Morocco

World Bank income group: Lower middle income

Legal
Legal framework: Yes
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: La commission nationale consultative des dispositifs médicaux’ Loi No 84-12, art 36.
Responsibilities of the NRA: The National Consultative Commission for medical devices aded to give its opinion on:
- Applications for the registration of medical devices;
- The suspension or revocation of registration;
- Withdrawal of a medical device from the market for public health reasons;
- Advertising visa applications and decisions to revoke those visas.

Medical device definition
Medical device defined: Yes
Text: A medical device means any instrument, apparatus, appliance, material, product, or other article used alone or in combination, including accessories and software involved in its functioning, intended by the manufacturer to be used for human beings for medical purposes or surgical and whose principal intended action by the medical device is not achieved by pharmacological, immunological or metabolic means, but whose function may be assisted by such means. Loi n°84-12, Ch. 1, Sec. 1, Art. 1. Notably, for the purposes of the law, additional items are considered medical devices. See id., Ch. 1, Sec. 1, Art. 2.

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

Medical device classification
Classification: Yes
Categories: Class I, IIA, IIB, and III
Classification rules: N/A
Classification rules details: Medical devices are classified by function according to:
- the duration of use
- invasiveness
- the means of use (surgical or not)
- activity
- use on the body
Loi n°84-12, Ch. 1, Sec. 2, Art 4.

Essential principles
Essential principles: Yes
Details: Medical devices must meet high safety level of use for the patient, professional and meet the essential requirements of quality, safety and performance set by regulation.

Conformity assessment
Conformity assessment bodies: N/A
Details: N/A
Pre-marketing / procedure: Yes - Whoever manufactures, imports, exports, or distributes medical devices must submit a declaration of that activity. Loi n° 84-12, 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: N/A
Details: N/A
Listing of medical devices: Yes
Details: One must receive a certificate of registration before one may place a medical device on the market. Loi n° 84-12, Ch. III, Sec. 1, Art. 12. Certain medical devices are exempt from the registration requirement, including device intended for experiments/research and custom-made ones. Id. at Ch. III, Sec. 1, Art. 13.

Import controls
Import controls: N/A
Details: N/A

Post market controls
Post Market Surveillance: Yes
Details: Loi n° 84-12 institutes a national system of market surveillance. See Ch. III, Sec. 2, Art. 24.
Inspection (QMS): Yes
Details: Inspectors are authorized to conduct periodic inspections of the manufacture, import, export, distribution and maintenance of medical devices. Loi n° 84-12, Ch. V, Art. 38.
Enforcement: Yes
Details: The administration, after consulting with the national commission on medical devices, may order those devices off the market. Loi n° 84-12, Ch. III, Sec. 2, Art 26.
Fines are available for violations of certain provisions of the Loi n° 84-12. See Ch. V, Arts. 40-47.
Adverse event reporting: Yes
Details: One who manufactures, imports, exports, or distributes medical devices as well as professional users of medical devices must report within 48 hours of learning of any adverse incident or risk of incident when using the device. Loi n° 84-12, Ch. III, Sec. 2, Art. 25.
Field safety corrective action monitoring: N/A
Details: N/A
Advertising: Yes
Details: Advertisements for medical devices may not be deceptive and must show good usage of the device. Loi n° 84-12, Ch. III., Sec. 3, Art. 35.
Labelling: Yes
Details: Each medical device must be accompanied by instructions or label with sufficient information for safe use and to identify the manufacturer. Loi n° 84-12, Ch. 1., Sec. 2, Art. 5.

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.