Legal


Guidelines: 

National Regulatory Authority

National Regulatory Authority present: Yes
Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes
Text: A medical device is an instrument, apparatus, gadget, software, material or other article, whether used alone or in combination, including the software has its manufacturer to be used specifically for diagnostic and (or) for therapeutic purposes and necessary for its proper use, and fuel manufacturer it intends to use the human disease diagnosis, prevention, monitoring, treatment or alleviation; an injury or disability diagnosis, monitoring, treatment, alleviation of or compensation; anatomy or of a physiological process, replacement or modification; control of conception, and which does not use the designated human body from the inside or i_ori_kai pharmacological, immunological or metabolic means, but of this measure can be used as a supplementary means of action. MS 4, 7.

In vitro diagnostic medical device (IVD) defined: Yes
Text: MS 4, Art. 7.

Medical device classification

Classification: Yes
Categories: Medical devices are divided into classes I, IIa, IIb, and III according to risk. MS 102, 17-19.
Classification rules: N/A
Classification rules details: N/A

Essential principles

Essential principles: Yes
Details: A device may only be placed on the market if it is in line with the requirements of MS 4, 8.

Conformity assessment

Conformity assessment bodies: Yes
Details: Notified bodies must inform any modifications, suspensions, supplemented, etc. certificates of conformity, MS 4, 49-55.

Pre-marketing / procedure: Class III devices must either comply with the EC declaration of conformity or follow the EC-type procedure, be it the verification or declaration of conformity procedure. MS 4, 20-22. Class IIb and I devices must follow other procedures. MS 4, 23-24.

Reliance

Reliance: Yes
Details: N/A

Jurisdictions: EU - When a device is designated with a CE marking, then it is deemed to comply with the requirements of the MN 102, 21.

Clinical investigation

Clinical investigation controls: Yes
Details: The manufacturer or his authorized representative may only proceed with a clinical trial following the approval of the Ministry of Health. MS 4, 46-48.
Registration and listing

Registration of establishment: Yes
Details: A registered manufacturer or its authorized representative (if the manufacturer does not have an enterprise in an EU member state) must submit its name, information on the product, etc. to the National Accreditation authority. NM 102, 39. Further, the State Accreditation Service must provide the European data bank with information on the manufacturers and devices, changes to a certificate of conformity, and data generated in monitoring adverse events. NM 102, para. 50-51; see also MS 4, 59-60.

Listing of medical devices: Yes
Details: N/A

Import controls

Import controls: N/A
Details: N/A

Post market controls

Post Market Surveillance: N/A
Details: N/A

Inspection (QMS): Yes
Details: Lithuanian Medical Standard MS 4 Annex 2.

Enforcement: N/A
Details: N/A

Adverse event reporting: Yes
Details: The manufacturer must inform the Agency about adverse events. NM 102, paras. 45-49.

Field safety corrective action monitoring: Yes
Details: A manufacturer shall provide and maintain a systematic procedure to review experience gained in the post-production of medical devices in the period, including the Annex 10 of the provisions, and to implement appropriate means to apply any necessary corrective action. MS 4 2009. Annex 2, 3.1.7

Advertising: N/A
Details: N/A

Labelling: Yes
Details: The label must contain the following information: the name or trade name and address etc. MN 102, 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.