Italy

World Bank income group: High income

Legal

Legal framework: Yes
Decreto Legislativo 24 febbraio 1997 http://www.salute.gov.it/imgs/C_17_normativa_515_allegato.pdf - Note: this decree does not apply to IVDs or Active Implantable Medical Devices
Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Ministry of Health http://www.salute.gov.it/portale/temi/p2_3_dispositivi.html
Responsibilities of the NRA: Ministry of Health, directorate for medical devices and pharmaceutical services. http://www.salute.gov.it/portale/ministro/p4_5_2_4_1.jsp?lingua=italiano&menu=uffCentrali&label=uffCentrali&id=1153 - The Directorate General of medical devices and pharmaceutical service performs the following functions: completion and implementation of the regulation of medical devices, including the tasks relating to market surveillance, the authorization for the notified bodies, the supervision of incidents, clinical investigation, technology assessment and Health Technology Assessment activities (HTA), monitoring of consumption of medical devices purchased directly by the NHS; general discipline of pharmacy, relations with the Italian Drug Agency (AIFA), including for exercising their responsibilities with regard to medical devices containing substances with characteristics of medicines and to future legislation in the pharmaceutical sector, support to address the Minister functions in respect of the same agency, advertising ‘of medicines and other health products whose interest spread and’ subject to authorization or control, exercise of state powers in the field of production, trade and use of narcotic drugs and psychotropic substances and drug precursors, collaboration with other bodies in the regulation in the area of drugs of abuse including the updating of the relevant tables, exercise of State powers affecting the production and trade of medical devices and biocides, exercise of state powers in the field of cosmetics and products and equipment used for aesthetic purposes.

Medical device definition

Medical device defined: Yes
Text: A medical device means any instrument, apparatus, appliance, material or other product, whether used alone or in combination, including the software necessary for its proper functioning, intended by the manufacturer to be used in human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, mitigation or compensation for an injury or handicap; investigation, replacement or modification of anatomy or if a physiological process; of control of conception, the which does Not achieve its principal action in or on the human body, which is intended, by pharmacological, immunological or by metabolic process but whose function may be assisted by such means. Decreto Legislativo 24 febbraio 1997, Art. 1, § 2.
In vitro diagnostic medical device (IVD) defined: Yes
Text: Included, defined separately.

Medical device classification

Classification: Yes
Categories: Devices are classified into class I, IIa, IIb, and III. Decreto Legislativo 24 febbraio 1997, Art. 8.
Classification rules: Yes
Classification rules details: Classification Rules are detailed in Annex IX. Decreto Legislativo 24 febbraio 1997, Art. 8.

Essential principles

Essential principles: Yes
Details: Devices may only be placed on the market if they meet the essential requirements of the Decreto Legislativo 24 febbraio 1997, Art. 3-4.

Conformity assessment

Conformity assessment bodies: Yes
Details: If a notified body needs to conduct the conformity assessment, then the manufacturer or its authorized representative may select the notified body. Id. notified bodies may carry out conformity assessment. The Ministry of Health and the Ministry of Industry, Commerce and Artisanship oversee the activities of the notified bodies. The notified body will provide other Notified bodies and the Ministry of Health all information about suspended, withdrawn, issued, or rejected certificates. Decreto Legislativo 24 febbraio 1997, Art. 15.
Pre-marketing / procedure: Specific conformity assessment rules for the four classes of medical devices are detailed in Decreto Legislativo 24 febbraio 1997, Art. 11

Reliance

Reliance: Yes
Details: Devices that meet the requirements that result in a CE marking fulfil the requirements under Decreto Legislativo 24 febbraio 1997, Art. 5-6.
Jurisdictions: EU
Clinical investigation
Clinical investigation controls: Yes
Details: For devices intended for clinical investigations, the manufacturer or its authorized representative must notify the Ministry of Health before commencing the investigation. Notification is not necessary for investigations that use devices with a CE marking, unless those investigations relate to a different use of the device. Decreto Legislativo 24 febbraio 1997, Art. 14.

Registration and listing
Registration of establishment: Yes
Details: The Ministry of Health also collects data on (1) the registration of manufacturers and devices; (2) on certificates issued, supplemented, suspended, withdrawn, or refused; and, (3) on vigilance. The purpose is transmission to the European database. Decreto Legislativo 24 febbraio 1997, Art. 13.
Listing of medical devices: Yes
Details: A manufacturer who places a device on the market must provide the Ministry of Health with its address and a description of the devices. If the manufacturer is not from a Member State, then the manufacturer must designate a person responsible to place the device on the market, and that person must provide the Ministry of Health with its address and the category of device. Decreto Legislativo 24 febbraio 1997, Art. 13.
Decreto di febbraio 2007 modifies the Decreto Legislativo 24 febbraio 1997 by detailing the process for the registration of information into the Directory of Medical Devices.

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

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): Yes
Details: In order to check the conformity of medical devices with the requirements of this decree, the vigilant Administrations referred to in paragraph 1 shall be entitled to carry out inspections and checks using their central or peripheral offices. Decreto Legislativo 24 febbraio 1997, Art. 17
Enforcement: Yes
Details: The Ministry of Health may order a medical device withdrawn from the market when that device does not meet the essential requirements under Art. 4, has an incorrect application, or carries a shortcoming. Decreto Legislativo 24 febbraio 1997, Art. 7.
If the Ministry of Health believes that a product or a group of products should be prohibited, restricted, or subjected to particular requirements, it may take measures to inform the EC and Member States. Decreto Legislativo 24 febbraio 1997, Art. 13b.
Legal representatives of public and private facilities, health professionals, or manufacturers or their representatives who fail to communicate serious incidents that result in deterioration or death may be punished by fines and/or imprisonment up to 6 months. In addition, false advertising or placing a device in the market without proper conformity assessment/marking may result in fines. Decreto Legislativo 24 febbraio 1997, Art. 23.
Adverse event reporting: Yes
Details: Public and private health workers must provide data on adverse events to the Ministry of Health. The Ministry of Health then classifies and evaluates the data on any malfunction or deterioration or inadequacy in Labelling or on any technical or medical related defect that lead to a manufacturer’s withdrawal of the product from market. Decreto Legislativo 24 febbraio 1997, Art. 9.
The Ministry of Health then informs the manufacturer. Further, if the manufacturer or his authorized representative is aware of any alteration of the characteristics and performance of the device that could result in death or serious harm placed on the market in Italy, then it must inform the Ministry of Health. Decreto Legislativo 24 febbraio 1997, Art. 10.
Field safety corrective action monitoring: Yes
Details: Decreto Legislativo 24 febbraio 1997 Art 17.6
Advertising: Yes
Details: Medical devices that may only be sold by prescription of used by a physician or other health care professional may not be advertised. Any other advertisements must receive permission from the Ministry of Health. Decreto Legislativo 24 febbraio 1997, Art. 21.
Labelling: Yes
Details: A manufacturer or his authorized representative must make available at his office a copy of instructions and Italian labels that come with a device. Decreto Legislativo 24 febbraio 1997, Art. 5.
Notably, the manufacturer who places a class IIa, IIb, or III device on the market must provide the Ministry of Health with labelling information and instructions for use. Decreto Legislativo 24 febbraio 1997, Art. 13.

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.