Legal

Legal framework: Yes


Director-General Circular 1/95: accessories, devices and medical implants (Jan. 1995)

Procedure 47: Classification of a medical product as a medicinal or medical device (Sept. 2002)


Notes: The Law on Medical Devices of 2012 has not entered into force since its publication is contingent on the completion of amendments to related regulations.

National Regulatory Authority

National Regulatory Authority present: Yes

Name: Medical Device Department, Ministry of Health http://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechNOlogies/MLD/Pages/default.aspx

Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes

Text: Medical equipment - each described below, and except as defined in the preparation Pharmacists [New Version], 1981;

(1) Device used for medical treatment, as well as a device or computer program needed to run such an instrument; In this regard, “device” - including accessory, chemical, or biological product biotechnological product;

(2) Contact lenses;


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

Text: 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: Importers are required to provide certification issued by a competent authority to show that the medical device has obtained USA FDA approval, EU CE marking, Australian, Canadian or Japanese regulatory approval.

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: All companies wishing to import medical equipment or devices must be registered with the Ministry of Health and have a local agent or distributor.
Listing of medical devices: Yes
Details: Medical devices must be registered by the Ministry of Health in order to be purchased by state-owned institutions.

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

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): Yes
Details: http://www.knesset.gov.il/privatelaw/data/18/3/337_3_2.rtf
Enforcement: N/A
Details: N/A
Adverse event reporting: N/A
Details: N/A
Field safety corrective action monitoring: N/A
Details: N/A
Advertising: N/A
Details: N/A
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.