Finland

Legal

Legal framework: Yes
CE-Marking of Medical Devices.

National Regulatory Authority

National Regulatory Authority present: Yes
Name: National Supervisory Authority for Welfare and Health (Valvira) http://www.valvira.fi
Note: surveillance of medical devices is conducted by the National Agency for Medicines
Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes
Text: A medical device is an instrument, apparatus, instruments, software, material or other used alone or in combination device or accessory, which the manufacturer to be used in human:
1) the diagnosis, prevention, monitoring, treatment or alleviation of disease;
2) a defect or disability diagnosis, monitoring, treatment, alleviation of or compensation;
3) investigation, replacement or modification of the anatomy or of a physiological process; or
4) control of conception.
Act on Medical Devices, Sec. 5.
In vitro diagnostic medical device (IVD) defined: Yes
Text: Defined Separately.

Medical device classification

Classification: Yes
Categories: Medical devices are classified on the basis of product characteristics for Class I, IIa, equipment and other devices, IIb and III, as well as in vitro diagnostic medical devices intended to list A and B devices, and devices intended for clinical investigation. Act on Medical Devices, Sec. 7.
Classification rules: Yes
Classification rules details: N/A

Essential principles

Essential principles: Yes
Details: A medical device must comply with essential requirements. Act on Medical Devices, Sec. 6.

Conformity assessment

Conformity assessment bodies: Yes
Details: The notified body must meet the harmonized European standards. Alvira may also lay down the content and application for the authorization of a notified body. Act on Medical Devices, Sec. 32.
The notified body carries out the conformity assessment procedures set out in the EC directives. Act on Medical Devices, Sec. 33. It may also withdraw or cancel a certificate of conformity. Sec. 35, 37.
Pre-marketing / procedure: A manufacturer or its authorized representative may bring a device to market only when it meets all the requirements under the Act on Medical Devices. Sec. 8.
An attestation of conformity by a manufacturer must include a clinical evaluation. Valvira may issued additional regulations on the evaluation. Act on Medical Devices, Sec. 13.

Reliance

Reliance: Yes
Details: The Act on Medical Devices incorporates EC directives
Jurisdictions: EU

Clinical investigation

Clinical investigation controls: Yes
Details: Clinical device trials are regulated under the Act on Medical Devices. Valvira may issue regulations on the procedures to be used in carrying out the research. Sec. 19.
A trial sponsor must provide Valvira notice of the trial. That device need not be CE marked if it does not deviate from the use as intended by the manufacturer for the trial. Act on Medical Devices, Sec. 20.
The regulation on Medical devices for clinical studies details the clinical trial process. notacity, all trials on medical devices that are CE-marked or on devices whose use differs from that of the manufacturer’s intended use must provide notice to Valvira. The responsible person must provide supporting documentation to Valvira, including the agreement between the sponsor and investigators, the opinion of the Ethics Committee, the research plan, information on equipment/supplies, and any other documents.
Registration and listing

**Registration of establishment:** Yes
**Details:** Manufacturers domiciled in Finland shall notify their contact details and information on the products they manufacture for the product register maintained by the National Supervisory Authority of Welfare and Health. [http://www.valvira.fi/web/en/healthcare/health-technology/registration](http://www.valvira.fi/web/en/healthcare/health-technology/registration)

**Listing of medical devices:** Yes
**Details:** Section 54 of the Act on Medical Devices provides for the collection of data on medical devices on licenses (issued, withdrawn, modified, etc.), incidents, and clinical studies. Class _ medical devices must be registered. Chapter 2, section 2. [https://www.valvira.fi/documents/18508/84955/Guideline_3_2005.pdf](https://www.valvira.fi/documents/18508/84955/Guideline_3_2005.pdf)

Import controls

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

Post market controls

**Post Market Surveillance:** Yes
**Details:** The Agency monitors medical devices by maintaining records of the incident, making an evaluation of changes, and taking the necessary health and safety measures. The Agency will also inform the EC and EEC member states of measures that are planned to be taken to prevent the recurrence of incidents. Act on Medical Devices, Sec. 38. [https://www.valvira.fi/documents/18508/85975/Valvira_market_surveillance_programme.pdf](https://www.valvira.fi/documents/18508/85975/Valvira_market_surveillance_programme.pdf)

**Inspection (QMS):** Yes
**Details:** Valvira will have the right to inspect premises and to access information relevant to complying with law. It may be made without notice. Act on Medical Devices, Sec. 39. The inspector may also issue orders to remedy any deficiencies. Sec. 40. It may also take products for examination and testing. Act on Medical Devices, Sec. 41.

**Enforcement:** Yes
**Details:** If a manufacturer or its authorized representative has not complied with the law, the Office may issue an order to comply within a certain time limit. Act on Medical Devices, Sec. 44. If a device is dangerous, used inappropriately, or has a wrongly affixed CE label, the Office may oblige the manufacturer or its representative to bring the device into compliance, prohibit the sale or export, or limit access. Act on Medical Devices, Sec. 46. The Office may also order repair of the device or its withdrawal from market. Act on Medical Devices, Sec. 47-48.

Section 59 of the Act on Medical Devices provides penalty provisions for intentional or grossly negligent failure to comply with provisions of the Act. Valvira will also have the right to inspect premises and to access information relevant to complying with law. It may be made without notice. Act on Medical Devices, Sec. 39. The inspector may also issue orders to remedy any deficiencies. Sec. 40. It may also take products for examination and testing. Act on Medical Devices, Sec. 41.

**Adverse event reporting:** Yes
**Details:** A manufacturer must inform Valvira of any adverse events or any deficiencies in the characteristics of the device, inadequate labelling, or improper documentation. Act on Medical Devices, Sec. 15. A professional user must also inform Valvira of any adverse events. Sec. 25.

**Field safety corrective action monitoring:** Yes
**Details:** The manufacturer or his authorized representative must take measures for the existing devices to correct the issue in a medical device, so that the health risk resulting from its properties or performance flaw or imperfection; and to remove them from the market medical devices which, due to technical or medical reasons can cause a health risk to the patient, user or other person. If a medical device or device group is liable to endanger the health, safety or public health, the Agency may prohibit the sale of the device. Act on Medical Devices, Sec 47-48.

**Advertising:** Yes
**Details:** False advertising of medical devices is prohibited. Act on Medical Devices, Sec. 11.

**Labelling:** Yes
**Details:** The manufacturer must provide safety information for the device in Finnish, Swedish, or English. The information must be in Finish and Swedish if the information is intended for a user or patient or if it is a custom-made medical device Act on Medical Devices, Sec. 12.