Belarus

World Bank income group: Upper middle income

Legal

Legal framework: Yes

Resolution No. 2435 XII - Health Care Law (2014)

Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes

Office of medical equipment of the Centre for Expertise and testing http://minzdrav.gov.by/en/static/export-of-services/center_expertise

Responsibilities of the NRA: The Office organizes and coordinates health care institutions activities. It also oversees the standardization and quality control of medical devices. More specifically it:
- elaborates on legal acts;
- participates in the development of integrated programs on medical equipment and supplies; and,
- works with the Department on Organization of Medical Protection in Emergency Situations for the receipt, distribution and quality of medical equipment obtained as humanitarian aid.
http://minzdrav.gov.by/en/static/about/central_device/dept_medEquipment

Medical device definition

Medical device defined: Yes

Notes: Limited definition

Text: Medical devices – products and auxiliary materials used for prophylaxis, diagnostics, medical treatment, rehabilitation, prosthetics of the population, research and development in the area of health care
Resolution No. 1269 (September 2, 2008), Chapter 1.

In vitro diagnostic medical device (IVD) defined: N/A

Text: N/A

Medical device classification

Classification: N/A

Categories: Categorized into four classes: I, IIa, IIb, and III and then further categorized by duration, invasiveness, and activity. Technical Regulations of Medical Devices (2014), Annex 1.

Classification rules: Yes


Essential principles

Essential principles: Yes

Details: N/A

Conformity assessment

Conformity assessment bodies: N/A

Details: N/A

Pre-marketing / procedure: A medical device must conform with technical regulations before placed on the market. A manufacturer is responsible to ensure conformity. Technical Regulations of Medical Devices (2014), Art. 6.

Reliance

Reliance: N/A

Details: N/A

Jurisdictions: N/A
Clinical investigation
Clinical investigation controls: Yes
Details: Clinical trials of medical devices are carried out pursuant to the procedural framework laid out by the Ministry of Health. Technical Regulations of Medical Devices (2014), Art. 7.

Registration and listing
Registration of establishment: N/A
Details: N/A
Listing of medical devices: Yes
Details: Medical devices and equipment must be registered in Belarus and certified for production, sales, and/or medical application. Resolution No. 1269 (2008), Ch. 1, 2.

Import controls
Import controls: Yes
Details: There is an import control to the extent a manufacturer must comply with registration requirements.

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): Yes
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: N/A
Details: N/A

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.