Estonia

Legal

Legal framework: Yes
Guidelines: Requirements for medical device design, manufacturing, packaging, and medical device information https://www.riigiteataja.ee/akt/130042014004
Rules for the Classification of Medical Devices https://www.riigiteataja.ee/akt/130042014006

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Medical Devices Department, Estonian Health Board http://www.terviseamet.ee/en/medical-devices.html
Responsibilities of the NRA: The Estonian Health Board has supervisory functions, including:
- market supervision
- compliance with requirements for notified bodies and manufacturers by the Act
- notification and investigation of adverse incidents
- organization of clinical investigations
- disputes between a manufacturer and notified body on the classification of devices
- compliance with requirements for professional use of medical devices by health care providers
Estonian Medical Device Act, Sec. 33.

Medical device definition

Medical device defined: Yes
Text: Medical device shall mean any instrument, apparatus, appliance, software, material or other product used on humans, whether used alone or in a combination, including the software determined by the manufacturer specifically for diagnostic or medical treatment purposes which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, intended by the manufacturer to be used for human beings for the purpose of:
1) diagnosis, prevention, monitoring, treatment or alleviation of diseases;
2) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
3) investigation or modification of the anatomy or of a physiological process or replacement of a part of body;
4) assisting or prevention of conception.
(2) If a product complies with the requirements specified in subsection (1) of this section, the Health Board shall have the right to identify the product as a medical device.
Estonian Medical Devices Act, Sec. 2.

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

Medical device classification

Classification: Yes
Categories: Medical devices, except IVDs, are classified by risk into four categories, class I, II a, II b, and III.
Estonian Medical Devices Act, Sec. 19.
Classification rules: Yes
Classification rules details: See Guideline: Rules for the Classification of medical devices.

Essential principles

Essential principles: Yes
Details: A medical device may only be placed on the Estonian market if it meets the requirements of the Estonian Medical Devices Act, the device has gone through a clinical evaluation or investigation, conformity assessment has been carried out, and the device is accompanied by conforming information necessary for identification of the manufacturer. Sec. 16.

Conformity assessment

Conformity assessment bodies: Yes
Details: After conducting a conformity assessment, the notified body will issue a certificate of conformity. The notified body has the right to suspend or revoke a certificate of conformity. Estonian Medical Devices Act, Sec. 23.
Pre-marketing / procedure: Yes, a manufacturer must provide a clinical evaluation of the medical device prior to a conformity assessment, which is based on harmonized standards. Estonian Medical Devices Act, Sec. 20.
The Medical Device Conformity Assessment Procedure details conformity assessment for medical devices.
Reliance
Reliance: Yes
Details: Estonia, as a member of the EU, incorporates EC directives into its laws. CE markings suffice for conformity assessments.
Jurisdictions: EU

Clinical investigation
Clinical investigation controls: Yes
Details: Clinical investigations involving a medical device are regulated pursuant to section 21 of the Estonian Medical Devices Act. https://www.riigiteataja.ee/akt/129122010165?leiaKehtiv
The Medical device clinical trial conditions and procedures regulation details the framework for trials.
Import aspects include:
- participant recruitment
- conditions to terminate a trial
- reporting requirements.

Registration and listing
Registration of establishment: N/A
Details: N/A
Listing of medical devices: Yes
Details: The manufacturer of a medical device or its authorized representative must provide data to the European Databank of Medical Devices on medical devices placed on the market, put into service, and distributed as well as any information on adverse incidents, clinical investigations, and supervision. Estonian Medical Device Act, Sec. 29. See also Sec. 26.

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

Post market controls
Post Market Surveillance: Yes
Details: The manufacturer must establish the post-production phase of a medical device for the treatment of information obtained from a systematic control procedures and update it regularly. Also, the manufacturer must take the necessary steps to correct the process, on the basis of the information collected on the nature and the risks associated with the device. Medical Device Conformity Assessment Procedure, Art. 13.
Inspection (QMS): Yes
Details: Estonian Medical Devices Act (13 Oct. 2004), Ch. 4
Enforcement: Yes
Details: In cases of nonconformity of a medical device, the health Board may initiate a supervisory proceeding to withdraw a device or to prohibit/restrict placing the device on the market. Estonian Medical Device Act, Sec. 34.
Further, violations of the requirements of placing a device on the market, distribution, or professional use of a device may result in fines. Estonian Medical Device Act, Sec. 39.
The notified body will perform surveillance and inspect quality assurance programs by the manufacturer. Procedure for conformity assessment of a medial device, Sec. 27.
Adverse event reporting: Yes
Details: The manufacturer or its authorized representative must inform both the Health Board and a notified body of any malfunction or deterioration. Estonian Medical Device Act, Sec. 27.
The Adverse incident procedures and information regulation details the procedure on adverse incident reporting. Under the regulation, the health board must lodge records of the incident pursuant to section 4. https://www.riigiteataja.ee/akt/110022011002?leiaKehtiv.
Field safety corrective action monitoring: Yes
Advertising: N/A
Details: N/A
Labelling: Yes
Details: The Requirements for medical device design, manufacturing, packaging, and medical device information provides detailed labelling requirements on medical devices, although none of those requirements pertain to the language of the label.
According to the Health Board’s website, information on packaging must be in English, and it is good practice to add the name an address of the distributor, if the product has been made outside of Estonia. http://www.terviseamet.ee/en/medical-devices.html.

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.