Legal
Legal framework: Yes
Rules on Medical Devices, No. 66/10 http://www.uradni-list.si/1/content?id=109690
Rules on the manufacturing and trade with medical devices, No. 37/10 http://www.uradni-list.si/1/objava.jsp?urlid=201037&stevilka=1777

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia http://www.jazmp.si/en/medical_devices/
Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: Yes
Text: A medical device is any instrument, apparatus, appliance, material 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:
- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of the sequels of injuries or damage, or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomical features or physiological processes of the organism, or
- conception control;
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. Act on Medical Devices, Art. 3.
Note: Active, active implantable, and in vitro medical devices are all defined separately.

In vitro diagnostic medical device (IVD) defined: Yes
Text: Defined separately.

Medical device classification
Classification: Yes
Categories: Medical devices are classified based on the level of risk for the user, the location and method of use, the dependence on a power source, useful life and other characteristics. As to the level of risk, medical devices are categorized into classes I, IIa, IIb, and III. Act on Medical Devices, Art. 16.
Classification rules: Yes
Classification rules details: Art. 4 of Act on Medical Device refers for the Classification rules to Annex IX of Directive 93/42 / EEC

Essential principles
Essential principles: Yes
Details: A medical device may be placed on the market and/or put into use only if it complies with the basic requirements of the Act. Act on Medical Devices, Art. 19.

Conformity assessment
Conformity assessment bodies: Yes
Details: A notified body guarantees that the manufacturing process or medical device meets the requirements by means of an EC certificate. Act on Medical Devices, Art. 9.
Pre-marketing / procedure: Conformity assessment procedures vary depending on the classification of the device. Act on Medical Devices, Arts. 22-23.

Reliance
Reliance: Yes
Details: Medical devices that meet national standards that are adopted on the basis of harmonized standards are deemed to meet the conformity requirements under Slovenian law. Act on Medical Devices, Art. 21.
Clinical investigation

Clinical investigation controls: Yes
Details: Clinical investigations of a medical device means an assessment of its safety and performance in compliance with the intended use as indicated by the manufacturer of devices. Act on Medical Devices, Art. 38.
An applicant for a clinical investigation may be a manufacturer or its representative. Before commencement, the applicant must notify the competent body and submit an application that includes data on the device, the plan of investigation, and the opinion of the Slovenian Medical Ethics Board. Act on Medical Devices, Art. 39.

Registration and listing

Registration of establishment: Yes
Details: A manufacturer of medical devices or its representative with an office within Slovenia must notify itself to the competent body and put its name, address, and name of devices. Act on Medical Devices, Arts. 45, 47.
Listing of medical devices: Yes
Details: After a manufacturer or its representative notifies the competent body that deals with registration of medical devices, the body must inform the EC and members of the EU of that data. Act on Medical Devices, Art. 49.

Import controls

Import controls: Yes
Details: A legal entity (which must be a manufacturer in the EU or its authorized representative in the EU) may only import medical devices that are compliant with the requirements of the Act on Medical Devices. The importer must make sure that the device manufacturer carried out adequate conformity assessment procedure, ensure that the manufacturer complied with technical documentation, state on the device the name of the contact for information about the device, and make available the EC declaration of conformity. See Art. 54.

Post market controls

Post Market Surveillance: Yes
Details: Manufacturers or their representatives and legal entities must establish and maintain their own system of vigilance. Act on Medical Devices, Art. 56.
Inspection (QMS): Yes
Enforcement: Yes
Details: The competent body for medical devices supervises medical devices. Inspectors may prohibit or withdraw medical devices that are not in compliance, order appropriate tests to assess compliance, collect samples, prohibit advertisements, and order other measures. Act on Medical Devices, Art. 65. Penalties are available for violations of certain provisions of the Act on Medical Devices. Art. 66–67.
Adverse event reporting: Yes
Details: Manufacturers or their representatives and legal entities must establish and maintain their own system of vigilance. Manufacturers of medical devices or their representatives and importers must inform the competent body with 24 hours of any adverse event. Healthcare providers must also inform the competent body within 24 hours of the occurrence and they may also inform the manufacturer or its representative. The manufacturer or its representative must investigate the complication and report its findings to the competent body for medical devices. It must then inform the EC and other competent bodies within the EU on any measures taken to rid the event. Act on Medical Devices, Art. 56.
Field safety corrective action monitoring: Yes
Details: Legal entities must ensure that adequate measures are taken to eliminate deficiencies or, if necessary, withdraw or recall the medical device. If a medical device threatens the life or health of people, a legal entity shall immediately inform the body competent for medical devices. Act on Medical Devices, Art. 52.
Advertising: Yes
Details: It is prohibited to advertise medical devices (except for those that are at presentations) that do not comply with the Act on Medical Devices. Art. 58. Advertisements may not be misleading. Id. At 59–60.
Labelling: Yes
Details: Instructions for for use of a medical device must be written in Slovenes. If translated, the contents must be the same. The Minister of Health will lay down more specific guidance. Act on Medical Devices, Art. 33.

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.