**Legal**

- **Legal framework:** Yes
- **Guidelines:** N/A

**National Regulatory Authority**

- **National Regulatory Authority present:** Yes
- **Name:** The Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products [http://en.urpl.gov.pl/general-information](http://en.urpl.gov.pl/general-information)

**Medical device definition**

- **Medical device defined:** Yes
- **Text:** A medical device is a tool, instrument, appliance, software, material or other article, whether used alone or in combination, including 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 to:
  a) the diagnosis, prevention, monitoring, treatment or alleviation of the disease,
  b) diagnosis, monitoring, treatment, alleviation or compensation of an injury or handicap,
  c) investigation, replacement or modification of the anatomy or physiological process,
  d) control of conception
  whose principal intended action in the body or on the human body is not achieved [through pharmacological], immunological or metabolic means, but which action can be assisted by such means.[] Act on Medical Devices, Art 2.1 (38).
- **In vitro diagnostic medical device (IVD) defined:** Yes
- **Text:** Defined separately.

**Medical device classification**

- **Classification:** Yes
- **Categories:** Medical devices are classified by risk into class I, IIa, IIb; or III. Act on Medical Devices, Art. 20.
  IVDs are classified into list A or B.
- **Classification rules:** Yes
- **Classification rules details:** N/A

**Essential principles**

- **Essential principles:** Yes
- **Details:** N/A

**Conformity assessment**

- **Conformity assessment bodies:** Yes
- **Details:** Yes - Conformity assessment is performed by the manufacturer or an authorized representative or under a notified body. Act on Medical Devices, Art 29.
- **Pre-marketing / procedure:** Yes - It is forbidden to place on the market, use, evaluate, distribute, share, deliver, etc. medical devices that pose a threat to safety, life of health or patients, users, or other persons exceeding the acceptable limits of risk. Act on Medical Devices, Art. 6.
  Conformity assessment is performed by the manufacturer or an authorized representative or under a Notified body. Act on Medical Devices, Art 29.

**Reliance**

- **Reliance:** Yes
- **Details:** Poland is a member of the EU, and its Act on Medical Devices explicitly implements EC directives. It is presumed that products that comply with national Polish standards insofar that they comply with the harmonized standards of the EU. Act on Medical Devices, Art. 26.
- **Jurisdictions:** EU

**Clinical investigation**

- **Clinical investigation controls:** Yes
- **Details:** Act on Medical Devices, Art. 64; Art. 65
Registration and listing
Registration of establishment: Yes
Details: Act on Medical Devices, Art 13.
Listing of medical devices: Yes
Details: The manufacturer having the place of residence or the registered office on the territory of
the Republic of Poland shall keep the list of all service providers and distributors to whom
he/she had delivered the devices, for the period for which he/she envisaged the device to be
used, and shall make the list available during inspection referred to in Article 69(1)(2) and
immediately upon request of the President of the Office for Registration of Medicinal Products,
Medical Devices and Biocidal Products, hereinafter referred to as “President of the Office.”
Act on Medical Devices, Art. 66

Import controls
Import controls: Yes
Details: An importer (and distributor) must act with due diligence to ensure product safety. Before
placing a product on the market, the importer must check that:
1) the manufacturer or its authorized representative carried out the appropriate product evaluation
process
2) the manufacturer appointed an authorized representative for the product
3) the product is CE marked as well as the identification number for the notified body conformity
assessment
4) the information provided by the manufacturer meets the essential requirements. The importer
(and distributor) must also check whether the products they place on the market, put into use, or
make available are properly labelled and have appropriate instructions for use.
Act on Medical Devices, Art. 17.

Post market controls
Post Market Surveillance: Yes
Details: An importer (or distributor) in Poland must act on the behalf of the manufacturer or
its authorized representative on matters of product safety. The importer (or distributor) must
share information if they learn that the marketed may be dangerous. Further, the importer (and
distributor) must accept from users and patients information on any adverse events. Act on
Medical Devices, Art. 18.1.

Inspection (QMS): Yes
Details: The President of the Office responsible for oversight exercises supervision of products
produced, introduced, and placed on the market. Act on Medical Devices, Art. 68, Art. 69.

Enforcement: Yes
Details: There are penal provisions (both fines and criminal penalties) for mislabelling or misleading
labelling, not following conformity procedures, etc. Act on Medical Devices, Arts. 93-103.

Adverse event reporting: Yes
Details: Anyone may submit information on an adverse incident to the President of the Office.
Healthcare providers are obliged to report information immediately to the manufacturer or its
authorized representative. Act on Medical Devices, Art. 74.

Field safety corrective action monitoring: Yes
Details: The manufacturer is obliged to ensure that the authorized representative and any other
entity authorized by the manufacturer to act on its behalf completes a Field Safety Corrective
Action. Those entities will notify the President of the Office on the implementation of the FSCA.
Additionally, the manufacturer or its representative must draw up a report and memo on the action
to inform customers or users. Act on Medical Devices, Arts. 75-85.

Advertising: N/A
Details: N/A

Labelling: Yes
Details: It is forbidden to place on the market, put into service, distribution, delivery, and sharing of
products whose names, Labelling or instructions for use can be misleading as to the characteristics
and operation of the product. Act on Medical Devices, Arts. 8.1, 41.

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.