Legal framework: Yes
prepareCreateTreatiesWorkspace/treatiesGeneralData.do?step=0&redirect=true&treatyId=160 - This treaty between the European Community (EC) and Monaco extends EC medical device acts to Monaco. Significantly, Monaco adopts all EC Directives related to medical devices.
Loi. n. 1.267 du 23/12/2002 relative aux dispositifs médicaux http:/ /www.legimonaco.mc/305/legismclois.nsf/db3b0488a44ebcf9c12574c7002a8e84/622e07fb7c2a1119c1257773f003cf6c1!OpenDocument
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes

Medical device definition
Medical device defined: Yes
Notes: The law also defines IVDs and active medical devices.
Text: A medical device is any instrument apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for the proper operation of it, intended by the manufacturer to be used in humans to purposes:
- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, mitigation or compensation for an injury or handicap;
- Investigation, replacement or modification of the anatomy or of a physiological process;
- Control of conception;
and whose principal intended action in or on the human body is not achieved by pharmacological, immunological or metabolic means, but whose function can be assisted by such means.
Loi n. 1.267, Sec. 1, Art. 1er.
In vitro diagnostic medical device (IVD) defined: Yes
Text: Included, defined separately.

Medical device classification
Classification: Yes
Categories: Medical devices and IVDs are grouped by risk category: class I, class II a, class II b, et class III. Arrêté ministériel n. 2003-581, Sec. I, Art. 1er.
Classification rules: N/A
Classification rules details: N/A

Essential principles
Essential principles: Yes
Details: N/A

Conformity assessment
Conformity assessment bodies: N/A
Details: N/A
Pre-marketing / procedure: A medical device may not be imported, put on the market, or used if the manufacturer has not met conformity requirements. Loi n. 1.267, Sec. II, Art. 6. Each medical device put on the market or into service in Monaco must have a conformity mark. Id. Sec. II, Art. 11.
**Reliance**

**Reliance:** Yes  
**Details:** A medical device that satisfies references published in the Journal of Monaco are presumed to meet conformity requirements. Loi n. 1.267, Sec. II, Art. 7.

**Jurisdictions:** EU

**Clinical investigation**

**Clinical investigation controls:** Yes  
**Details:** Medical devices used in clinical trials are exempt from conformity requirements; however, the trials must comply with standards to guarantee the health and safety of research subjects. Further guidelines are set to be issued by a ministerial order. Loi n. 1.267, Sec. II, Art. 8.

A manufacturer that intends to perform clinical investigations in Monaco or in the EU or EEA must inform its intention to the Minister of State as well as certify conformity with requirements. Arrêté ministériel n. 2003-581 du 10/11/2003, Sec. 3, Art. 15.

**Registration and listing**

**Registration of establishment:** Yes  
**Details:** Any manufacturer headquartered in the Principality of Monaco and puts in its own medical devices on the market of a Member State of the European Union or party to the Agreement on the European Economic Area, must inform the Directorate of health and social welfare the address of its head office and of devices concerned. Loi n. 1.26, Article 12

**Listing of medical devices:** Yes  
**Details:** Any manufacturer headquartered in the Principality of Monaco and puts in its own medical devices on the market of a Member State of the European Union or party to the Agreement on the European Economic Area, must inform the Directorate of health and social welfare the address of its head office and of devices concerned. Loi n. 1.26, Article 12

**Import controls**

**Import controls:** Yes  
**Details:** A medical device may not be imported if it does not meet conformity requirements. Loi n. 1.267, Sec. II, Art. 6.

**Post market controls**

**Post Market Surveillance:** Yes  
**Details:** The Ministry fixes guidelines on the surveillance of medical devices. Loi n. 1.267, Art. 18.

Most importantly, Arrêté ministériel n. 2003-586 du 10/11/2003, establishes a system of post-market surveillance, with the aims to:
- record adverse incidents;
- evaluate this data to prevent future incidents;
- study or work on the safe use of devices; and,
- follow corrective actions.

That system informs manufacturers of adverse incidents and may call for investigations, and those manufacturers are obliged to provide certain information, as listed in the law.

**Inspection (QMS):** Yes  
**Details:** The inspectors pharmacists and the medical inspector shall ensure compliance with laws and regulations relating to medical devices. They are appointed by ministerial order and must hold the degree of doctor of medicine, doctor of pharmacy or pharmacist recognized by the Minister of State. Loi n. 1.267 Titre II, Art. 25

**Enforcement:** Yes  
**Details:** The state minister may suspend trials, fabrication, importation, use, distribution, marketing, etc. of medical devices if (1) that device is used of placed on the market without meeting conformity requirements or (2) it presents health risks. Loi n. 1.267, Ch. II, Art. 31.

Further, the state may impose penalties for NOT meeting conformity requirements prior to use or marketing, etc. Loi n. 1.267, Titre III, Art. 36-42.

**Adverse event reporting:** Yes  
**Details:** Under the post-market surveillance program, adverse events must be recorded. Arrêté ministériel n. 2003-586 du 10/11/2003, Art. 23

Arrêté ministériel n. 2003-581 du 10/11/2003, Sec. VI, Art. 24-27 compels the Director of the NRA (L’action Sanitaire et Sociale) to inform manufactures of any adverse events.

**Field safety corrective action monitoring:** Yes  
**Details:** Loi. n. 1.267 , Art. 18.

**Advertising:** N/A  
**Details:** N/A

**Labelling:** Yes  
**Details:** Loi. n. 1.267 du 23/12/2002, Art. 10.

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.