**Legal**

**Legal framework:** Yes


**Guidelines:** Additional guidelines are available in Bulgarian at http%3A%2F%2Fwww.bda.bg%2Findex.php%3Flang%3Dbg&edit-text=&act=url.

**National Regulatory Authority**

**National Regulatory Authority present:** Yes

**Name:** Bulgarian Drug Agency (BDA) http://en.bda.bg/

**Responsibilities of the NRA:** Pursuant to Art. 6 of the Medical Devices Act, the BD:
- carries out the registration of medical devices;
- issues authorizations for clinical trials; with medical devices and for wholesale trade;
- exercises surveillance over medical devices;
- exercises control over storage, trade, clinical investigations, and safety of medical devices;
- maintains a vigilance system for registration and analysis of incident reports;
- participate in the Central Ethics Committee;
- provide information in the European database relating to medical devices already on the market; and,
- take part in the regulatory activities of other international bodies and other states.

**Medical device definition**

**Medical device defined:** Yes

**Text:** Medical device shall be any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, intended by the manufacturer to be specifically used for diagnostic and/or therapeutic purposes and necessary for its proper application, which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its functioning by such means, and which is intended by the manufacturer to be used for human beings for the purpose of:
- a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
- b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- c) investigation, replacement or correction of an anatomical part or of a physiological process;
- d) control of conception. Medical Devices Act, Art. 21.

**In vitro diagnostic medical device (IVD) defined:** Yes

**Text:** Defined Separately.

**Medical device classification**

**Classification:** Yes

**Categories:** Medical devices other than in vitro diagnostics and active implantable devices are grouped by risk category into classes I, IIa, IIb, and III. Special categorization applies to IVDs. Medical Devices Act, Art. 2.

**Classification rules:** Yes

**Classification rules details:** Classification rules are defined in the ordinances under Article 18. Medical Devices Act, Art. 2.

**Essential principles**

**Essential principles:** Yes

**Details:** Medical Devices Act, Art. 4.

**Conformity assessment**

**Conformity assessment bodies:** Yes

**Details:** Authorisation for conducting conformity assessment of medical devices shall be issued to any natural or legal person who is registered under the Commerce Act. Medical Devices Act, Art. 61.

**Pre-marketing / procedure:** Medical devices (except for custom-made ones) may enter the Bulgarian market only when they have an affixed CE marking. Medical Devices Act, Art. 8. It is the responsibility of the manufacturer or its authorized representative. Id. Art. 10. Additional conformity requirements must be defined by the Council of Ministers, at the proposal of the Minister of Health and the Minister of Economy, Energy and Tourism. Id. Art. 18.

For IVDs, performance evaluation is based on data and test results from accredited labs. Id. Art. 25.
Reliance

Reliance: Yes
Details: N/A
Jurisdictions: EU

Clinical investigation

Clinical investigation controls: Yes
Details: A clinical trial shall be conducted in medical therapeutic institutions under the Medical Treatment Facilities Act. Medical Devices Act, Chap. 3, Section I, Art. 33.

Registration and listing

Registration of establishment: Yes
Details: Manufacturers of medical devices must register with the BDA. Medical Devices Act, Art. 27.
Listing of medical devices: Yes

Import controls

Import controls: N/A
Details: N/A

Post market controls

Post Market Surveillance: Yes
Details: The market surveillance shall be carried out to ensure the conformity of the medical devices released on the market. Medical Devices Act, Chapter 6, Art. 86.

Inspection (QMS): Yes
Details: Medical Devices Act, Chapter Four, Chapter Five.

Enforcement: Yes
Details: See Chapter 9 of the Medical Devices Act for administrative penal provisions (Arts. 119-153).

Adverse event reporting: Yes
Details: Manufacturers are obligated to provide adverse event information. Medical Devices Act, Art. 105.

Field safety corrective action monitoring: Yes
Details: Manufacturers must have available mechanisms for applying the necessary corrective actions. Medical Devices Act, Art. 103.

Advertising: N/A
Details: N/A

Labelling: Yes
Details: The CE marking shall be placed in a visible place on the device, in the instruction for use and on its sterile package, if there is such. Wherever possible, it shall also be placed on the sales package. Any other mark that is affixed on the device, on its package and/or in its instruction for use, must not mislead the user. Medical Devices Act, Art. 15. The manufacturer of medical devices shall be obliged to place his name, seat and business address on the device, on its package and in the instruction for use. The instruction for use shall be drafted in the Bulgarian language as well. Medical Devices Act, Art. 16.