Register. The Register is available online and fully searchable. See http://www.hsa.gov.sg/content/hsa/en/Health_Products_Registration/MEDICS_e-Services/Singapore_Medical_Device_Register_smdr_MEDICS.html
For the registration of a medical device, it is required that it is: safe to use, of suitable quality as to its specifications, manufacture, and measures taken to ensure that quality, effective for its intended purpose. Health Products Act (Medical Devices) Regulations, 25.

Import controls
Import controls: Yes
Details: Importers are required to have a license to import. See http://www.hsa.gov.sg/content/hsa/en/Health_Products_Registration/Manufacturing_Importation_Distribution/Overview/Group_Import.html

Post market controls
Post Market Surveillance: Yes
Details: Every manufacturer, importer, supplier, or registrant of a medical device must maintain a record of every received complaint and produce that record for inspection by HSA. The record must contain detailed information. Health Products Act (Medical Devices) Regulations, 41.

Inspection (QMS): Yes
Details: The Authority may conduct inspections or assessments of licensees to determine their compliance with the Act and Regulations, and any applicable licence conditions.
Licensees are required to ensure full compliance with the conditions of the licence. See Medical Device Guidance on Product Registration, Ch. 8.

Enforcement: Yes
Details: There are several penalties for violations of the Health Act (Medical Devices) Regulations.
- 31(5) - A person who contravenes the inspection requirements by the enforcement officer may be punished by fine or imprisonment.
- 41(3), (4) - A person who does not fulfill the requirements to maintain a record of all complaints or knowingly furnishes a misleading record may be liable for a fine or imprisonment.

An enforcement officer may conduct routine inspections of any premises that are used for the manufacture, supply, or storage of medical devices and of any conveyances of medical devices. He or she may also take any samples for testing and examination. Health Products Act (Medical Devices) Regulations, 31.

Adverse event reporting: Yes
Details: Every manufacturer, importer, supplier or registrant of a medical device must report any adverse event the Authority of the event within certain time periods, depending on the gravity of the event. Health Products Act (Medical Devices) Regulations, 42(1); see also id. at 42(2) (defining “adverse event”).

Field safety corrective action monitoring: Yes
Details: Recalls: Every manufacturer, importer, supplier or a registrant that intends to recall a device must notify the HSA. The HSA may inspect the device and provide a report and take other measures it deems appropriate. Health Product Act (Medical Devices) Regulations, 44.
Every manufacturer, importer, supplier, or registrant of a medical device must furnish the HSA with a preliminary report within 24 hours of the recall stating the reason of the recall. Health Product Act (Medical Devices) Regulations, 45.
FSSCAs: Every manufacturer, importer, supplier, or registrant of a medical device must notify the HSA before it carries out an FSCA. The HSA may issue or require the issuance of a public statement. Health Product Act (Medical Devices) Regulations, 46.

Advertising: Yes
Details: If a medical device is intended for public use, that advertisement may not contain any statements on intended use and efficacy unless that statement has been verified by objective evidence and that evidence has been provided to the HSA. Health Products Act (Medical Devices) Regulations, 19. For advertisements that contain an assertion, statement, certification, award, or unique feature, any of the aforementioned must be supported by facts or evidence. Health Products Act (Medical Devices) Regulations, 20.

Labelling: Yes
Details: Trade descriptions (labels?) must not be false or misleading. (Medical Devices) Regulations, 14.
The trade description (label?) must contain the trade/brand name of the device as well as the contact information of the manufacturer if the device is not manufactured in Singapore. Id. at 15.
All information on a label of a medical device must be in English and may be in another language. Health Products Act (Medical Devices) Regulations, 16.

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.