Legal

Legal framework: Yes


Regulations on Medical Devices - Ordinance 4

Additional regulations and guidelines at the State level (i.e. Bosnia, Serbia, etc.) (in Croatian and Bosnian) may be found at http://www.almbih.gov.ba/dokumenti/regulative/

Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes


Responsibilities of the NRA: The Agency’s responsibilities include:
- protect and promote public health by ensuring the quality of medical devices and through the establishment of a uniform system of regulation for medical products and devices;
- establish and supervise a unified market for medical devices
- make proposals and amendments on legislation on medical devices as well as harmonize those regulations with international standards


The Agency is charged with several tasks by law:
- keep a register of medical devices for Bosnia and Herzegovina
- keep a register of manufacturers of medical devices for Bosnia and Herzegovina
- keep a register of legal entities engaged in wholesale of medical devices for the territory of Bosnia and Herzegovina
- issue certificates of registering legal entities engaged in wholesale of medical devices
- issue certificates of registering medical devices in the Registry of medical devices
- collect information, analysis, and response to adverse events
- assess conformity and labelling with harmonized European standards and the Technical Requirements ad Conformity Assessment of Products Act
- carry out inspection and supervision of manufacture and wholesale marketing of medical devices
- organize an information system on medical devices

Medical Products and Medical Devices Act (2008), Art. 8.

Medical device definition

Medical device defined: Yes

Text: Medical devices are defined as instruments, devices, materials and other products including any software necessary for their proper application; which are used on people, and which do NOT perform their main function, set by the manufacturer, on the basis of any pharmacological, immunological, or metabolic activities, but are used alone or in combination. Medical Products and Medical Devices Act (2008), Art. 96.

In vitro diagnostic medical device (IVD) defined: Yes

Text: In vitro medical devices are also defined by the act id. Art. 97.

Medical device classification

Classification: Yes

Categories: Categorized into four classes: I, IIa, IIb, and III and then further categorized by duration, invasiveness, and activity. In vitro diagnostic medical devices are classified according to a different scheme. Medical Products and Medical Devices Act (2008), Art. 99.

Classification rules: Yes

Classification rules details: N/A

Essential principles

Essential principles: Yes

Details: Medical devices must conform with requirements regarding general safety of the product and comply with basic requirements classified as general and special ones. Medical Products and Medical Devices Act (2008), Art. 100.

Conformity assessment

Conformity assessment bodies: N/A

Details: N/A
Pre-marketing / procedure: The Committee for Medical Devices assesses applications for registering medical devices. Conformity assessment procedure depends on the classification of the medical device in question. Medical Products and Medical Devices Act (2008), Art. 101. Manufacturers of Class I devices must provide a declaration of conformity or certificate of risk (with a few exceptions). Other device classes must follow special requirements, announced by the Minister of Civil Affairs. Id. Art 101.

Reliance
Reliance: N/A
Details: N/A
Jurisdictions: N/A

Clinical investigation
Clinical investigation controls: Yes
Details: Clinical testing of medical devices must conform with good clinical practice, and any documentation of those tests must be detailed enough to permit one to make an objective assessment on the safety and efficacy of devices. Medical Products and Medical Devices Act (2008), Art. 115. The Agency or the Department of Health may request clinical testing of the device. Id. Art 121.

Registration and listing
Registration of establishment: Yes
Listing of medical devices: Yes
Details: Manufacturers shall be required to submit to the Agency the documentation regarding the specifications of the medical device. Medical Products and Medical Devices Act (2008), Art. 106, 112.

Import controls
Import controls: Yes
Details: In the case where a medical device is imported, the importer takes on the responsibility of the manufacturer to register the device. Medical Products and Medical Devices Act (2008), Art. 106.

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): Yes
Details: Authorities of pharmaceutical inspectors in the area of medical devices. Medical Products and Medical Devices Act (2008), Art. 127
Enforcement: Yes
Details: The pharmaceutical inspector has a right and duty to recommend the initiation of penalty procedures, including the supervision of quality control of device manufacture, the temporary suspension of manufacture in light of threats to public safety, banning advertisements, etc.
Adverse event reporting: Yes
Details: Adverse events are reported, and any actions taken against a manufacturer or importer are detailed on the Inspectorate’s website.
Field safety corrective action monitoring: N/A
Details: N/A
Advertising: Yes
Details: All medical devices must receive advertising approval. Medical Products and Medical Devices Act (2008), Art. 122.
Labelling: Yes
Details: Any medical device must be labelled as such on the outside or immediate packaging in one of the official languages and must have instructions for use enclosed. Medical Products and Medical Devices Act (2008), Art. 113.