Iceland

World Bank income group: High income

Legal

Legal framework: Yes
Authorizing legislation: Act on Medical Devices, No. 16/2001 (as amended) http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/16012012_Act-on-Medical-Devices-NO-16-2001-as-amended.pdf
Regulation on Medical Devices, No. 934/2010 http://eng.velferdarraduneyti.is/media/Reglugerdir-enska/Regulation-on-Medical-Devices-No-934-2010.pdf
Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Icelandic Medicines Agency http://www.ima.is/
Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes
Text: Medical device means any instrument, apparatus, appliance, material (excluding medicinal products) or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
- a. diagnosis, prevention, examination, treatment or alleviation of diseases,
- b. diagnosis, monitoring, treatment, alleviation or compensation for an injury, disability or impaired capacity,
- c. investigation, change or replacement of an organ or of a physiological process,
- d. prevention of conception.
A device which forms part of a medical device, or which is in any other way connected with the use of a medical device shall also constitute a medical device.
A device which primarily has an effect on or in the human body by pharmacological, immunological or metabolic means does not constitute a medical device, although it may form part of a medical device. In the event of any doubt as to whether a device or item constitutes a medical device, [the Icelandic Medicines Agency] shall decide.
Act on Medical Devices, Art. 1.
In vitro diagnostic medical device (IVD) defined: N/A
Text: N/A

Medical device classification

Classification: Yes
Categories: Devices are categorized by risk into category I, category IIa, category IIb, and category III.
Regulation of Medical Devices, Art. 9
Classification rules: Yes
Classification rules details: Classification rules are set out in Annex IX. Regulation of Medical Devices, Art. 9

Essential principles

Essential principles: Yes
Details: The devices must fulfil basic requirements as prescribed in Annex I, Regulation of Medical Devices, Art 4

Conformity assessment

Conformity assessment bodies: Yes
Details: YES, The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and must supply the manufacturer with an assessment report. Regulation of Medical Devices, Art. 5.3
Pre-marketing / procedure: YES - The conformity assessment procedure varies depending on the classification of medical device. Regulation on Medical Devices, Art. 11

Reliance

Reliance: Yes
Details: Requirements under the Regulation on Medical Devices are considered fulfilled by compliance to harmonized European standards. § 6.
Jurisdictions: EU

Clinical investigation

Clinical investigation controls: Yes
Details: The manufacturer must submit an application for clinical testing of a medical device to the Icelandic Medicines Agency to ensure that the investigation complies with rules of good practice and rules on patients' rights. The Icelandic Medicines Agency may halt the conduct of a clinical investigation in the event of non-observance of the terms governing the investigations. Act on Medical Devices, Art. 9.
For medical devices intended for clinical tests, the manufacturer or its representative will notify the Medical Director of Health and other competent authorities in member states of the EEA, where tests will be conducted. Regulation on Medical Devices, Art. 21.
Registration and listing

Registration of establishment: Yes
Details: The Icelandic Medicines Agency will maintain a register of all parties operating in Iceland that manufacture medical devices or are responsible for marketing. Act on Medical Devices, Art. 8. An Icelandic manufacturer must notify the Medical Director of Health of its address as well as describe the medical device. If the manufacturer who places a device on the market does not have a registered place of work within the EEA, then he will nominate a representative in the EEA. Regulation on Medical Devices, Art. 18.

Listing of medical devices: Yes
Details: The Medical Director of Health will maintain a register of medical devices that are used under his authority. Regulation on Medical Devices, Art. 16. The Medical Director of Health will register all information about manufacturers of medical devices that are based or market in Iceland, which will be used for registration in the European database. Regulation on Medical Devices, Art. 19.

Import controls

Import controls: Yes
Details: Importers are responsible parties that bear certain obligations, including providing information to the Medical Director of Health for surveillance purposes and ensuring proper labels are affixed to the device. Regulation on Medical Devices, Art. 2, 33, and Annex I, para. 13.

Post market controls

Post Market Surveillance: Yes
Details: The Medical Director of Health is responsible for market surveillance in Iceland. Surveillance parties may request necessary information for surveillance, take samples, and make comments. Regulation of Medical Devices, Art. 8. The Icelandic Medicines Agency performs both market surveillance as well as surveillance on the maintenance of medical devices and their use. Surveillance bodies may request data, take samples, and carry out the investigations or tests as necessary. Act on Medical Devices, Art. 10.

Inspection (QMS): Yes
Details: The Notified Body must carry out inspections. Regulation on Medical Devices, Chap. 3; Annex III, Art. 4; Annex VII, Art. 2.

Enforcement: Yes
Details: If the Medical Director of Health bans or imposes other restrictions on the marketing/use of a medical device, then she must inform the EFTA Surveillance Authority and other member states of the EEA. The EFTA then determines whether the measures were justified and issues opinion. Regulation on Medical Devices, Art. 20. If the Medical Director of Health discovers that a device had been wrongly CE marked or lacks a marking, then the manufacturer must ensure the device will be changed, otherwise the Medical Director of Health may limit or ban the device. Regulation on Medical Device, Art. 24. If medical devices threaten the health or safety of patients, users, or other parties, then the Medical Director of Health may remove the device from market or in use. Regulation of Medical Devices, Art. 7. The Medical Director of Health may demand information on how the medical devices are used or a certification on their use. Regulation on Medical Devices, Art. 16.

Adverse event reporting: Yes
Details: Manufacturers that sell, own, or use medical devices that are aware of defects or non-functionality that may injure or damage a user must notify the Icelandic Medicines Agency. Act on Medical Devices, Art. 11. Entities that manufacture, sell, own, or use services are bound to report the Medical Director of Health of incidents and of product withdrawals. Following the Medical Director of Health’s assessment of the incident, then he will inform the EFTA Surveillance Authority and other member states of the EEA. Regulation of Medical Devices, Art. 10.

Field safety corrective action monitoring: Yes
Details: Regulation of Medical Devices, Annex IV

Advertising: N/A
Details: N/A

Labelling: Yes
Details: A medical device must be labelled pursuant to EU rules before it may be placed on the market, sold, or used. The Icelandic Medicines Agency may remove a medical device from market if it poses a danger. Act on Medical Devices, Art. 5. All medical devices must have user instructions that allow for safe use. Medical devices intended for public use must have instructions in Icelandic. Regulation on Medical Devices, Art. 14.

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.