Legal
Legal framework: Yes

Authorizing legislation: Cosmetics, Devices and Drugs Act No. 27 of 1980
http://www.hrclsl.lk/PFF/Library_Domestic_Laws/Legislation_related_to_Environment/
Cosmetics%20and%20drugs%20Act%20No%2027%20of%201980.pdf


Guidelines: N/A

Notes: Sri Lankan law requires application for licenses for all activities related to medical devices, including a license to import, a license to import to conduct clinical investigations, and a license to manufacture. See generally Devices Regulations No. 38.

National Regulatory Authority
National Regulatory Authority present: Yes

Name: Cosmetics, Devices & Drugs Regulatory Authority

Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: Yes

Text:
A medical device is any article, instrument, apparatus or contrivance, including any component, part of accessory thereof; manufactured or sold for use in the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state or the symptoms thereof, in man or animal, restoring, correcting or modifying a body function or the body structure of man or animal, the diagnosis of pregnancy in human beings or animals, or the care of human beings or animals during pregnancy and at and after birth of the off-spring, including care of the off-spring and includes a contraceptive device but does not include a drug. Act No. 27, § 40.

In vitro diagnostic medical device (IVD) defined: N/A

Medical device classification
Classification: N/A

Categories: N/A

Classification rules: N/A

Classification rules details: N/A

Essential principles
Essential principles: N/A

Details: N/A

Conformity assessment
Conformity assessment bodies: N/A

Details: N/A

Pre-marketing / procedure: N/A

Reliance
Reliance: N/A

Details: N/A

Jurisdictions: N/A

Clinical investigation
Clinical investigation controls: Yes

Details: Every applicant for a license to import a device for the purpose of clinical investigations must make a separate application to the Authority. Devices Regulations No. 38, §§ 20-21.
Registration and listing

Registration of establishment: Yes
Details: The Cosmetics, Devices and Drugs Authority maintains a registry of devices that contains the name of the device, the manufacturer, the country of the manufacturer, the registration number assigned to the device, the name and address of the holder of the certificate of registration, and the license number issued to the registrant. It also maintains a registry of imported devices, the name of the importer and its address, the date of issue of the importation license, and the number and date of the certificate of registration. Devices Regulations No. 38, ¶¶ 3, 17, 34.

Listing of medical devices: Yes
Details: The Authority keeps a register of all devices, including imported ones. Devices Regulations No. 38, ¶¶ 3, 17.

Import controls

Import controls: Yes
Details: No person may import a device that may cause injury when used under customary or usual use or according to the directions on the label. Act No. 27, ¶ 5. Further, no person may import a device without a license from the Cosmetics, Devices, and Drugs Authority. See ¶ 6.

No person may import a registered device unless that person has a license to import. Devices Regulations No. 38, ¶ 9-11.

Every license to import a device is subject to conditions:
- the importer must allow any officer from the Authority to enter premises where the device is stored to inspect and test/examine the devices
- the importer must furnish samples
- if the device is found not to be in conformity, the importer must withdraw the batch
- the importer must maintain a record of all imports, sales, and supplies and provide the record for inspection. Devices Regulations No. 38, ¶ 12.

Post market controls

Post Market Surveillance: N/A
Details: N/A

Inspection (QMS): N/A
Details: N/A

Enforcement: Yes
Details: An Authorized Officer may inspect, at any time, any article (defined to include medical devices) and take samples as well as examine anything related to the manufacture, preparation, preservation, packaging, or storage of the article. Act No. 27, ¶ 22.

Following analysis of the device, the Authorized Officer will issue a certificator or report on results. Act No. 27, ¶ 24.

Adverse event reporting: N/A
Details: N/A

Field safety corrective action monitoring: N/A
Details: N/A

Advertising: Yes
Details: No person may advertise a device in a manner that is false, misleading, deceptive, or likely to create an erroneous impression regarding its composition, merit or safety. Act No. 27, ¶ 7(1).

No person may advertise a device in a manner that does not conform to established standards. Act No. 27, ¶ 8.

Device labels must contain information on the brand name, any special storage conditions, any warnings, the date of manufacture, the date of expiry, the batch or lot number, the name and address of the manufacturer, and adequate directions for use. Devices Regulations No. 38, ¶ 40.

Labelling: Yes
Details: No person may label a device in a “manner that is false, misleading, deceptive, or likely to create an erroneous impression regarding its composition, merit or safety.” Act No. 27, ¶ 7(1); see also Devices Regulations No. 38, ¶ 44.

No person may label a device in a manner that does not conform to established standards. Act No. 27, ¶ 8.

No person may import advertising materials for a device that is not registered with the Authority. Devices Regulations No. 38, ¶ 43.

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.