Legal
Legal framework: Yes
Registration Rules
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Department of Pharmaceuticals of State Regulatory Agency for Medical Activities
Responsibilities of the NRA: Registers certain medical devices, i.e. diagnostic test-systems, invasive contraceptives and dental materials

Medical device definition
Medical device defined: Yes
Notes: The same rules that apply to pharmaceutical products also apply to medical devices
Text: Medical goods - medical goods used in medical practice for disease prevention, diagnostics, treatment, and patient care: instruments, devices, appliances, medical equipment, dressing material, prosthetic and orthopaedic appliances, etc.
In vitro diagnostic medical device (IVD) defined: 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: Yes
Details: Only certain medical device products must be registered, like contraceptive products, dental materials, etc. Law on Drugs and Pharmaceuticals, Art. 11, 20. Registration Rules detail the registration process for radiopharmaceutical products. Art 11, 19.
Import controls
Import controls: Yes
Details: Some medical device products must be registered.

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

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.