Legal

Legal framework: Yes


National Regulatory Authority

National Regulatory Authority present: Yes

Name: Norwegian Directorate of Health https://helsedirektoratet.no/english/medical-devices

Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes

Text: A medical device is any instrument, apparatus, equipment, software, material or other article, whether used alone or in combination, including the software that the manufacturer is intended to be used specifically for diagnostic and/or therapeutic purposes and necessary for proper use, and that is intended to be used on humans, for:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation for injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- pregnancy prevention,
and in which the desired main action in or on the human body is provoked by pharmacological or immunological effects or by affecting the metabolism, but where such effects contribute to its function.

Regulations on Medical Devices, § 1-5 (a).

In vitro diagnostic medical device (IVD) defined: Yes

Text: Defined separately.

Medical device classification

Classification: Yes

Categories: Class I, class IIa, class IIb, and class III Regulations on Medical Devices § 05.03

Classification rules: Yes

Classification rules details: Classification shall be performed in accordance with Annex IX EMU (EU directive) Regulations on Medical Devices § 05.03

Essential principles

Essential principles: Yes

Details: Medical devices must comply with basic requirements of Chapters 3 to 5 of the Regulations on Medical Devices. § 2.1

Conformity assessment

Conformity assessment bodies: Yes

Details: Yes - A Notified Body may require any additional information or data that is necessary for the conformity assessment. Regulations on Medical Devices, § 2.3

Pre-marketing / procedure: Yes

Reliance

Reliance: Yes

Details: N/A

Jurisdictions: EU - Devices that comply with the requirements under 2006/42/EC of 16 May 2006 also meet Norwegian standards to the extent that the EC requirements are more specific than the essential requirements set out under Norwegian law. Regulations on Medical Devices, § 2.1
**Clinical investigation**

**Clinical investigation controls:** Yes

**Details:** For devices intended for clinical investigations the manufacturer or the responsible representative established within the EEA, no later than 60 days before the trial begins, issue a declaration as referred to in Annex VI Aims to the supervisory authority in the Member States where the trials will take place Regulations on Medical Devices, § 4-5.

**Registration and listing**

**Registration of establishment:** Yes

**Details:**
- Entities with a business address in Norway that produces and markets in its own name medical devices must register their company name, business address, and other data.
- Entities without a business address in the EEA but markets equipment within the Community must designate a responsible representative within the EEA.
- Manufacturers of IVDs must notify the competent authority in each country within the EEA where they market that equipment. Regulations on Medical Devices, § 2-8

**Listing of medical devices:** Yes

**Details:**
- Anyone with a business address in Norway, which produces and in their own name markets equipment, or conduct activities described in § 8.5, shall insert their company name, registration number, business address, and data that make it possible to uniquely identify the equipment in a public equipment registry. Regulations on Medical Devices, § 2-8.

**Import controls**

**Import controls:** Yes

**Details:** For devices that are imported into the European Community, the medical device must display the responsible entity within the EEA for marketing and distribution. Regulations on Medical Devices, § 2-5.

**Post market controls**

**Post Market Surveillance:** N/A

**Details:** N/A

**Inspection (QMS):** Yes

**Details:**

**Enforcement:** Yes

**Details:**
- Violations of regulations or decisions made pursuant to the Regulations on Medical Devices are punishable by law. Regulations on Medical Devices § 5.6
- The Norwegian Directorate of Health and Norwegian Directorate for Civil protection may in some cases order a medical device withdrawn from the market, restrict of prohibit the right to place a device on the market, or use the device. Regulations on Medical Devices § 6-4

**Adverse event reporting:** Yes

**Details:**
- Whoever produces or sells equipment must inform the supervisory authority about:
  a) any malfunction or deterioration in the performance as well as any lack of labelling or instructions for use that may lead to harm to the patient, another user, or a third party
  b) any technical or medical reason connected with the characteristics or performance that led to the recall of device from the market

Regulations on Medical Devices, § 2-11

Under the Regulations on Use of Medical Devices, an entity is obliged to Notify the Health Directorate and Directorate for Civil protection and Emergency Planning of events that have or may be related to the use of medical devices and which have led or could have led to death or serious deterioration of a patient, user, or another’s health. § 16.

**Field safety corrective action monitoring:** Yes

**Details:**
- Regulation on medical devices; FOR-2005-12-15-1690
- Appendix AIMU VI.5

**Advertising:** N/A

**Details:** N/A

**Labelling:** Yes

**Details:**
- Regulation on medical devices; FOR-2005-12-15-1690 § 5.