Serbia

World Bank income group: Upper middle income

Legal

Legal framework: Yes


National Regulatory Authority

National Regulatory Authority present: Yes

Name: Medicines and Medical Devices Agency (ALIMS) http://www.alims.gov.rs/eng/

Responsibilities of the NRA: The ALIMS is authorized to:
- issue, terminate, renew, and transfer marketing authorizations
- enter medical devices into the Registerm of Medical Devices
- authorize clinical trials of medical devices
- monitor adverse medical device incidents
- authorize imports of medical products for treatment and for research
- classify medical devices
- authorize advertising of medical devices
- collect data on the marketing and use of medical devices
- perform quality control of medical devices

Law on Medicinal Products and Medical Devices, Art. 3.

Medical device definition

Medical device defined: Yes

Text: General medical devices mean any instruments, apparatuses, appliances, and products intended to be used for human beings, whether they are used alone or in combination, including the software necessary for their proper application, for the purposes of:
1) diagnosis, prevention, monitoring, treatment, or alleviation of disease
2) diagnosis, monitoring, treatment and alleviation of or compensation for an injury or handicap;
3) investigation, replacement or modification of the anatomy or of a physiological process;
4) control of conception

According to paragraph 1 of this Article, a medical device is also a device which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which can be assisted by the substances in its composition functioning by such means. [emphasis added]

Law on Medicinal Products and Medical Devices, Art. 172.

In vitro diagnostic medical device (IVD) defined: Yes

Text: Defined separately

Law on Medicinal Products and Medical Devices, Art. 172.

Medical device classification

Classification: Yes

Categories: General medical devices are classified according to risk for a user (class I, II(a), II(b), and III), according to the nature of the device (non/invasiveness and activity), and by duration. Law on Medicinal Products and Medical Devices, Art. 175.

IVDs are classified according to different standards contained in Art. 176.

Classification rules: Yes

Classification rules details: N/A

Essential principles

Essential principles: Yes

Details: N/A

Conformity assessment

Conformity assessment bodies: N/A

Details: N/A

Pre-marketing / procedure: Conformity assessment appears to be required, but it is not detailed, as a stand alone provision, within the Law on Medicinal Products and Medical Devices.
Reliance
Reliance: Yes
Details: The Agency does not require clinical tests on medical devices that conform with EU standards (or those countries that have similar ones). Law on Medicinal Products and Medical Devices, Art. 202. In other words, when a device bears a CE marking, an application for registration in Serbia becomes administrative. http://www.alims.gov.rs/eng/files/2012/10/Law-on-Medicines-and-Medical-Devices-teacher2010.pdf

Jurisdictions: EU

Clinical investigation
Clinical investigation controls: Yes
Details: Clinical trials must be approved by the Agency, and those trials must be conducted in accordance with current laws on clinical trials. Law on Medicinal Products and Medical Devices, Art. 199.

Registration and listing
Registration of establishment: Yes
Details: Application for registration and entry of a medical device in the Register of Medical Devices shall be submitted to the Agency by: 1) a manufacturer of a medical device licensed to produce the medical device in the Republic of Serbia; 2) an authorized representative. Law on Medicinal Products and Medical Devices, Art. 178.
Listing of medical devices: Yes
Details: A device must be registered before it may be placed on the market in Serbia. Law on Medicinal Products and Medical Devices, Art. 178. Devices approved for clinical trial or intended for continuation therapy, custom-made devices, and devices intended for scientific research are not registered on the Register of Medical devices. Id. Art. 183.

Import controls
Import controls: Yes
Details: Generally, medical devices must be registered on the Register of Medical Devices. In exceptional circumstances, this requirement is waived. Law on Medicinal Products and Medical Devices, Art. 195.

Post market controls
Post Market Surveillance: Yes
Details: The Agency performs quality control testing on marketed medicinal products by taking random samples (market surveillance), conducting trials on every batch of devices not in compliance with EU regulations, and solving detected problems. Law on Medicinal Products and Medical Devices, Art. 202.

Inspection (QMS): Yes
Details: The Agency is authorized to perform the other activities in accordance with the Law. Law on Medicinal Products and Medical Devices. Official Gazette of the Republic of Serbia, No. 20/2010, Article 3

Enforcement: Yes
Details: If the Agency finds deviance from the established standards of quality, then it must notify the Ministry of Health. Law on Medicinal Products and Medical Devices, Art. 201. Also, the Law provides penal provisions for violations on registration, marketing, etc. Id. Art. 217-221.

Adverse event reporting: Yes
Details: The Agency collects adverse events information. Health care institutions as well as private practices are obliged to notify regional centers about adverse events. The Agency publishes that data online and analyzes it. Law on Medicinal Products and Medical Devices, Art. 203.

Field safety corrective action monitoring: N/A
Details: N/A

Advertising: N/A
Details: N/A

Labelling: Yes

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.