Legal

Legal framework: Yes
Ordinance on the essential requirements, classification, registration of producers in the register, the registration of medical devices in the register of medical devices, and conformity assessment of medical devices (Official Gazette, 84/13) http://narodne-NOvine.nn.hr/clanci/sluzbeni/2013_07_84_1875.html
Ordinance on monitoring adverse events related to medical devices (Official Gazette NO. 125/13) http://www.almp.hr/upl/zakoni/zakoni_59_en.pdf
Ordinance on good practice in wholesale distribution of medicinal products and the conditions for the entry in the register of wholesalers of medical devices (Official Gazette NO. 83/13) http://www.almp.hr/upl/zakoni/zakoni_51_en.pdf
Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Agency for Medicinal Products and Medical Devices (HALMED) http://www.almp.hr/
Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes
Text: A medical device is any instrument, apparatus, appliance, software, material or other object that is used alone or together with any other object, including software, which is its manufacturer for diagnostic or therapeutic purposes and that the software necessary for its proper application intended by the manufacturer for use in humans in order to:
- diagnosis, prevention, monitoring, treatment and alleviation of disease,
- diagnosis, monitoring, treatment, control, mitigate or eliminate injury or handicap,
- tests, elimination or replacement or modification of anatomical or physiological process,
- control of conception, and that its principal intended action in/on the human body is not achieved by pharmacological, immunological or metabolic effects, although its effect may be aided such effects. Law on Medical Devices, Art. 3.
In vitro diagnostic medical device (IVD) defined: Yes
Text: Defined Separately.

Medical device classification

Classification: Yes
Categories: Divided into classes based on the degree of risk for the user: class I, class IIa, class IIb, and class III. Law on Medical Devices, Art. 13; see also Official Gazette, 84/13, Art. 6.
Classification rules: N/A
Classification rules details: N/A

Essential principles

Essential principles: Yes
Details: A medical device may only be placed on the market in Croatia if they meet essential requirements. Official Gazette, 84/13, Art. 3.

Conformity assessment

Conformity assessment bodies: Yes
Details: Prior to marketing authorization, a conformity assessment body performs such an assessment. Law on Medical Devices, Art. 36, see also Official Gazette, 84/13, Art. 17
Pre-marketing / procedure: Any manufacturer of a medical device must ensure that the device is designed in accordance with the requirements of the Law, to make technical documentation and carry out conformity assessment procedure, mark the device “CE”. Law on Medical Devices, Art. 27.
Before placing a device on the market, a manufacturer must provide a declaration of conformity and also employ the “CE” mark. Law on Medical Devices, Art. 32.

Reliance

Reliance: Yes
Details: N/A
Jurisdictions: EU
Clinical investigation

Clinical investigation controls: Yes
Details: Clinical investigations of a medical device must gain approval by a Central Ethics Committee, and the conditions to conduct such a trial will be provided through regulations through the Minister. Law on Medical Devices, Art. 21.

Once a trial has been implemented, one is obliged to share clinical trial reports. Id Art. 22.

Article 23 of the Law on Medical Devices provides additional details on the performance of trials, such as obtaining informed consent.

For medical devices to be used in a clinical trial, the manufacturer must put together a statement that details the investigation, instructions, and informed consent. Ordinance on the essential requirements, classification, registration of producers in the register, the registration of medical devices in the register of medical devices, and conformity assessment of medical devices. Official Gazette, 84/13, Appendix VIII.

Registration and listing

Registration of establishment: N/A
Details: N/A

Listing of medical devices: Yes
Details: The registration of medical devices in the register of medical devices, the Agency shall issue a decision that is required to bring in within 60 days of receipt of proper request. Law on Medical Devices, Art. 41.

Import controls

Import controls: Yes
Details: Yes - One may import only medical devices that meet all the requirements under Croatian law and has an authorized representative in the EU. Law on Medical Devices, Art. 51.

When an active substance is imported from a third country, the delivery must include a statement from that third country confirming adherence to good manufacturing practices, as prescribed by the EU. Ordinance on good practice in wholesale distribution of medicinal products and the conditions for the entry in the register of wholesalers of medical devices. Official Gazette 83/13, Art. 7.

Post market controls

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

Inspection (QMS): Yes
Details: The manufacturer must grant a notified body view of relevant date and documentation on the quality system. The notified body must supervise the manufacturer and perform studies as necessary. Ordinance on the essential requirements, classification, registration of producers in the register, the registration of medical devices in the register of medical devices, and conformity assessment of medical devices. Official Gazette, 84/13, Annex II, 5.

Enforcement: Yes
Details: If a medical product is found to pose a risk to health or patient safety, then the Agency may request to withdraw that product or restrict its use. The Agency will also inform the EC of those measures. Law on Medical Devices, Art. 11.

Articles 84-85 provide penal provisions for violations of the Law.

Adverse event reporting: Yes
Details: The manufacturer, its authorized representative, and any importers are obliged to notify the agency in writing about any adverse events. Those events must report serious incidents. When the agency receives such a report, then it must notify the manufacturer or its representative, which, in turn, must take remedial actions. Law on Medical Devices, Art. 61.

The Ordinance on Monitoring Adverse Events provides the definition of an adverse event. Ordinance on monitoring adverse events related to medical devices. Official Gazette 125/13, Art. 6.

Further, the manufacturer must report to the Agency on medicinal products and medical devices all use errors that have led to death or serious deterioration. Ordinance on monitoring adverse events related to medical devices. Official Gazette 125/13, Art. 11.

Field safety corrective action monitoring: Yes
Details: The Ordinance on Monitoring Adverse Events details a field safety corrective monitoring that includes the manufacturer, the medicinal products and medical devices agency, notified bodies, patients/other users, and the EC. Ordinance on monitoring adverse events related to medical devices. Official Gazette 125/13, Art. 3, Art. 4.

Advertising: Yes
Details: It is prohibited to advertise a medical product that does Not meet the requirements. Misleading advertisement is also proscribe. Law on Medical Devices. Art. 59.

Labelling: Yes
Details: Instructions for use and labelling of a product must be in the Croatian language. And, the instructions for use of medical devices must be comprehensible to the user. Law on Medical Devices, Art. 12.

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.