IMDRF Stakeholders Forum - Regulatory Update Swissmedic

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How are Medical Devices regulated in Switzerland?

**Therapeutic Products Act (TPA)**
812.21

**Medical Devices Ordinance (MedDO)**
812.213

**Ordinance on In Vitro Diagnostic Medical Devices (IvDO)**
812.219

**Human Research Act (HRA)**
810.30

**Ordinance on Clinical Trials with Medical Devices (ClinO-MD)**
810.306
MDR/IVDR cast into Swiss legislation

**Goal:** maintain equivalence to MDR/IVDR

Our legislation is equivalent to EU regulatory system (new and global approach), but medical devices are no longer part of the “single market”
“swissdamed” - Swiss Database on Medical Devices

- Registration of actors and medical devices placed on the market in Switzerland
- "Go live": foreseen for 2023
- swissdamed consists of two interconnected modules and a public website
  - 1. Release – Module Economic Operators
  - 2. Release – Module UDI/Devices
- Issuing Agencies: GS1, IFA, HIBCC, ICCBBA (same as EU)
- Use of Basic UDI concept (in line with EU-system)
- Data model compatible with EUDAMED3
Sources & Links

Medical Devices Ordinance (MedDO; SR 812.219)
Ordinance on In Vitro Diagnostic Medical Devices (IvDO)

CE-conformity
Frequently Asked Questions on medical devices (swissmedic.ch) > Market access

Swiss authorized representative
Swiss authorised representative (CH-REP) (swissmedic.ch)
Art. 66 para. 2bis MedDO / Art. 59 para 3 IvDO

Registration of economic actors
Swiss Single Registration Number (CHRN) (swissmedic.ch)
Swiss economic operators registered at Swissmedic (Medical devices) | opendata.swiss

Labelling, transition periods and other obligations of economic operators
Language requirements: Art. 16 MedDO / Art. 15 IvDO

Obligations for authorised representatives, importers and distributors (swissmedic.ch)

Registration of products & swissamed
Notification of medical devices (swissmedic.ch)
Notification of IVDs (swissmedic.ch)
Notification of devitalised human tissue (swissmedic.ch)
Medical devices database (swissmedic.ch)

Revision of Swiss medical devices legislation
Revision of Swiss medical devices legislation (admin.ch)
Versorgung mit Medizinprodukten ist gewährleistet (admin.ch)