Legal
Legal framework: Yes
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: CSEEA Analytical Expertise Centre http://www.pharma.az/
Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: Yes
Text: Medical devices are included within the definition of “medicinal products”. “This includes the medicinal products used for the diagnostics, prophylaxis and treatment of diseases (i.e. medical devices, goods, objects and materials, tools, equipment, medical reagents and optical equipment)”. Law on Medicinal Products, Art. 1.

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: Yes
Details: Pharmaceutical activity, including the production, wholesale, and retail sale of medicinal products (which include medical devices) must be licensed. Law on Medicinal Products, Art. 5.
Listing of medical devices: Yes
Details: Under the Law on medicinal products, the state regulation of such products is implemented through the registration of medicinal products and the certification of medical devices. Law on medicinal products, 4.1. The appropriate executive authority carries out registration. Id., 4.2.1

Import controls
Import controls: Yes
Details: Import of medical devices is carried out in conformity with established legislation. Law on Medicinal Products, Art. 6.1.
Post market controls

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

Inspection (QMS): N/A
Details: N/A

Enforcement: Yes
Details: The Law on medicinal products imposes liability on those who engage in the application and circulation of medical devices for cases of harm to health. Law on medicinal products, Art. 17.

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: Yes
Details: Instructions for use must be in the Azerbaijani language, and they must include information on the name of the product, where the product was produced, etc. Law on Medicinal Products, Art. 11.

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.