Legal
Legal framework: Yes

Authorizing legislation: Medical Devices Act 1996
http://www.basg.gv.at/ueber-uns/gesetzliche-grundlagen/medizinprodukte/
Regulation on operation and use of medical devices (2007)
https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005279
Regulation on the Medical Devices Registry (2011)
https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20003188
Regulation on classification of medical devices (2015)
https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20006291

Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Austrian Medicines and Medical Devices Agency

Responsibilities of the NRA: The responsibilities of the Agency include issuing marketing authorization for medicinal products (human and veterinary), assessing the efficacy and safety of medicinal products and medical devices, market surveillance, and inspection of manufacturers.

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 and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
1. diagnosis, prevention, monitoring, treatment or alleviation of disease,
2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
3. investigation, replacement or modification of the anatomy or of a physiological process,
4. control of conception,
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.


In vitro diagnostic medical device (IVD) defined: Yes

Medical device classification
Classification: Yes
Categories: Categorized generally into three types:
(1) Active implantable medical devices
(2) General medical devices
(3) Medical devices for in-vitro diagnosis or in-vitro diagnostic medical devices.

General medical devices are further classified:
Class I - low risk
Class IIa - medium risk
Class IIb - increased risk
Class III - highest risk

In-vitro diagnostic medical devices are further classified:
General IVD - low risk
IVD for self-diagnosis - medium risk
List B IVD - increased risk
List A IVD - highest risk

Classification rules: Yes
Classification rules details: The Regulation on the Classification of Medical Devices details the classification rules, which follow EEC directives.

Essential principles
Essential principles: Yes
Details: Medical devices must be designed and manufactured so that their application not compromise the clinical condition or the safety of patients. They must be designed, manufactured and packaged so that they are suitable to achieve the performances intended by the manufacturer. Design and construction
Conformity assessment
Conformity assessment bodies: Yes
Details: Notified bodies carry out the conformity assessment procedures. Medical Devices Act, Section 6.
Pre-marketing / procedure: Medical devices may only be used or put onto the market in Austria if their conformity has been assessed. Medical Devices Act, Section 4. See also Regulation on conformity assessment of medical devices (2004).

Reliance
Reliance: Yes
Details: N/A
Jurisdictions: EU

Clinical investigation
Clinical investigation controls: Yes
Details: Clinical evaluation of a medical device must follow the harmonized standards to account, any clinical trials involving medical devices must conform with the Declaration of Helsinki. Medical Devices Act, § 38-66.

Registration and listing
Registration of establishment: Yes
Details: Medical Device Reporting Ordinance.
Listing of medical devices: Yes
Details: Medical Devices Act, IV, Section 4.

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

Post market controls
Post Market Surveillance: Yes
Inspection (QMS): Yes
Details: Facilities are subject to monitoring by the federal office for safety and health or by a notified body. Medical Devices Act, § 68.
Enforcement: Yes
Details: Medical Devices Act, § 111, 117.
Adverse event reporting: Yes
Details: Any incidents must be reported immediately to the Federal Office for Safety in Health. Medical Devices Act, § 70.
Field safety corrective action monitoring: Yes
Details: Medical Devices Act § 70.
Advertising: Yes
Details: Any labelling, packaging and advertising information may not be misleading. Advertising materials may not contradict the labelling and instructions for use. For advertising requirements. Medical Devices Act, § 102-109.
Labelling: Yes
Details: Every medical device must be accompanied by the information required for safe use and must be indicated on the medical device itself, on a piece of it and, or on the sales packaging. Medical Devices Act, § 9.