Ireland

Legal

Legal framework: Yes
Authorizing legislation:

Guidelines:

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Health Products Regulatory Authority http://www.hpra.ie/
Responsibilities of the NRA:
- Responsibilities of the HPRA are: monitoring the safety of medical devices in Ireland after they are placed on the market.
- to designate and continuously monitor the performance of the Irish Notified Body which must have the capability to assess and approve specific medical devices.
- operate a national reporting system for medical devices
- carry out on site audits of selected manufacturers of medical devices to monitor compliance with relevant standards and legislation.
http://www.hpra.ie/homepage/medical-devices/medical-devices-information

Medical device definition

Medical device defined: Yes
Text:

Device means a medical device, that is to say an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which—

(a) is intended by the manufacturer to be used 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 or handicap,
(iii) investigation, replacement or modification of the anatomy or of a physiological process, or
(iv) control of conception; and

(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means. S.I. No. 252/1994, § 2.

In vitro diagnostic medical device (IVD) defined: Yes

Medical device classification

Classification: Yes
Classification rules: Yes

Essential principles

Essential principles: Yes
Details: All devices placed on the market or put into service must comply with the relevant essential requirements. S.I. No. 252/1994, § 5

Conformity assessment

Conformity assessment bodies: Yes
The Minister may designate and withdraw designation of a notified body. S.I. No. 252/1994, § 17.
Pre-marketing / procedure: YES
S.I. No. 253/1994, § 6, details the conformity assessment procedure for active implantable medical devices:
- A device may bear the CE marking only if the manufacturer (a) follows the EC declaration of conformity or (b) follows the EC-type examination procedure with a verification procedure or a declaration of conformity.
Reliance
Reliance: Yes
Details: N/A
Jurisdictions: EU

Clinical investigation
Clinical investigation controls: Yes
Details: The manufacturer must provide notice to the Minister before it may conduct a clinical investigation depending on the class of medical device. S.I. No. 252/1994, § 16; see also S.I. No. 253/1994, § 10.

Registration and listing
Registration of establishment: Yes
Details: A manufacturer who places a device on the market shall ( a ) inform the Minister of his registered address; and ( b ) supply the Minister with a description of the device which is sufficient to identify it. (2) A person engaged in the activities referred to in article 11 within the State shall— ( a ) inform the Minister of his place of business; and ( b ) supply the Minister with descriptions of the devices to which article 11 applies which are sufficient to identify them. (3) A person in the State who has been designated by a manufacturer who does not have a registered place of business in the Community to place on the market a device referred to in sub article (1) shall inform the Minister of ( a ) his registered place of business; and ( b ) the type of device. S.I. No. 252/1994 § 14. Listing of medical devices: N/A
Details: A person in the State who has been designated by a manufacturer who does not have a registered place of business in the Community to place on the market a device referred to in sub article (1) shall inform the Minister of ( a ) his registered place of business; and ( b ) the type of device S.I. No. 252/1994 § 14.3 The manufacturer may be required to submit to the Minister a list of custom-made devices which have been put into service in the State. S.I. No. 252/1994 § 15

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

Post market controls
Post Market Surveillance: Yes
Details: Post-market surveillance is carried out either by (1) proactive surveillance or (2) for cause audit. Proactive surveillance is carried out according to what HPRA deems appropriate and a for-cause audit is conducted as a result of a market issue. Guide for Medical Device Manufacturers, §6.

Inspection (QMS): Yes
Details: An authorised officer of the HPRA may visit the manufacturing premises to conduct a postmarket surveillance audit. Other technical staff from the HPRA may attend in support of the authorised officer. Guide for Medical Device Manufacturers, §6.

Enforcement: Yes
Details: The S.I. No. 252/1994 provides criminal penalties for interference with the interference of an authorized officer, refusal to comply with the request of that officer, the failure to take reasonable measures to guarantee confidentiality, or contravening other requirements. § 26.

Adverse event reporting: Yes
Details: The Health Products Regulatory Authority publishes adverse events and warnings on its website at http://www.hpra.ie/homepage/medical-devices/safety-information/safety-notices. All adverse events occurring in Ireland should be reported to the HPRA. Users are encouraged to report. Guide to Vigilance System, § 4. The manufacturer bears the responsibility to investigate an incident and reporting the outcome to the HPRA. The HPRA is to be informed of the progress of the investigation with an interim report. The HPRA may contact the manufacturer at any time to determine progress or request information. Guide to Vigilance System, § 7.

Field safety corrective action monitoring: Yes
Details: The Guide to Field safety corrective action (FSCA) adopts the EC’s definition for an FSCA contained in MEDDEV 2.12-1. FSCA applies only to medical devices that have been distributed by the manufacturer. The manufacturer should issue field safety notices (FSNs) when implementing an FSCA, and those FSNs should be sent to the competent authorities of countries, where applicable, and to the relevant notified bodies. § 3, 5. The manufacturer takes on responsibility to determine the need for an FSCA. It should consider the hazard arising form the device, the probability of the hazard, and whether the risk outweighs the hazard caused by the FSCA. On occasion the HPRA may advise manufacturers or their authorized representatives to implement an FSCA. Guide to FSCA, § 4.

Advertising: N/A
Details: N/A

Labelling: Yes
Details: A label must include details on the name and address of the manufacturer. For imported devices, the label must provide the name and address of the importer. S.I. No. 252/1994, Schedule I, §13.

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.