Montenegro

World Bank income group: Upper middle income

Legal
Legal framework: Yes
Amendments to the Law on Medical Devices, no. 53/09 http://www.calims.me/Portal/faces/servlet1?putanja=Zakon_o_izmjenama_i+_opunama_Zakona+_+medicinskim_sredstvima.pdf&_afrWindowMode=0&_afrLoop=18093503552496608&_adf.ctrl-state=fd0uhhrhp_194
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Agency for Medicines and Medical Devices of Montenegro http://calims.me/Portal/faces/glavna.jspx?_afrWindowMode=0&_afrLoop=18093784927814901&_adf.ctrl-state=17pyrlqel8_92
Responsibilities of the NRA: The Ministry for Health Affairs will: 1) issues regulations, 2) provides the content and the mechanism to keep the registry, 3) performs all other duties. The Law on Medical Devices, Art. 6.
The Agency for medicines and medical devices carries out the administrative and expert work related to medical devices: 1) decision on the accreditation of legal entities to determine conformity, revoke accreditation, keep the register of accredited entities, 2) perform the registration in the register and keep the register of producers who sell, import, and export medical devices, 3) carry out registration in the register, 4) keep track of clinical trials of medical devices and give consent to the commencement of trials 5) assess the relationship between risks and benefits, 6) decide on the classification of medical devices as to combination products, 7) carry out inspection of accredited legal entities to determine compliance on medical devices, manufacturers, and legal persons, 8) prohibit the traffic, suspension, or withdrawal of medical devices that do not meet standards, 9) cooperate with international operators and national regulatory authorities, 10) perform other duties.
The Law on Medical Devices, Art. 7.

Medical device definition
Medical device defined: Yes
Text: Medical devices are instruments, appliances, devices and products that apply to the people and the animals, in accordance with the intended purpose to them from the manufacturer, that its basic function not achieved on the basis of pharmacological, chemical, immunological and metabolic traits. Medical devices can be used alone or in combination, including the software required for proper application, for:
- determine the diagnosis, prevention, monitoring, treatment or alleviation of disease;
- determine the diagnosis, monitoring, treatment or alleviation of the injury or disability;
- testing, replacement or modification of the Anatomy or a physiological functions;
- control of conception. The Law on Medical Devices, Art. 2.

In vitro diagnostic medical device (IVD) defined: Yes
Text: Law on medical devices, Art.2

Medical device classification
Classification: Yes
Categories: Medical devices are classified according to:
1) the degree of risk - class I, class IIa, class IIb, and class III
2) the nature of the product, links to sources of energy, and on other characteristics - non-invasive, invasive, active
3) according to the length of the application in/pn humans or animals - transient application (intended for continuous use for a period shorter than 60 minutes, short-term use (intended for continuous use for a period of time that is not longer than 30 days, fixed applications (intended for continuous use for a period longer than 30 days) The Law on Medical Devices, Art. 12. IVDs are classified differently. Amendments to the Law on Medical Devices, Art. 12.
Classification rules: Yes
Classification rules details: N/A

Essential principles
Essential principles: Yes
Details: Only medical devices that meet the general and special requirements may be in circulation. The Law on Medical Devices, Art. 15

Conformity assessment
Conformity assessment bodies: Yes
Details: An accredited legal entity performs conformity assessment. The Law on Medical Devices, Art. 18.
Pre-marketing / procedure: Yes - The process to determine conformity depends on the degree of risk
1) for class I, the manufacturer provides a statement of risk (except for sterile products and products with a fixed measuring scale?)
2) for classes IIa, IIb, and III, compliance is determined by an accredited legal entity
The Law on Medical Devices, Art. 18
## WHO European Region

### Montenegro

#### Reliance
- **Reliance:** Yes
- **Details:** N/A
- **Jurisdictions:** EU

The Amendments to the Law on Medical Devices permit reliance on EU (EN ISO) standards. See Art. 19 (amending Art. 27).

#### Clinical investigation
- **Clinical investigation controls:** Yes
- **Details:** The Law on Medical Devices, Art. 47. Those that perform clinical trials on class IIA, IIB, and III devices must inform the competent authority. Id. Art. 48.

#### Registration and listing
- **Registration of establishment:** Yes
- **Details:** Manufacturers must register their activities. The Law on Medical Devices, Art. 29. The register entry must include:
  1) the name and Head Office of the manufacturer and the location of production
  2) the list of medical devices
  3) description of the manufacturing process
  4) other data Id. at 31.
- **Listing of medical devices:** Yes
- **Details:** Only devices placed on the register may be placed in circulation in Montenegro. The Law on Medical Devices, Art. 37.

#### Import controls
- **Import controls:** Yes
- **Details:** Those who import (and export) medical devices must register their activity in accordance with general regulations on registration. Those persons are also responsible for adverse event monitoring and for taking measures to address said events. The Law on Medical Devices, Art. 40.

The Agency may authorize the importation of medical devices that are not on the register in cases of medical emergency to protect the public health as well as:
- for research
- for clinical trials
- in case of natural disasters or other extraordinary conditions.

Amendments on the Law on Medical Devices, Art. 33 (amending Art. 44)

#### Post market controls
- **Post Market Surveillance:** Yes
- **Details:** Manufacturers must have in place features to monitor adverse effects and take actions in the event of accident, and, if necessary, fill out the form and other requirements for the performance of production activities. The Law on Medical Devices, Art. 30.
- **Inspection (QMS):** Yes
- **Details:** Inspection of medical device is carried out by the competent authority. The Law on Medical Devices, Art. 55. Inspectors oversee medical devices on:
  - identification of conformity, technical documentation, and the marking of devices,
  - implementation of appropriate examinations and test of medical devices
  - advertising of medical devices

The Law on Medical Devices, Art. 56.

- **Enforcement:** Yes
- **Details:** Both financial and criminal penalties may be imposed on a legal person if:
  1) a medical device is put into circulation without meeting the requirements or is not properly marked
  2) publishes or sells medical devices contrary to the law. The Law on Medical Devices, Art. 57.
- **Adverse event reporting:** Yes
- **Details:** The supplier, manufacturer, or other registered entity must inform the competent body and the administration of any adverse events. The Board then tracks the data and then the public, if necessary. The competent authority may require the suspension or withdrawal of the product from the market. The Law on Medical Devices, Art. 52.
- **Field safety corrective action monitoring:** N/A
- **Details:** N/A
- **Advertising:** Yes
- **Details:** It is prohibited to advertise medical devices from the Article 14, Para 1, Point 1 of this Law.

Notwithstanding, competent administrative authority can allow advertisings of the medical devices which are not classified as a high level of risk. Qualifiable terms and method of the medical device advertising from Para 2 of this Article are stipulated by the competent ministry. The Law on Medical Devices, Art. 45.

- **Labelling:** Yes
- **Details:** A medical device must have a printed user manual in the official language of the Montenegro and prepared in a manner understandable to the user. The Law on Medical Devices, Art. 28.

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.