Legal
Legal framework: Yes
Authorizing legislation:
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Swiss Agency for Therapeutic Products, Swissmedic - https://www.swissmedic.ch

Medical device definition
Medical device defined: Yes
Text: Medical Devices are instruments, apparatus, appliance, software, substances, accessories or other medical technology articles, whether used alone or in combination, including software that is specifically intended for diagnostic or therapeutic purposes and necessary for the proper functioning of a medical device:
   a. that are intended for use on humans;
   b. whose principal intended action in or on the human body is not achieved by pharmacological, immunological or metabolic means, but which action can be assisted by such means; and
   c. that serve to:
      1. Diagnose, prevent, monitor, treat or alleviate diseases;
      2. Diagnose, monitor, treat or alleviate injuries or handicap, or compensate handicap;
      3. Investigate or modify the anatomical structure, to replace partsthereof, or to investigate, modify or replace a physiological process;
   In vitro diagnostic medical device (IVD) defined: Yes
   Text: Included, defined separately - The Ordinance on Medical Devices, Art. 1.

Medical device classification
Classification: Yes
Categories: Classical medical devices are classified into Class I, IIa, IIb, and III by the person who first places them on the market. Classification is done pursuant to Annex IX of the Directive 93/42/EEC. Ordinance on Medical Devices, Art. 5.
Classification rules: Yes
Classification rules details: N/A

Essential principles
Essential principles: Yes
Details: Reference is made to Annex I of 93/42/EEC and Directive 90/385/EEC.

Conformity assessment
Conformity assessment bodies: Yes
Details: Conformity assessment bodies must be accredited by and authorized under Swiss law. Ordinance on Medical Devices, Art. 11.
Pre-marketing / procedure: A person that places a medical device on the market in Switzerland must provide a Declaration of Conformity and other information. Ordinance on Medical Devices, Art. 9.
A representative of the European Commission and two representatives of two EU Member States may participate in conformity assessment conducted by the Agency. Ordinance on Medical Devices Amendment (2015)

Reliance
Reliance: Yes
Details: Pursuant to Art. 4 of the Ordinance on Medical Devices, Switzerland relies on one of three EEC directives, depending on the class of device:
   b. IVDs - Annex I of Directive 98/79/EC
   c. active implantable medical devices - Annex I of 90/385/EEC
Classic medical devices and active implantables must meet additional requirements under Swiss law if they are more specific than those set out in the directive 2006/42/EU (or the new version Directive 96/16/EU).
Also, Switzerland classifies its devices pursuant to Directive 93/42/EEC. Ordinance on Medical Devices, Art. 5.
Jurisdictions: EU

Clinical investigation
Clinical investigation controls: Yes
Details: The Federal Council will lay down requirements for medical devices for use in clinical trials. TPA, Art. 45.
Clinical trials of therapeutic products must follow requirements under the Human Research Act. TPA, Art. 53.
Further, clinical trials of therapeutic products, including medical devices, require authorization from the Agency, except for medical devices that have a use matching that of the conformity assessment. TPA, Art. 54.
Registration and listing
Registration of establishment: Yes
Details: The person first placing the following medical devices on the market in Switzerland or in a treaty country and whose place of business is in Switzerland must notify the Agency of the name and address and the description of the devices. Ordinance on Medical Devices, Art. 6
Listing of medical devices: Yes
Details: The person first placing the following medical devices on the market in Switzerland or in a treaty country and whose place of business is in Switzerland must notify the Agency of the name and address and a description of the devices concerned at the latest by the time they are placed on the market: class I medical devices; custom-made classical or active implantable medical devices, systems and procedure packs (and IVDs) Ordinance on Medical Devices, Art. 6

Import controls
Import controls: Yes
Details: The Federal Council may restrict or prohibit the importation of certain medical devices. TPA, Art. 50.
The Agency may issue an import certificate where a third country demands evidence on the medical device to be placed on the market. It may, in turn, revoke the certificate on the basis of incorrect documentation, not meeting conformity requirements, or the device representing a health danger. Ordinance on Medical Devices, Art. 22.

Post market controls
Post Market Surveillance: Yes
Details: Anyone who places a device on the market must introduce and maintain a product-tracking system that allows for the collection and analysis of consumer experiences. TPA, Art. 47.
The Ordinance on Medical Devices details the minimum requirements of a self-control surveillance system. It must contain specific device information on:
- complaints
- relevant experience concerning use and effectiveness
- reports from specialized literature
- results of own investigations
- corrective actions
See Art. 14.
Inspection (QMS): Yes
Details: The institutions responsible for compliance monitoring may, in order to examine the conformity of medical devices, and free of charge:
enter and inspect, during normal working hours, the business premises and facilities of persons who have an obligation to provide information. Ordinance on Medical Devices (17 Oct. 2001), Art. 26
Enforcement: Yes
Details: A person may be subject to criminal penalties when he or she wilfully endangers human life by:
- neglecting duty to exercise diligence
- manufacturinfor placing on the market or importing products without authorization or license
- dispensing medical products without authorization
- placing medical devices on the market that do not satisfy the requirements of the Act
- neglecting the obligation to maintain medical devices
TPA, Art. 86.
Adverse event reporting: Yes
Details: If the person who places a device on the market becomes aware of a serious adverse incident in Switzerland, then it must notify the Agency. And, if it becomes aware of such incidents in a treaty country, then it must provide notice to the authority in that country. Ordinance on Medical Devices, Art. 15. Further, that person must take necessary internal measures such as recall, modification, etc. to reduce risk.
Field safety corrective action monitoring: Yes
Details: The Agency is responsible to monitor the safety of products on the market. It may take samples, request additional information, and procure documents. Compliance monitoring is carried out by sampling or as a consequence of serious adverse incidents. Ordinance on Medical Devices, Art. 23.
The Agency takes necessary measures in case of health threats. TPA, Art. 58; see also Ordinance on Medical Devices, Art. 25.

Advertising: Yes
Details: The Federal Council may restrict or prohibit advertising of certain medical devices and enact regulations concerning cross-border advertising. TPA, Art. 51.
The Ordinance on Medical Devices prohibits misleading advertising of medical devices. Id. Art. 21.

Labelling: Yes
Details: Therapeutic Products Act (TPA) (15 Dec. 2000, as amended, Art. 11.

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.