Legal
Legal framework: Yes
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: National Authority of Medicines and Health Products (INFARMEDC, IP) http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS
Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: Yes
Text: A medical device means any instrument, apparatus, appliance, software, material or article used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for the proper functioning of the medical device, whose main effect intended in the human body is not achieved by pharmacological, immunological or metabolic means, although its function may be supported by these means intended by the manufacturer to be used in humans to purposes: i) diagnosis, prevention, monitoring, treatment or alleviation of disease; ii) diagnosis, monitoring, treatment, mitigation or compensation for an injury or a defect; iii) study, replacement or modification of the anatomy or of a process physiological; iv) control of conception. Decree Law No, 145/2009, Art. 3.

In vitro diagnostic medical device (IVD) defined: Yes
Text: Included, defined seperately. Decree Law No. 145/2009, Art. 3.X.

Medical device classification
Classification: Yes
Categories: Medical devices are classified by risk into class I, IIa, IIb; or III. Decree Law No. 145/2009, Art. 4 (this article does not apply to active implantable devices)
Classification rules: Yes
Classification rules details: Classification rules are described in Annex IX of Decree Law No. 145/2009, Art. 4

Essential principles
Essential principles: Yes
Details: A medical device may only be placed on the market or into service if it
- meets the essential requirements
- shows the CE marking
- has been subject to conformity assessment.
Decree Law No. 145/2009, Art. 5. There are exceptions to this rule for custom-made devices, devices on display at trade fairs, and for devices slated for clinical research.

Conformity assessment
Conformity assessment bodies: Yes
Details: A notified body must meet be accredited by the Portuguese Institute of Accreditation, IP (IPAC, IP) and be in compliance with the harmonized EU standards. The competent authority must exercise ongoing supervision over the notified bodies. If the competent authority determines that the notified body no longer meets the criteria, it must restrict or rescind the notification (?) and notify the EC and member states. If a notified body withdraws or otherwise imposes restrictions on certificates, then it must notify the competent authority, which must then inform the EC and member states. Decree Law No. 145/2009, Art. 22.
Pre-marketing / procedure: Yes - A medical device may only be placed on the market or into service if it
- meets the essential requirements
- shows the CE marking
- has been subject to conformity assessment.
Decree Law No. 145/2009, Art. 5. There are exceptions to this rule for custom-made devices, devices on display at trade fairs, and for devices slated for clinical research.

Reliance
Reliance: Yes
Details: N/A
Jurisdictions: EU - A device is presumed to be in compliance with the essential requirements of Portuguese law if it meets harmonized EU standards. Decree Law No. 145/2009, Art. 6.
Clinical investigation
Clinical investigation controls: Yes

Registration and listing
Registration of establishment: Yes
Details: Any manufacturer domiciled or based on Portugal that places class I or custom-made devices on the market must notify the competent authority of its name and all data necessary or identify the device. For classes II through III, the manufacturer or its authorized representative must provide its name, additional details on the device, and other information. If the manufacturer does not have a domicile or office in an EU member state, the manufacturer must designate a single authorized representative in the EU for each device. Decree Law No. 145/2009, Art. 11.
Listing of medical devices: Yes
Details: Information (on the device and the manufacturer or authorized representative) will be registered on the European database. Decree Law No. 145/2009, Art. 58.

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

Post market controls
Post Market Surveillance: N/A
Details: N/A

Inspection (QMS): Yes
Details: Capítulo II, art. 21 https://dre.pt/application/dir/pdf1s/2012/02/04000/0088400890.pdf

Enforcement: Yes
Details: When devices may compromise the health and safety of a patient or third parties (i.e. the device does not fulfill essential requirements, does not comply with other standards, or is based on specious standards), the competent authority determines its withdrawal from the market and service. It must immediately communicate its decision to the EC as well as the manufacturer or its authorized representative. Decree Law No. 145/2009, Art. 29.

INFRAMED, IP, is the competent authority and it may supervise compliance with the Decree Law No. 145/2009 and regulations. Art. 60. Violations of the Decree Law No. 145/2009 are punishable by fines. Art. 61.

Adverse event reporting: Yes
Details: Manufacturers, agents, distributors, health professionals, and other users related to the use of medical device must communicate to the competent authority all information on incidents occurring in Portugal, including:
- any malfunction, deterioration, omission or inadequacy in Labelling or instructions for use of a device that may cause death or deterioration in a patient, user, or third party
- any indirect damage as a result of an incorrect medical devices as it relates to a medical device
- any technical reason or related medical characteristics of the performance of a device that has led to an FSCA for the same device type by the manufacturer. A competent authority must carry out an assessment (preferably with the manufacturer or its authorized representative) and then inform the EC and other member states of the measures taken to minimize recurrence of the incident. Decree Law No. 145/2009, Art. 27.

The National System of Medical Devices Vigilance has the takes to monitor incidents from the use of medical devices. The system aims to minimize risks from the use of medical devices, ensure the implementation of preventative/corrective measures, promote awareness among health professionals, supervise manufacturers’ performance, collect and analyse data, and allow information sharing between authorities and relevant entities between member states. Decree Law No. 145/2009, Art. 28.

Field safety corrective action monitoring: Yes

Advertising: Yes
Details: Advertising of a medical device may be performed directly by the manufacturer or a medical device or on behalf of a third party. Such advertisements must contain information that is not misleading. Decree Law No. 145/2009, Art. 43.
Advertisements to the public must contain minimum information such as the device name or trade mark and information necessary for the safe use of the device. It may not include any misleading material, and it may not take the form of comparative advertising. Decree Law No. 145/2009, Art. 46. Violations of the Decree Law No. 14572009's rules on advertising are punishable specially. Art. 62.

Labelling: Yes
Details: Labels and instructions for devices should be write in Portuguese. Decree Law No. 145/2009, Art. 5.