The former Yugoslav republic of Macedonia

World Bank income group: Upper middle income

Legal

Legal framework: Yes
Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Bureau of Drugs, Ministry of Health - http://www.moh.gov.mk
Responsibilities of the NRA: The Medicines Agency
- issues regulations on the production, distribution, and retail of medical devices
- approves advertising for medical products
- maintains a register of medical devices and manufacturers in Macedonia
- issues authorizations and/or notifications for clinical trials of medical devices
- issues classification requirements for medical devices
- inspects medical devices
- ensures the quality of medical devices
- cooperates with other institutions on the use of medical devices

Law on Medicines and Medical Devices, Art. 5.

Medical device definition

Medical device defined: Yes
Text: A medical device is any instrument, apparatus, appliance, material or other products used in human medicine, there are no pharmacological, immunological or metabolic activity, and used alone or in combination, including software necessary for proper use of the device in order to
- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring and supervision, treatment, alleviation or compensation for injury or handicap,
- investigation, replacement or modification of anatomical or physiological process,
- control of conception

Medical devices also include
1) materials designated by their manufacturers for use with medical device to enable its use
2) materials that have specific design features and made according to a written prescription of a qualified individual use a patient
3) materials intended for clinical trials.

Law on Medicines and Medical Devices, Art. 2.

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

Medical device classification

Classification: Yes
Categories: Medical devices are classified in terms of risk into class I, IIa, IIb, and III. They are further categorized by their nature, power, and other characteristics into:
1) non-invasive
2) invasive and
3) active.
Law on Medicines and Medical Devices, Art. 111. Medical devices are further grouped in terms of duration of use into: (1) transient, (2) short term, and (3) long term. Art. 112.
IVDs are classified separately into lists A and B. Law on Medicines and Medical Devices, Art. 113.

Classification rules: Yes
Classification rules details: N/A

Essential principles

Essential principles: Yes
Details: Medical devices must comply with general conditions of safety and to meet general requirements. Law on Medicines and Medical Devices, Art. 116.

Conformity assessment

Conformity assessment bodies: Yes
Details: The procedure for conformity assessment depends on the classification of the medical device:
- For class I devices, the producers themselves assess product conformity with the general and particular conditions and on that basis draw up declarations of conformity or provide a certificate.
- For class IIa, IIb, and III devices, they must meet the general and specific requirements and have a certificate of conformity from the EU-notified body for conformity assessment.

Law on Medicines and Medical Devices, Art. 117.

Pre-marketing / procedure: Medical devices must comply with general conditions of safety and to meet general requirements. Law on Medicines and Medical Devices, Art. 116.
The procedure for conformity assessment depends on the classification of the medical device:
- for class I devices, the producers themselves assess product conformity with the general and particular conditions and on that basis draw up declarations of conformity or provide a certificate.
- for class IIa, IIb, and III devices, they must meet the general and specific requirements and have a certificate of conformity from the EU-notified body for conformity assessment.

Law on Medicines and Medical Devices, Art. 117.
WHO European Region

**Reliance**
- **Reliance:** Yes
- **Details:** N/A

**Jurisdictions:** EU

Macedonia relies on the conformity assessment bodies recognized by the EU or by equivalent bodies. Law on Medicines and Medical Devices, Art. 118.

**Clinical investigation**
- **Clinical investigation controls:** Yes
- **Details:** Clinical trials of medical devices refer to confirming the safety of medical devices and their compliance with general and special requirements. Medical device trials must be conducted in accordance with modern scientific and ethical principals. Documentation should record the tests and results and the risks/benefits of medical devices. Law on Medicines and Medical Devices, Art. 133. Before commencing a clinical trial, the sponsor or its authorized representative must provide clinical trial reports to the Agency. The application must contain all information on the medical device and other trial protocols. Law on Medicines and Medical Devices, Art. 134.

**Registration and listing**
- **Registration of establishment:** Yes
- **Details:** Manufacturers of medical devices must provide notice to the Agency to be entered into the register of manufacturers. Law on Medicines and Medical Devices, Art. 121. Manufacturers will be registered in the register of manufacturers of medical devices and provide information on their premises, address, devices, etc. Art. 123. The Agency will keep a register of producers as well as of medical devices available on the market. Art. 131.

- **Listing of medical devices:** Yes
- **Details:** The Agency will keep a register of medical devices available on the market. Law on Medicines and Medical Devices, Art. 131.

**Import controls**
- **Import controls:** N/A
- **Details:** N/A

**Post market controls**
- **Post Market Surveillance:** N/A
- **Details:** N/A

- **Inspection (QMS):** Yes
- **Details:** Law on Medicines and Medical Devices Art. 5 number 18

- **Enforcement:** Yes
- **Details:** Pharmaceutical inspectors have the right and duty to also inspect medical devices, including the rights to:
  - monitor the quality control system of the manufacturer
  - order tests of medical devices to assess conformity
  - take samples of medical devices and order conformity assessment
  - prohibit manufacturing, testing, marketing, or sales of medical devices for non-compliance with requirements
  - prohibit advertisement of a medical device is not in compliance with the law
  - order destruction of medical devices
  - prohibit or pause a clinical trial

Law on Medicines and Medical Devices, Art. 153.

Penalties are available for violations of the Law on Medicines and Medical Devices. See Art. 154.

**Adverse event reporting:** Yes
- **Details:** The Minister of Health is instructed by Art. 138 of the Law on Medicines and Medical Devices to prescribe the manner of reporting adverse events (side effects during the use of medical devices, the types of reactions it, duties of medical staff and suppliers as well as how to organize the system for monitoring adverse events and reactions to medical devices).

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

**Advertising:** Yes
- **Details:** Advertising of medical devices that are used in health institutions is prohibited. The Minister of Health is instructed to prescribe rules on the advertisement of medical devices. Law on Medicines and Medical Devices, Art. 139.

**Labelling:** Yes
- **Details:** Medical devices must be labeled in Madeconian on the packaging, which must contain at minimum: information on the manufacturer/improter, information to identify the medical device, other markings, etc.

Guidelines for use of the medical device must also be in Macedonian. Law on Medicines and Medical Devices, Art. 132.

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.