Germany

World Bank income group: High income

Legal
Legal framework: Yes
Ordinance on Clinical Trials of Medical Devices (MPKPV) http://www.gesetze-im-internet.de/mpkpv/BJNR055510001.html
General Administrative Regulation Implementing the Medical Devices Act (MPGVwV) http://www.verwaltungsvorschriften-im-internet.de/bsvwvbund_18052012_BMG.htm
Regulation on the database-supported information system on medical devices of the German Institute of Medical Documentation and Information (DIMDIV) http://www.gesetze-im-internet.de/dimdiv/BJNR445610002.html
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Federal Institute for Drugs and medical Devices (BfArM) http://www.bfarm.de/EN/Home/home_node.html
Responsibilities of the NRA: By law, the BfArM is responsible for assessment and safety of medical devices, approvals of clinical trials, decisions on classification of medical devices, special authorizations, and advising competent authorities. Medical Devices Act, § 32. www.bfarm.de%2FDE%2FMedizinprodukte%2FrechtlicherRahmen%2Faufgaben%2F_node.html

Medical device definition
Medical device defined: Yes
Text: Medical devices are all individually or linked instruments, apparatus, appliance, software, material and preparations of substances or other items including the designated by the manufacturer specifically to be used for diagNOstic or therapeutic purposes and used for a proper of medical device software used by the manufacturer to be used for people using its functions for the purpose a) the diagnosis, prevention, monitoring, treatment or alleviation of disease, b) the diagnosis, monitoring, treatment, alleviation or compensation for injuries or disabilities, c) investigation, replacement or modification of the anatomical structure or of a physiological process or d) the control of conception, intended to serve and its principal intended action in the or on the human body is achieved by pharmacological or immuNOlogical acting means NOr by metabolism, whose mode of action but can be supported by such means.
Medical Devices Act, § 3.
In vitro diagnostic medical device (IVD) defined: Yes
Text: Included, Defined Separately.

Medical device classification
Classification: Yes
Categories: Medical devices are classified, by risk into classes I, IIa, IIb, and III, according to Directive 93/42/EEC. Medical Devices Act, § 13.
Classification rules: Yes
Classification rules details: The classification is according to the classification rules set out in Annex IX to Directive 93/42 / EEC. Medical Devices Act, § 13.

Essential principles
Essential principles: Yes
Details: It is forbidden to bring medical products on the market if they do not comply with the essential requirements. The essential requirements are the requirements of Annex 1 of Directive 90/385 / EEC of 20 June 1990. Medical Devices Act, §§ 4, 7.

Conformity assessment
Conformity assessment bodies: Yes
Details: Notified bodies perform conformity assessments. Medical Devices Act, § 15.
Pre-marketing / procedure: The Ministry of Health is authorized to regulate the conditions to grant conformity certificates, implement conformity assessment procedures, and assign classes of medical devices. Medical Devices Act, § 37.
The Ordinance on Medical Devices details the conformity assessment procedures for each category of medical device. Medical Devices Act §82-7

Reliance
Reliance: Yes
Details: N/A
Jurisdictions: EU
Clinical investigation
Clinical investigation controls: Yes
Details: Clinical trials for certain medical devices are not necessary for devices that pose a low risk or for devices that have a CE marking and have undergone a clinical audit shows. For those devices, one must apply for an exemption from the German Institute for Medical Documentation. Ordinance on Clinical Trials for Medical Devices, § 7.
Medical device trials may only begin in Germany if both the Ethics Committee and the federal authority provides approval. Section 20 details additional requirements of the Medical Devices Act.
The Ordinance on Clinical Trials for Medical Devices details the procedure for clinical trials, which are required to carry out the conformity assessment procedure for certain devices. § 1.

Registration and listing
Registration of establishment: Yes
Details: Medical Devices Act, § 25
Listing of medical devices: Yes
Details: The German Institute of Medical Documentation and Information has an information system to support enforcement of the Medical Devices Act. It collects information on the medical devices (use, evaluation, risk assessment, etc.), transmits data to other Member States and the EU, and maintains other databases related to medical devices. Medical Devices Act, § 33.
Manufacturers have to notify their products when they are marketed for the first time: IVDs, active implantables, medical devices with a measuring function.
http://www.gesetze-im-internet.de/mpg/BJNR196300994.html

Import controls
Import controls: Yes
Details: Medical devices may be imported if they bear a CE marking. Medical Devices Act, § 6.

Post market controls
Post Market Surveillance: Yes
Details: Under the MPGvWvV, there are three principles of market surveillance:
- risk-based surveillance
- monitoring measures
- personnel and equipment
§ 2.
Inspection (QMS): Yes
Details: Inspections are carried out to determine whether marketing, commissioning, installation/use of medical devices, conduct of clinical trials, and the reprocessing of devices meet requirements under law. Inspections may be unannounced. MPGvWvV, § 5.
Samples may be taken as part of monitoring activities. MPGvWvV, § 6
Enforcement: Yes
Details: A notified body may revoke or suspend a certificate of conformity if one does not comply with requirements. The notified body must also inform the German Institute, the responsible authority, other competent authorities, and/or other third parties. Medical Devices Act, § 18.
The competent authority must ensure that a German manufacturer has complied with health and safety standards. It may inspect premises, take samples, see all documents related to the medical devices, and demand any other information. Medical Devices Act, § 26, Act, § 27, Act, § 28.
Both criminal and civil penalties (i.e. fines) may be imposed on one who violates provisions of the Medical Devices Act. §40-41.
Adverse event reporting: Yes
Details: The safety officer for medical devices shall collect and evaluate existing information concerning risks connected to medical devices and shall co-ordinate the necessary measures. He/she is responsible for the fulfilment of reporting obligations in so far as they concern risks related to medical devices. Medical Device Act, Section 30.4
Field safety corrective action monitoring: Yes
Details: Medical device Act, Section 29
Advertising: Yes
Details: The MPGvWvV instructs competent authorities to develop rules on advertising. § 13.
Labelling: Yes
Details: The address and name of the manufacturer or its authorized representative must be included on the label or in the instructions for use on the medical device. Medical Devices Act, § 5.

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.