Legal

Legal framework: Yes


Guidelines: N/A

Notes: Decree Law n°22/2013: Establishment of the Agency of Regulation and Supervision of Pharmaceutical Products and Food. The decree consolidates prior regulatory agencies and explicitly mentions the regulation of medical devices.

National Regulatory Authority

National Regulatory Authority present: Yes

Name: Agency of Regulation and Supervision of Pharmaceutical and Food Products (ARFA) http://www.arfa.cv/

Responsibilities of the NRA: ARFA has authority to oversee the entire regulatory process pursuant to Decree Law N°23/2013.

Medical device definition

Medical device defined: Yes

Text: Medical device means any instrument, apparatus, appliance, material or articles used alone or in combination including the software necessary for its proper application intended by the manufacturer to be used in humans for the diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap, investigation replacement or modification of the anatomy or of a physiological process, and to control the design and whose principal intended action in the human body is not achieved by means pharmacological, immunological or metabolic, although its function may be assisted by such means. Decree Law N°23/2013, Art. 3.

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: N/A

Details: N/A

Listing of medical devices: N/A

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

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:
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.