Tunisia

World Bank income group: Upper middle income

Legal
- Legal framework: No
- Authorizing legislation: N/A
- Guidelines: N/A

National Regulatory Authority
- National Regulatory Authority present: N/A
- Name: Ministry of Health http://www.santetunisie.rns.tn/fr/
- Responsibilities of the NRA: No specific responsibilities assigned for regulation of medical devices

Medical device definition
- Medical device defined: No
- Text: N/A
- In vitro diagnostic medical device (IVD) defined: No
- Text: N/A

Medical device classification
- Classification: No
- Categories: N/A
- Classification rules: No
- Classification rules details: N/A

Essential principles
- Essential principles: No
- Details: N/A

Conformity assessment
- Conformity assessment bodies: No
- Details: N/A
- Pre-marketing / procedure: N/A

Reliance
- Reliance: No
- Details: N/A
- Jurisdictions: No

Clinical investigation
- Clinical investigation controls: No
- Details: N/A

Registration and listing
- Registration of establishment: No
- Details: N/A
- Listing of medical devices: No
- Details: N/A

Import controls
- Import controls: No
- Details: N/A
Post market controls
Post Market Surveillance: No
Details: N/A
Inspection (QMS): No
Details: N/A
Enforcement: No
Details: N/A
Adverse event reporting: No
Details: N/A
Field safety corrective action monitoring: No
Details: N/A
Advertising: No
Details: N/A
Labelling: No
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.