Legal

Legal framework: Yes

Authorizing legislation: Federal Law No 323-FZ (21 Nov. 2011)


Order No. 737 (14 Oct. 2013) "The Administrative Regulations of the Federal Service on Surveillance in Healthcare for Providing the State Service of Medical Device Registration,"


Order No. N12h (June 20, 2012) "Communications actors treatment health products all cases of detection of undesired effects, not mentioned in the operating instructions or owners manual medical articles about unwanted reactions when it is application about the peculiarities of interaction of medical products among themselves about the facts and circumstances endangering the life and health of citizens and health professionals when applying and operation of medical products" (google translation)


Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes

Name: Federal Service on Surveillance (Roszdravnadzor) http://roszdravnadzor.ru/

Federal Agency for Technical Regulation and Metrology (Gosstandart)

Federal Service for Supervision in the Area of Consumer Rights and Welfare Protection (Rospotrebnadoz)

Responsibilities of the NRA: Roszdravnadzor is the competent authority and is responsible for registration, clinical safety and efficiency of all medical devices.

Gosstandart ensures that all medical devices meet established Russian standards.

Rospotrebnadoz is responsible for ensuring that all medical devices that come into contact with the human body, or which may otherwise negatively affect patients or doctors, meet sanitary and epidemiological regulations.

Medical device definition

Medical device defined: Yes

Notes:

Text: Any medical appliances, apparatuses, devices, equipment, materials, and other products used for medical purposes either separately or in combination with each other and with other accessories required for the use of these products as intended, including customized software, and designed manufacturer (producer) for the prevention, diagnosis, treatment and aftercare of diseases, monitoring of the human body for medical research, medical tests, rehabilitation, replacement, modification of anatomy or physiological functions of the body, pregnancy prevention or termination, the functional purpose of which is not implemented by pharmacological, immunological, genetic or metabolic impact on the human body (hereinafter “medical devices”)

Government Decree of 27/12/2012 No. 1416, Art. 2.

In vitro diagnostic medical device (IVD) defined: Yes

Text: Medical devices for the diagnosis in vitro. Information provided by the manufacturer (labeling). Part 1: Terms, definitions and general requirements, 3.27.

http://docs.cntd.ru/document/1200126382

Medical device classification

Classification: Yes

Categories: Russia uses a risk based classification system for medical devices with four classes (1, 2a, 2b, and 3) where class 1 is the lowest and class 3 the highest level of risk.

Classification rules: N/A

Classification rules details: N/A
Essential principles
Essential principles: Yes
Details: see Order No. 1353n (21 Dec. 2012)

Conformity assessment
Conformity assessment bodies: Yes
Details: Yes - State registration is granted based on the results of technical trials, toxicology studies, and clinical trials, which take into account risk-based classification. Government Decree No. 1416, Rule 5.
Pre-marketing / procedure: N/A

Reliability
Reliability: No
Details: N/A
Jurisdictions: N/A

Clinical investigation
Clinical investigation controls: Yes
Details: Clinical trials are held as part of the conformity assessment procedure, which is to be approved by the Ministry of Health. Order No. 737, 51-58.

Registration and listing
Registration of establishment: Yes
Details: Decree No 615 (June 19, 2012).1
Listing of medical devices: Yes
Details: Medical devices (except for custom made devices) are subject to state registration, which must be carried out by the Federal Surveillance Service of Healthcare. Government Decree No. 1416, Rule 2.

Import controls
Import controls: Yes
Details: A GOST-R quality certificate is required before any medical device can be imported into Russia

Post market controls
Post Market Surveillance: Yes
Details: Roszdravnadzor is responsible for post-market surveillance.
http://jrs.sagepub.com/content/105/suppl_1/S12.full
Inspection (QMS): Yes
Details: State control over the handling of medical products means:
 auditing compliance with treatment subjects of medical devices regulations in the field of medical devices; permit to import into the Russian Federation of medical devices for the purpose of state registration; medical product safety monitoring; public safety and quality control of medical practice by conducting audits:
RF Government Resolution dated June 30, 2004 N 323, chapter II, Art. 5.2 http://base.garant.ru/12135989/#friends
Enforcement: N/A
Details: N/A
Adverse event reporting: Yes
Details: See Federal Law No 323-FZ (21 Nov. 2011), Art. 96. and Order No. N12h (20 June 2012)
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.