Legal
Legal framework: Yes
Guideline on Advertising, etc. of Medical Devices http://sundhedsstyrelsen.dk/en/medicines/medical-devices/legislation-and-guidance/-/media/C3E28514CC994543A8EF6DBBCD6D3C79.ashx

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Danish Medicines Agency http://sundhedsstyrelsen.dk/en/medicines/medical-devices
Responsibilities of the NRA: Pursuant to the Act on Medical Devices, the Ministry may lay down all the necessary rules for the implementation of EC legislation on medical devices, including:
- requirements for safety, quality, and performance
- requirements for the approval of products
- restriction of access to marketing, distribution, and use
- registration or persons responsible for marketing
- regulatory oversight and control
- mandatory reporting of adverse incidents
- withdrawal from the market and mitigation of harmful medical devices
- clinical testing of medical devices in humans and clinical trials
- rules on advertising of medical devices
Act on Medical Devices, Sec. 1.

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 or therapeutic purposes and necessary for its proper application, intended by the manufacturer for use in humans in order to:
a) the diagnosis, prevention, monitoring, treatment or alleviation of disease,
b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
c) investigation, replacement or modification of the anatomy or of a physiological process, or
d) contraception,
and its principal intended action in or on the human body not by pharmacological, immunological or metabolic means, but which may be assisted in this way.
Order No. 1263, Sec. 1; see also Order on Importers and Distributors of Medical Devices, Sec. 1.
In vitro diagnostic medical device (IVD) defined: N/A
Text: N/A

Medical device classification
Classification: Yes
Categories: Medical devices are divided into classes I, IIa, IIb, and III. Order No. 1263, Sec. 5.
Classification rules: Yes
Classification rules details: Classification rules are described in Annex IX of Order No. 1263.

Essential principles
Essential principles: Yes
Details: Medical devices may only be marketed, sold, distributed, or used if they (1) meet the essential requirements contained within Order No. 1263, Sec. 3. See Annex I for Essential Requirements.
Conformity assessment

Conformity assessment bodies: Yes
Details: The CE marking must be accompanied by the identification number of the notified body responsible for implementation of the procedures. Order No. 1263, Art. 4.

Pre-marketing / procedure: Medical devices may only be marketed, sold, distributed, or used if they (1) meet the essential requirements contained within Order No. 1263, Sec. 3, (2) been subject to conformity assessment, and (3) bear the CE marking. Sec. 2-4. Medical devices must meet the harmonized European standards. Depending on the classification of the medical device, one must follow a different conformity procedure, detailed in Order No. 1263, Sec. 6.

Reliance

Reliance: Yes
Details: N/A
Jurisdictions: EU

Clinical investigation

Clinical investigation controls: Yes
Details: The Notice of application for authorization of clinical investigations provides the rules governing an application for an authorization of a clinical trial of medical devices in humans. Under Order No. 1263, the Danish Medicines Agency must authorize clinical trials of medical devices. Sec. 9.

Registration and listing

Registration of establishment: Yes
Details: A manufacturer or his representative must notify the Danish Medicines Agency with information. Order No. 1263, Sec. 12.
Listing of medical devices: Yes
Details: Only Class I medical devices, system and medical treatment packages and devices that are sterilised must be listed. https://laegemiddelstyrelsen.dk/en/devices/registration-and-marketing/manufacturers-of-medical-devices

Import controls

Import controls: Yes
Details: The Order on Importers details import controls on medical devices, including the definition of an importer. An importer must inform the Board of Health with information on its address as well as the products it imports into Denmark. It must also provide information in an electronic register that may be used as part of market surveillance. Order No. 1263, Ch. 2.

Post market controls

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

Inspection (QMS): Yes
Details: Order No. 1263, Ch. 8, § 15.

Enforcement: Yes
Details: Violation to the regulations is punishable by a fine. Order No. 1263 Chap. 9 on Penalties.

Adverse event reporting: Yes
Details: A manufacturer or its representative must immediately notify the Danish Medicines Agency of any adverse event. It must also submit notice, as soon as possible, of the reason for any product recall. Order No. 1263, Sec. 14.

Field safety corrective action monitoring: Yes
Details: Product Safety Act, Art 9

Advertising: Yes
Details: The Guideline on Advertising of Medical Devices supplements Executive Order no. 1155 of 22 October 2014 on advertising. The Guideline defines advertising activity and carves out exemptions. Advertising must be factual and consistent with the manufacturer's intended purposes.

Labelling: Yes
Details: A manufacturer must provide consumers with the information necessary to enable consumers to assess the risks associated with the product when used in foreseeable manner and within the expected lifetime. This information is given in the form of warning labels, instructions, installation instructions, and the like. Product Safety Act, Art. 7.

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.