Afghanistan
Legal
Legal framework: Yes
Resolution on the Manufacture and Importation of Medicines and Medical Devices http://gdpa.gov.af/Content/Media/Documents/ManufactureandImportationOfMedicinesandMedicalDevices_English911201415182641553325325.pdf
Guidelines: N/A
National Regulatory Authority
National Regulatory Authority present: Yes
Name: General Directorate Pharmaceutical Affairs, Ministry of Public Health
Responsibilities of the NRA: N/A
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: A real person must obtain a license for either the manufacture or importation of medical devices. Resolution, Ch. II, Arts. 3-4.
A medical devices manufacturing company must send its manufactured products to the Drugs and Food Quality Control Department of the Ministry of Health for qualitative and quantitative analysis before marketing. Resolution, Ch. II, Art 7.
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: Companies must be registered with the Pharmaceutical Affairs General Directorate. Resolution, Ch. III, Art. 19.
Listing of medical devices: N/A
Details: N/A
**Import controls**

**Import controls:** Yes

**Details:** Individuals, private companies, and organizations may import medical devices so long as they:

1. obtain a license for the importation of drugs and medical devices;
2. register (if a foreign manufacturer);
3. register of medicine items based on the Licensed Drug List (LDL); and,
4. observe the quality standard of imported items.

Resolution, Ch. III, Art. 16. Importation of medicines not on the LDL is possible so long as it is certified by the National Medicine Board and approved by the Ministry of Health. Resolution, Ch. III, Art. 17, see also Ch. IV, Art. 50 (medical devices may only be imported from registered companies).

A medical devices importer may not operate without a pharmacist. That pharmacist must take care of all technical affairs of the company, including transport, storage, and rational distribution of medical devices. Resolution, Ch. III, Art. 36.

If an imported medical device cannot be analysed either quantitatively or qualitatively within a country, the importing county will provide analysis certificate of each mentioned item and shipment by an independent laboratory. Resolution, Ch. III, Art. 23.

**Post market controls**

**Post Market Surveillance:** N/A

**Details:** N/A

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

**Details:** N/A

**Enforcement:** Yes

**Details:** The General Directorate of Pharmaceutical Affairs may ban the importation of medical devices that are below international standards (Art. 49), take action against unregistered importers (Art. 50), or suspend or cancel manufacturing licenses (Arts. 51, 52). Resolution, Ch. IV, Arts. 49-52. After the medical device manufacturer or importer receives a license, the General Directorate of Pharmaceutical Affairs conducts an inspection. Resolution, Ch. VI, Art. 54.

**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:** Medical device manufacturers must label devices with the manufacturing and expiry dates, the batch number, retail price, the name/address of the manufacturing company, and the brochure in any official languages. Resolution, Ch. II. Art. 8.

The contents of that leaflet must be certified by the Technical Board of Pharmaceutical Affairs Directorate. Resolution, Ch.III, Art. 25.