**Legal**

Legal framework: Yes


Guidelines: N/A

**National Regulatory Authority**

National Regulatory Authority present: Yes

Name: Dutch Healthcare Inspectorate http://www.igz.nl/english/medical_devices/

Responsibilities of the NRA: Enforcing compliance with the provisions under or pursuant to this Act are officials of the Dutch Health Care Inspectorate.

**Medical device definition**

Medical device defined: Yes

Text: A medical device means any instrument, apparatus, appliance, software, material or article used alone or in combination, including the software necessary for its proper operation satisfying, by the manufacturer, is specifically intended to be used for diagnostic or therapeutic purposes, and by the manufacturer, is intended to be used for human beings for:
- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conception, with its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted by such means.

Law on Medical Devices, Art. 1.

In vitro diagnostic medical device (IVD) defined: Yes

Text: Defined separately in the Decision on in vitro diagnostics.

**Medical device classification**

Classification: Yes

Categories: Class I, IIa, IIb, and III.

Classification rules: Yes

Classification rules details: Devices are classified pursuant to EC directives. e.g., Decision on Medical Devices, Art. 8.

**Essential principles**

Essential principles: Yes

Details: Decision on Medical Devices, Art. 4.

**Conformity assessment**

Conformity assessment bodies: Yes

Details: Yes

See Decision on Medical Devices, Art. 11.

Pre-marketing / procedure: Yes - Article 9 of Decision on Medical Devices details the conformity assessment procedure for different classes of medical devices with reference to EU relevant directives

**Reliance**

Reliance: Yes

Details: Decision on Medical Devices, Art. 6.

Jurisdictions: EU

**Clinical investigation**

Clinical investigation controls: Yes

Details: For medical devices intended for clinical investigations, the manufacturer must follow a procedure to gain permission from the Dutch Health Care Inspectorate pursuant to Annex VIII of the EU Directive. Decision on Medical Devices, Art. 13, and if applicable permission from the Central Committee on Research involving human Subjects (CCMO). http://www.ccmo.nl/en/search
Registration and listing
Registration of establishment: Yes
Details: A Netherlands-based manufacturer or a foreigner’s authorized representative delivering Class I devices must provide the Minister with its residence and a description of Class I devices. Decision on Medical Devices, Art. 5
Listing of medical devices: Yes
Details: A Netherlands-based manufacturer or a foreigner’s authorized representative delivering Class I devices must provide the Minister with its residence and a description of Class I devices. Decision on Medical Devices, Art. 5.

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

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): Yes
Details: Law on Medical Devices, Art. 11 http://wetten.overheid.nl/BWBR0002697/2015-01-01#Artikel11
Enforcement: Yes
Details: Law on Medical Devices, Art. 14
Adverse event reporting: Yes
Details: Decision on Medical Devices, Art. 11
Field safety corrective action monitoring: Yes
Details: Decision on Medical Devices, art 11
Advertising: N/A
Details: N/A
Labelling: Yes
Details: Decision on Medical Devices, Art. 1d.

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.