Hungary

Legal

Legal framework: Yes

Authorizing legislation: Joint Decree on the Regulation of Medical Devices 4/2009 (III. 17.)
http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900004.EUM


Note: This law encompasses medical devices according to the National Institute of Pharmacy’s website.

Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes

Name: Department for Medical Devices, National Institute of Pharmacy http://ogyei.gov.hu/presidency2011/about_department_for_medical_devices

Responsibilities of the NRA: The Department for Medical Devices:
- supervises the national market of medical devices in coordination with the National Public Health and Medical Officer Service, the Hungarian Authority for Consumer Protection
- maintains a register of medical device manufacturers or authorized representatives
- supervises and maintains a register of devices intended for clinical investigations
- supervises manufacturers and distributors of devices
- authorizes and maintains a register of notified bodies to carry out inspections
- resolves disputes between manufacturers and notified bodies on classification rules
- make exceptions and grant licenses for putting a device into use
- manages the affairs of the Designation Committee that designates the notified bodies and supervises the notified bodies’ activities
http://ogyei.gov.hu/presidency2011/about_department_for_medical_devices

Medical device definition

Medical device defined: Yes

Text: A medical device is considered to be non-viable tissues or cells made using instruments;
(b) the administration of the medicinal product as preparation) tool;
(c)) the means, which is an integral part of a medicinal product as applied to itself, which is the instrument to amplify the human body;
(d)) the means, which is an integral part of human blood or human plasma, nor from using drug by itself or as a medicinal product, which is the instrument to amplify the human body (hereinafter referred to as human vérszármazék)
Joint Decree, § 5.

In vitro diagnostic medical device (IVD) defined: N/A

Text: N/A

Medical device classification

Classification: Yes

Categories: Class I, IIa, IIb, III
Joint Decree, § 12

Classification rules: Yes
Classification rules details: Joint Decree, Annex 9

Essential principles

Essential principles: Yes

Details: Medical devices placed on the Hungarian market must meet the essential requirements set out in Annex 1. Joint Decree

Conformity assessment

Conformity assessment bodies: Yes

Details: The notified body inspects and tests medical devices, and it issues conformity certificates. Joint Decree, § 14.

Pre-marketing / procedure: YES - To place a medical device on the market, it must bear a CE marking and the manufacturer or its authorized representative must have certifying documents. Joint Decree, § 5.

Conformity assessment procedures vary based on the classification of a device. Joint Decree, § 12.
The notified body inspects and tests medical devices, and it issues conformity certificates. Joint Decree, § 14. The conformity marking must be placed legibly on the device, packaging, and the user guide. Joint Decree, § 20.

**Reliance**

**Reliance:** Yes
**Details:** Harmonized standards shall be deemed to conform with the essential requirements of the Joint Decree. § 11.

**Jurisdictions:** EU

**Clinical investigation**

**Clinical investigation controls:** Yes
**Details:** Joint Decree, § 16

**Registration and listing**

**Registration of establishment:** Yes
**Details:** The manufacturer or the authorized representative’s name, residence or head office must be indicated (to the ENKK)
Joint Decree, § 17, annex 16
**Listing of medical devices:** Yes
**Details:** Hungarian manufacturers must provide information on location, name, and description of the device when it first places it on the market. Joint Decree, § 17
The ENKK will also provide information to the European database. Joint Decree, § 26.

**Import controls**

**Import controls:** Yes
**Details:** The importer must ensure that the manufacturer has carried out the conformity assessment procedure and complied with technical documentation as well as ensure the product bears the conformity marking(s) as required by law. § 11.
Products from third party countries (Non-EU) will be subject to control. Law on Market Surveillance, §13

**Post market controls**

**Post Market Surveillance:** Yes
**Details:** The Law on Market Surveillance details market surveillance for all products manufactured or marketed in Hungary and sold in Hungary. The manufacturer is required to have undergone the appropriate conformity assessment procedure. § 7. The manufacturer must also carry out surveillance of its devices

**Inspection (QMS):** Yes
**Details:** http://ogyei.gov.hu/presidency2011/about_department_for_medical_devices

**Enforcement:** Yes
**Details:** If the ENKK determines that a medical device may compromise health or safety, it may suspend the marketing and use of that device. Joint Decree, § 22. Further, when the device is incorrectly CE marked, the ENKK may suspend marketing and use of that device. Id. § 23.

**Adverse event reporting:** Yes
**Details:** The manufacturer or its authorized representative must report any adverse incident. Reporting requirements on timing vary based on the nature of the incident. Joint Decree, § 21.

**Field safety corrective action monitoring:** Yes
**Details:** Joint Decree § 62

**Advertising:** N/A
**Details:** N/A

**Labelling:** Yes
**Details:** Joint Decree § 13.3.

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.