Belgium

**Legal**

**Legal framework:** Yes

**Authorizing legislation:** Arrêté royal portant instructions pour les pharmaciens (30 Jan. 2009) [link]

Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999) (as amended in 2010) [link]

Arrêté royal relatif aux dispositifs médicaux de diagnostic in vitro.(14 November 2001) [link]

**Guidelines:** N/A

**Notes:** Belgian law integrates several European Economic Council Directives into its law, namely:
- Directive 90/385/EEC concerning active implantable medical devices
- Directive 93/42/EEC concerning medical devices
- Directive 98/79/EC concerning IVDs

**National Regulatory Authority**

**National Regulatory Authority present:** Yes

**Name:** Health Products Division, Agence Fédérale des Médicaments et des Produits de Santé (AFMPS) [link]

**Responsibilities of the NRA:** N/A

**Medical device definition**

**Medical device defined:** Yes

**Text:** A medical device is defined as: 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 operation thereof intended by the manufacturer to be used in humans for purposes 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 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 whose function can be assisted by such means.

Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), Art 1., § 1er.

**In vitro diagnostic medical device (IVD) defined:** Yes

**Text:** Arrêté royal relatif aux dispositifs médicaux de diagnostic in vitro, Art. 1, Par. 2.

**Medical device classification**

**Classification:** Yes

**Categories:** Categorized into four classes: I, IIa, IIb, and III. Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), Art 4., § 1er.

**Classification rules:** Yes

**Classification rules details:** Annex IX of Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999).

**Essential principles**

**Essential principles:** Yes

**Details:** No medical device may be placed in the market or distributed if essential principles are not met (See Annex I).

Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), Art 3.

**Conformity assessment**

**Conformity assessment bodies:** Yes

**Details:** Depending on the class of device (IIa, IIb, and III), a manufacturer must meet certain documentation and inspection requirements (performed by a designated notified body). Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), at Art. 5.

Manufacturers of class I devices only need to provide notice with a notified body. [link]

**Pre-marketing / procedure:** N/A
Reliance
Reliance: Yes
Details: If the medical device satisfies harmonized norms, then they are presumed to conform with Belgian requirements. Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), Art 1., § 3.
Jurisdictions: EU

Clinical investigation
Clinical investigation controls: Yes
Details: A medical device manufacturer must apply for and receive permission from the AFMPS to undertake a clinical trial. Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), Art 9.

Registration and listing
Registration of establishment: Yes
Details: Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), Art 10.
Listing of medical devices: Yes
Details: Manufacturers must provide a notification of any Class I devices they put in the market. Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), Art 10.

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

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): Yes
Details: Inspections are performed by a Notified Body. Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), Annexe I, Art. 5N2.5.
Enforcement: Yes
Details: A Commission of Evaluation, a composite of members chosen either by the Minister of Health, Nuclear Control, or Affairs, may pull a device off the market following an investigation and report. Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), Art 1.1-13.
Adverse event reporting: Yes
Details: A manufacturer or its designee must provide adverse event information to the AFMPS. The AFMPS may then solicit the advise of experts to obtain additional information. Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), Art 11.
Field safety corrective action monitoring: Yes
Details: Manufacturers and authorized representatives must take the necessary measures following an incident report. The measures to be taken following an incident report. Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), Art. 11.
Advertising: Yes
Details: No medical device may be advertised without the CE marking. Arrêté royal relatif aux dispositifs médicaux (14 Apr. 1999), Art 17.
Labelling: Yes