Spain

Legal

Legal framework: Yes


Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes

Name: Agencia Española de Medicamentos y Productos Sanitarios- http://www.aemps.gob.es/


Medical device definition

Medical device defined: Yes

Text: Medical device means any instrument, apparatus, appliance, software, material, or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application intended by the manufacturer to be used in human beings for the purpose of:
1. Diagnosis, prevention, monitoring, treatment or alleviation of disease,
2. diagnosis, monitoring, retatment, alleviation or compensation for an injury or defiency
3. investigation, replacement or modification of the anatomy or of a physiiological process,
4. control of conception, and does not achieve its principal intended action in or on the surface of the human body, immunological, pharmacological or metabolic means, but whose function may contribute to such means. Royal Decree 1591/2009, Art. 2.

In vitro diagnostic medical device (IVD) defined: Yes

Text: Defined separately.

Medical device classification

Classification: Yes

Categories: Products are classified into class I, IIa, IIb, and III. Royal Decree 1591/2009, Art. 11.

Classification rules: N/A

Classification rules details: N/A

Essential principles

Essential principles: Yes

Details: N/A

Conformity assessment

Conformity assessment bodies: Yes


The notified body must verify that the product meets the essential requirements and carry out conformity assessment tasks. Royal Decree 1591/2009, Art. 19.

Pre-marketing / procedure: A manufacturer must choose the appropriate conformity assessment procedure, depending on the class of the product. Royal Decree 1591/2009, Art. 13.

Reliance

Reliance: Yes

Details: When healthcare products meet the relevant national standards adopted pursuant to EU harmonized standards, they are presumed to comply with Spanish law. Royal Decree 1591/2009, Art. 6.

Jurisdictions: EU
Clinical investigation
Clinical investigation controls: Yes
Details: The Spanish Agency for Medicines and Health Products will keep a register of all clinical investigations, and it may grant/revoke permission for trials. Royal Decree 1591/2009, Art. 30. An investigator must seek permission from the Spanish Agency of Medicines and Health products before it commences an investigation. Royal Decree 1591/2009, Art. 31.

Registration and listing
Registration of establishment: Yes
Details: Any legal person who places a product for distribution and or use in Spain, must provide notice to the Spanish Agency of Medicines and Health Products. That notification must include information about the person as well as details on the device. Royal Decree 1591/2009, Art2. 22-23.
Listing of medical devices: Yes
Details: Any legal person who places a product for distribution and or use in Spain, must provide notice to the Spanish Agency of Medicines and Health Products. That notification must include information about the person as well as details on the device. Royal Decree 1591/2009, Art2. 22-23. Any manufacturer established in Spain that puts a class I or custom-made device on the market must notify the Agency for inclusion in the Register. Royal Decree 1591/2009, Art. 24.

Import controls
Import controls: Yes
Details: Importers must ensure that the product bears a CE marking, if applicable, and that the manufacturer has an authorized representative in the EU and has carried out the conformity assessment. Royal Decree 1591/2009, Art. 26. The Spanish Agency for Medicines and Health Products verifies that medical devices imported from third countries meet requirements, including:
- the importer has a license to operate
- the product has a CE mark
- the product has undergone conformity assessment
Goods that do not meet these criteria will be rejected. Royal Decree 1591/2009, Art. 28.

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): Yes
Details: The Spanish Agency for Medicines and Health Products exercises control over inspection activities. Royal Decree 1591/2009, Art. 34.
Enforcement: Yes
Details: Penalties may be imposed for violations of the Act. Royal Decree 1591/2009, Art. 42.
Adverse event reporting: Yes
Details: Manufacturers or their authorized representatives must send notice to the Spanish Agency for Medicines and Health Products of any incidents and corrective measures, including:
- any malfunction or deterioration in a product as well as any inadequate labelling or instructions for use that may lead to death or harm
- any technical or medical reason connected to the recall of the device of the same type
Royal Decree 1591/2009, Art. 32.
Field safety corrective action monitoring: Yes
Details: Manufacturers, authorized representatives, distributors and importers must take any restrictive measures or recalling action in case of evidence or suspicion that a product poses a health risk. Royal Decree 1591/2009, Art. 26.
Advertising: Yes
Labelling: Yes
Details: Labels and instructions for use must be in Spanish or a translation into Spanish. Royal Decree 1591/2009, Art. 23.

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.