France

World Bank income group: High income

Legal

Legal framework: Yes


Guidelines: Guide Général pour la mise sur le marché de dispositifs médicaux sur mesure http://ansm.sante.fr/var/ansm_site/storage/original/application/8ffa2bc41c5d915d398280e0e404130d.pdf.

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Agence nationale de sécurité du médicament et des produits de santé
http://ansm.sante.fr/
Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes
Text: Medical device means any instrument, apparatus, equipment, material, product, except for products of human origin, or other article used alone or in combination, including the accessories and software involved in its functioning, intended by the manufacturer to be used in humans for medical purposes and whose principal intended action is not obtained by pharmacological, immunological or metabolic means, but whose function can be assisted by such means. Code de la santé publique, Art. l5211-1.

In vitro diagnostic medical device (IVD) defined: Yes
Text: Defined separately.

Medical device classification

Classification: Yes
Categories: Class I, IIa, IIb, III.
Classification rules: Yes
Classification rules details: See Annex II of Guideline for the marketing of medical devices with measuring function.

Essential principles

Essential principles: Yes
Details: Medical devices can not be imported, put on the market or put into service if they have not received, in advance, a certificate of their performance and compliance to the essential requirements regarding safety and health of patients, users and third parties. Code de la santé publique, Art, l5211-3.

Conformity assessment

Conformance assessment bodies: Yes
Details: Certification of conformity is established, according to the class in which the device or the customer himself manufacturer or by a body appointed for the purpose by the National Drug Safety Agency health products or by the competent authority of another Member State of the European Union or party to the Agreement on the European Economic Area. Code de la santé publique L. 5211-3

Pre-marketing / procedure: A certificate of conformity is established according to the class of the device. Code de la santé publique, Art, l5211-3.

Reliance

Reliance: N/A
Details: N/A
Jurisdictions: EU
**Clinical investigation**

**Clinical investigation controls:** Yes

**Details:** Code de la santé publique, Livre II: Dispositifs médicaux, dispositifs médicaux in-vitro et autres produits et objets réglementés dans l’interêt de la santé publique. Titre 1, chap. 1er, section 6, sous-section 3, par. 2

**Registration and listing**

**Registration of establishment:** Yes

**Details:** Medical device manufacturers or their authorized representatives, and any person, individual or corporate, that engages in the manufacture, distribution, import or export of medical devices must declare their activities to the Agency. Code de la santé publique, Art. IS211-3-1.

**Listing of medical devices:** Yes

**Details:** Class I medical devices, medical device sterile Class I (Is), class I medical devices with measuring function (Im), medical device sterile Class I with measuring function, custom devices, systems / kits medical devices, sterilization of medical devices) http://ansm.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/DM-classe-I-DM-sur-mesure-assemblage-Declaration/(offset)/3

**Import controls**

**Import controls:** N/A

**Details:** N/A

**Post market controls**

**Post Market Surveillance:** Yes

**Details:** Code de la Santé Publique 5212

https://www.legifrance.gouv.fr/eli/decret/2004/7/29/SANP0422530D/jo#JORFARTI000001462356

**Inspection (QMS):** Yes

**Details:** Manufacturers are subject to inspection. Guideline. See also Code de la santé publique, Art. IS313-1.

**Enforcement:** Yes

**Details:** See Livre IV, Titre VI of the Code de la santé publique for penal and financial sanctions.

**Adverse event reporting:** Yes

**Details:** Manufacturers and users of devices who have knowledge of an incident or a risk of an incident involving a device, which resulted or may result in death or serious deterioration in a patient’s condition, must report without delay to the Agency. Code de la santé publique, Art. IS212-2.

**Field safety corrective action monitoring:** Yes

**Details:** Code de la santé publique Art R. 5232-17

**Advertising:** Yes

**Details:** Advertising can be neither misleading nor present a risk to public health. Chapter III, Titre Ier, Livre II of Code de la santé publique.

**Labelling:** Yes

**Details:** The labelling and instructions for use should be communicated to the Agency including the data describing the degree of risk it poses to human health. Code de la santé publique, Art. IS211-4.

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.