### Legal

- **Legal framework:** Yes
- **Authorizing legislation:** NO. DY8d / G.P.oik.130648
- **Guidelines:** N/A

### National Regulatory Authority

- **National Regulatory Authority present:** Yes
- **Name:** National Organization for Medicines www.eof.gr%2Fweb%2Fguest%2Flawmedical
- **Responsibilities of the NRA:** N/A

### Medical device definition

- **Medical device defined:** Yes
- **Text:** Medical device: 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 the proper application of the device, intended by the manufacturer to be used for human beings for the purpose of:
  - Diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
  - Investigation, replacement or modification of the anatomy or of a physiological process,
  - Control of conception,
- And whose principal intended action in or on the human body is not achieved by pharmacological, immunological or metabolic means, but which may be assisted by such means.
- **DY8d / G.P.oik.130648.**
- **In vitro diagnostic medical device (IVD) defined:** Yes
- **Text:** Defined Separately.

### Medical device classification

- **Classification:** Yes
- **Categories:** Medical devices are classified, by risk into classes I, IIa, IIb, and III No. DY8d / G.P.oik.130648, Art. 9
- **Classification rules:** Yes
- **Classification rules details:** No. DY8d / G.P.oik.130648 ANNEX IX

### Essential principles

- **Essential principles:** Yes
- **Details:** The devices must meet the essential requirements listed in Annex I, which forces them according to the intended use of products. No. DY8d / G.P.oik.130648, Art. 3

### Conformity assessment

- **Conformity assessment bodies:** Yes
- **Details:** Notified bodies perform conformity assessments. . DY8d / G.P.oik.130648, Art. 16
- **Pre-marketing / procedure:** N/A

### Reliance

- **Reliance:** Yes
- **Details:** N/A
- **Jurisdictions:** EU

### Clinical investigation

- **Clinical investigation controls:** Yes
- **Details:** For Class III devices, IVDs and invasive devices, or long term use of IIA, IIB an overview of the clinical investigation plan must be submitted to EOF and must be approved. For other devices an overview must be submitted. And the NEJ must be informed. No. DY8d / G.P.oik.130648. Art. 15
Registration and listing

Registration of establishment: Yes
Details: Any manufacturer who sells pre-produce of his name, in accordance with the procedures referred to in Article 11 paragraphs 4 and 5, each other natural or legal person who exercises the activities referred to in Article 12 and is based in Greek territory, inform the EMEA for the address of the seat and to describe specific products, No. DY8d / G.P.oik.130648 Art. 14.1

Listing of medical devices: Yes
Details: For all medical devices of classes I, IIA, IIB and III, the manufacturer or his authorized representative shall submit to the EMEA all items allowing identification of those products and the labelling and the user guide before from the start of use of these products in Greek territory. No. DY8d / G.P.oik.130648 Art.14.1

Import controls

Import controls: N/A
Details: N/A

Post market controls

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

Inspection (QMS): Yes
Details: NO. DY8d / G.P.oik.130648 Annex 2, 5.2

Enforcement: N/A
Details: N/A

Adverse event reporting: Yes
Details: All serious adverse events must be fully recorded and be notified immediately. Essential requirements (medical devices) Regulation nr 598/2003. Annex 4.3 No. DY8d / G.P.oik.130648 Annex X. 1.1.5

Field safety corrective action monitoring: Yes

Advertising: Yes
Details: The advertising and general promotional material must to respond accurately to the intended use of the product. No. DY8d / G.P.oik.130648, Art. 22

Labelling: Yes

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.