Kyrgyzstan

World Bank income group: Lower middle income

Legal

Legal framework: Yes
Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes
Name: State Department of Medicine Provision and Medical Equipment under the Ministry of Health of the Kyrgyz Republic - http://www.pharm.kg/ru/about
Responsibilities of the NRA: Yes. Realization of the state policy on population and medical institutions of the republic of medicines, medical supplies and medical equipment; Organization for the provision of management and control systems of the population safe, effective, quality medicines, medical supplies, medical equipment, health food and cosmetics; define and organization of research work on the improvement of management practices, control and standardization of medicines.

Medical device definition

Medical device defined: Yes
Notes: Medical products and medical devices are used interchangeably.
Text: Medical products are instruments, apparatus, tools, devices, systems, systems with security software, equipment, spare parts and accessories, accessories, dressing and suture, dental materials, tool kits of reagents, reference materials and standard samples, calibrators, consumable materials, articles made of polymer, rubber and other materials used in medical purposes alone or in combination with each other, which are intended for:
- prevention, Diagnostics, Inc. in vitro, treatment, rehabilitation, medical procedures, medical research, replacement and modification parts, tissues, human organs, restore or compensate for impaired or lost physiological functions, control of conception;
- effects on the human body in such a way that their function is not implemented by the chemical, pharmacological, immunological or metabolic interactions with human organism, mode of action which can be supported by such means. Technical regulation N.74, Art. 7.

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

Medical device classification

Classification: Yes
Categories: Safety classes 1, 2A, 2B and 3. Technical regulation N.74, Art. 24
Classification rules: Yes
Classification rules details: Art. 24 specifies the classification rules. Technical regulation N.74

Essential principles

Essential principles: Yes
Details: Medical products must meet the general safety requirements when they are being developed. Technical regulation N.74, Chapter 3, e.g. Art. 12.

Conformity assessment

Conformity assessment bodies: Yes
Details: Medical devices conformity assessment requirements set out in these regulations shall be conducted by:
1) the authorized State Agency of the Kyrgyz Republic in the area of health, in the sphere of circulation of medicines in State registration procedures;
2) manufacturer (dealer) medical products in the form of the adoption of the Declaration of conformity;
3) accredited certification bodies in the form of product certification and issue of certificate of conformity. Technical regulation N.74, Art. 26

Pre-marketing / procedure: YES- conformity assessment of medical devices are made in the following forms:
1) State registration;
2) confirmation of compliance;
3) State supervision. Technical regulation N.74, Art. 25
Reliance
Reliance: N/A
Details: N/A
Jurisdictions: N/A

Clinical investigation
Clinical investigation controls: N/A
Details: N/A

Registration and listing
Registration of establishment: Yes
Details: For placing medical devices on the market one must have a registration certificate. Registration at the State applies when a medical item is: 1) for the first time created in the Kyrgyz Republic and proposed for medical use in the Kyrgyz Republic; 2) produced in other countries and, for the first time proposed for medical use in the Kyrgyz Republic; 3) similar to registered, but produced by another manufacturer.
Technical regulation N.74, Art. 27
Listing of medical devices: Yes
Details: Medical devices listed in Annex I must be included in the State Register of registered medical products. Technical regulation N.74, Art. 31

Import controls
Import controls: Yes
Details: With a view to the availability of population and health organizations to vital medical supplies, products originating in limited quantities, by the decision of the authorized body of the Kyrgyz Republic in the area of health, in the sphere of circulation of medicines, is allowed to import unregistered medical products with mandatory conformity attestation procedure. Technical regulation N.74, Art. 11

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

Inspection (QMS): Yes
Details: State supervision. Technical regulation, Art. 110

Enforcement: N/A
Details: Persons who violate the requirements of these regulations, shall bear responsibility in accordance with the legislation of the Kyrgyz Republic. Technical regulation, Art. 119

Adverse event reporting: Yes
Details: The applicant is obliged to submit to the authorized State body of the Kyrgyz Republic in the area of health, in the sphere of circulation of medical devices information about any serious adverse reactions identified in the medical application of products of medical purpose, not later than within one month after receipt of such information. Technical regulation, Art. 84

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

Advertising: N/A
Details: N/A

Labelling: Yes
Details: Marking of medical devices containing the information for the consumer, should be submitted for each unit of medical products in the form of text, individual graphic, colour marks (legend) and/or figures and combinations of them, nanesennyx directly on the product, packaging (packaging) or plate, and contain in -line documentation. Technical regulation N.74, Art. 21.

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.