Legal

Legal framework: Yes

Authorizing legislation:
- Cabinet of Ministers of Ukraine No. 1497 “On approval of state registration of medical devices and medical devices” (9 Nov. 2004) http://zakon1.rada.gov.ua/laws/show/1497-2004-%D0%BF
- Cabinet of Ministers of Ukraine, N. 548 “On Amendments to the Procedure of State Registration of Medical Equipment and Medical Devices” (20 June 2012) http://zakon2.rada.gov.ua/laws/show/548-2012-%D0%BF

Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes

Name: State Administration of Ukraine on Medicinal Products (SAUMP) http://www.diklz.gov.ua/control/main/en/index

Responsibilities of the NRA: The SAUMP’s main objectives include:
- put forward proposals for national policy-making in the areas of quality control and safety for medical devices
- implement a national policy on quality control and safety for medical devices
- exercise control of compliance to legislative requirements on the safety and quality of medical devices
- supervise compliance on technical requirements of medical devices
- enforce control and supervision of compliance to standards of transport, storage, and application of medical devices
- take samples of medical devices for quality control
- issue recalls and bans on medical devices that do not comply with requirements
- conduct state registration of medical devices
- provide a one-time permission for importation of unregistered medical devices into Ukraine
- prepare drafts of programs for quality control of medical devices

Decree of the President of Ukraine

Medical device definition

Medical device defined: Yes

Text:
A medical device is any instrument, apparatus, appliance, software, material or other product used both separately and in combination with each other (including software provided by the manufacturer for use specifically for diagnostic and/or therapeutic purposes and necessary for the proper functioning of medical device) designed by the manufacturer for use with the purpose of providing diagnosis, prevention, monitoring, treatment or facilitate the flow of patient in case the disease, diagnosis, monitoring, treatment, patient relief in case of injury or disability or their compensation, research, replacement, modification or maintain the Anatomy or a physiological process, control of the process and the main alleged which in the body or on the human body is not achieved with pharmacological, immunological or metabolic means, but with which such remedies can help[.] Technical Regulations on Medical Products 753, Art. 2.

NOTE: The Technical Regulation 753 does not apply to IVDs or active implantable medical devices.

In vitro diagnostic medical device (IVD) defined: Yes

Text: Defined Separately.

Medical device classification

Classification: Yes

Categories: Medical devices are divided into three classes I, Iia, Iib, and III. Technical Regulations on Medical Products, 14. They are further classified according to the scheme in Annex 2.

Classification rules: Yes

Classification rules details: N/A
**Essential principles**

**Essential principles:** Yes

**Details:** Medical devices shall be designed and constructed so as to ensure compliance with their characteristics and operational performance requirements. See Technical Regulations on Medical Products, Annex 1: Essential Requirements.

**Conformity assessment**

**Conformity assessment bodies:** Yes

**Details:** Conformity assessment bodies that meet European harmonized standards are deemed to also meet national ones. Technical Regulations on Medical Products, 39. That body informs the Agency about any granted, revoked, modified, or supplemented certificates. See 41-42.

**Pre-marketing / procedure:** Conformity procedures for the three classes of products differ, and they are laid out in the annexes/appendices of the Technical Regulations on Medical Products. 15-19.

**Reliance**

**Reliance:** Yes

**Details:** Relies on European harmonized standards as proof of conformity. Technical Regulations for medical products, 9.

**Jurisdictions:** EU

**Clinical investigation**

**Clinical investigation controls:** Yes

**Details:** For medical devices intended for clinical investigations, the manufacturer must follow the procedures of Annex 9 in the Technical Regulations for medical products. According to Appendix 9, a medical device intended for clinical investigations, the manufacturer must provide specialized information, including the plan for research, participant confirmations, etc. The manufacturer must also retain information on the description of the device, methods of manufacture, descriptions, and the results of risk analysis. Under Annex 10 of the Technical Regulations for medical products, compliance with the technical regulation must be shown with clinical data.

**Registration and listing**

**Registration of establishment:** Yes

**Details:** Persons responsible for putting medical devices in circulation must submit information about their location and list and description of the products. Technical Regulations for medical products, 31.

**Listing of medical devices:** Yes

**Details:** Approved medical devices are issued a certificate of registration. For the registration procedures see Resolution No. 1497: On approval of state registration of medical devices.

**Import controls**

**Import controls:** Yes

**Details:** Import into the customs territory, the implementation and use of medical products in Ukraine is allowed only after their state registration. Resolution No. 1497, Art. 1.

**Post market controls**

**Post Market Surveillance:** Yes

**Details:** Conformity assessment bodies carry out surveillance. Manufacturers must provide the particular body with all relevant information, from documentation to data on the quality management system. Technical Regulations for medical products, Annex 3, 12-15. The body periodically conducts testing and inspections without notice.

**Inspection (QMS):** Yes

**Details:** The SAUMP in accordance with its functions: supervises over compliance with requirements of technical regulations on medical devices; Decree of the President of Ukraine (8 April 2011, 440). http://www.diklz.gov.ua/control/main/en/publish/article/568051

**Enforcement:** N/A

**Details:** N/A

**Adverse event reporting:** N/A

**Details:** N/A

**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.