



Uzbekistan

World Bank income group: Lower middle income



Legal

Legal framework: N/A

Authorizing legislation: N/A

Guidelines: N/A

Notes: Medical devices: the document regulating medical devices seems not publicly available: Decree No. 404 on immediate initiatives to improve the provision and distribution of pharmaceuticals and medical devices in the country, 6 August 1994.



National Regulatory Authority

National Regulatory Authority present: Yes

Name: Ministry of Health <http://www.minzdrav.uz/>

General Directorate for the quality control of medicines and medical equipment (GDQC).

Responsibilities of the NRA: The Ministry of Health creates the norms and standards for medical devices.



Medical device definition

Medical device defined: N/A

Text: N/A

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

Text: N/A



Medical device classification

Classification: N/A

Categories: N/A

Classification rules: N/A

Classification rules details: N/A



Essential principles

Essential principles: N/A

Details: N/A



Conformity assessment

Conformity assessment bodies: N/A

Details: N/A

Pre-marketing / procedure: N/A



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: N/A

Details: Yes - See: Republican Foreign Economic Enterprise Uzmedexport: one of the structural divisions of the Ministry of Public Health of the Republic of Uzbekistan. http://www.uzmedexport.uz/register_en.html



Import controls

Import controls: N/A

Details: N/A



Post market controls

Post Market Surveillance: N/A

Details: N/A

Inspection (QMS): N/A

Details: N/A

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