### Legal
- **Legal framework:** Yes
- **Authorizing legislation:** Code de la Santé Publique (13 May 2009) (Public Health Law)
  
- **Guidelines:** N/A

### National Regulatory Authority
- **National Regulatory Authority present:** N/A
- **Name:** Direction des Pharmacies Laboratoires et Equipements Techniques
  Ministère de la Santé et de la Population
- **Responsibilities of the NRA:** N/A

### Medical device definition
- **Medical device defined:** Yes
- **Text:**
  
  A medical device is any instrument, apparatus, equipment, material, product, except for products of human origin or other article alone or in combination, including the accessories and software involved in its functioning, intended by the manufacturer to be used in the humans for medical purposes and whose principal intended action is not obtained by pharmacological or immunological means or by metabolism, but whose function can be assisted by such means. Public Health Law, Art. 378.
  
  Note: active implantable medical devices are defined separately.

- **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:** Yes
- **Details:** Medical devices may not be imported, placed on the market, or put into use unless there is a certificate that shows their compliance with essential requirements on the health of patients. The ministry of health provides the certificate. Public Health Law, Art. 379.

### Conformity assessment
- **Conformity assessment bodies:** N/A
- **Details:** N/A
- **Pre-marketing / procedure:** The manufacturer is responsible for meeting conformity requirements, as set by the Ministry of Health. Public Health Law, Art. 379.

### 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:** Yes

**Details:** Medical devices may not be imported, placed on the market, or put into use unless there is a certificate that shows their compliance with essential requirements on the health of patients. The ministry of health provides the certificate. Public Health Law, Art. 379.

**Post market controls**

**Post Market Surveillance:** N/A

**Details:** N/A

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

**Details:** N/A

**Enforcement:** Yes

**Details:** The failure to report adverse events may result in a fine and imprisonment. Public Health Law, Art. 382.

**Adverse event reporting:** Yes

**Details:** Manufacturers, users, and those familiar with any adverse event must report that event to the Ministry of Health. Public Health Law, Art. 381.

**Field safety corrective action monitoring:** N/A

**Details:** N/A

**Advertising:** N/A

**Details:** N/A

**Labelling:** N/A

**Details:** N/A

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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.