Legal

Legal framework: Yes

Authorizing legislation: Code of the Republic of Kazakhstan About the Health of the Nation and Health System http://adilet.zan.kz/eng/docs/K090000193_

Order of the Minister of Health of the Republic of Kazakhstan No. 735 of Nov. 18 2009
On Approval of the Procedure of State Registration, Re-Registration and Amendments to Registration Dossier of Medical Products (Drugs), Medical Devices, and Equipment http://www.google.ch/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=2&ved=0CCgQFjAB&url=http%3A%2F%2Fwww.dari.kz%2Fupload%2Fimages%2Fdownloads%2Fprikazy%2FOrder_735_eng.doc&ei=3wuNVYDqJqGpyQPxrIAusg=AFQICNHVI-J0irZULpGvmFNoJ_gCfsJo-A&sig2=rbnOLMehoBJmlI58-oOQ&bvm=bv.96782255,d.bGQ

Order of the Minister of Health of the Republic of Kazakhstan dated November 18, 2009 No. 736

Order of the Minister of Health of the Republic of Kazakhstan dated November 24, 2009 No 764

On approval of the rules on Labelling of medicines, medical devices and medical equipment, and amending the Decree of the Government of the Republic of Kazakhstan dated July 14, 2010 _ 712

Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes

Name: National Centre for Medicines, Medical Devices, and Medical Equipment Expertise http://dari.kz/category/mainpage

Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes

Text: Medical devices – the items and materials, used for preventive, diagnostic and therapeutic actions: medical instruments, dental supplies, expendables, dressings and sutures, appliances and medical optics items; Code of the Republic of Kazakhstan, Chapter 1, art. 75

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

Text: N/A

Medical device classification

Classification: Yes

Categories: N/A

Classification rules: Yes

Classification rules details: Order No. 764 provides classification rules. Principles of classification include (1) duration of use, (2) invasiveness, (3) availability of body contact, (4) route into the body, (4) application for vital organs, and (6) use of energy sources. Code, Art. 83.

Essential principles

Essential principles: Yes

Details: N/A

Conformity assessment

Conformity assessment bodies: N/A

Details: N/A

Pre-marketing / procedure: Yes - Evaluation of the safety and quality of medical devices registered in Kazakhstan is carried out by the Republican State Enterprise. Code, Art. 63-1.
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: N/A
Details: N/A
Listing of medical devices: Yes
Details: The registration of medical devices is performed by the governmental body for medical and pharmaceutical activity control. Order No. 735, Art 1.

Import controls
Import controls: N/A
Details: N/A

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): Yes
Details: As a pre-requisite to registration, re-registration, or changes in registration to the dossier of medical equipment, is an assessment of the production of the device and QMS, carried out by visiting the manufacturer’s organization. The expert organization reviews documents and samples. Code, Art. 71.
Enforcement: N/A
Details: N/A
Adverse event reporting: Yes
Details: Entrepreneurs and legal persons must inform the authorized body of any adverse events in medical devices. Code, Art. 81.
Field safety corrective action monitoring: N/A
Details: N/A
Advertising: Yes
Details: Medical device advertisements are treated no differently than other advertisements of goods under Kazakh law. Order No. 277.
Labelling: Yes
Details: Order N. 1692 governs both labelling of medicines and of medical devices.

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.