swissmedic
20 Jahre 2002 - 2022

IMDRF Stakeholders Forum - Regulatory Update Swissmedic

André Breisinger, Expert Medical Devices Regulation

How are Medical Devices regulated in Switzerland?

Therapeutic Products Act (TPA)
812.21

Human Research Act (HRA)
810.30

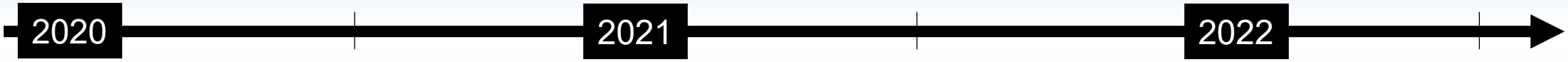
Medical Devices Ordinance (MedDO)
812.213

Ordinance on In Vitro Diagnostic Medical Devices (IvDO)
812.219

Ordinance on Clinical Trials with Medical Devices (ClinO-MD)
810.306

MDR
05-26-2021

IVDR
05-26-2022



MDR/IVDR cast into Swiss legislation

Goal: maintain equivalence to MDR/IVDR

MedDO, revised
ClinO-MD, new
05-26-2021

IvDO, new
ClinO-MD, revised
05-26-2022

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 lign 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 & swissdamed
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)

Swissmedic IVD webinar (free): 03 Nov 2022

DE / FR
Slides in DE, FR, IT and **EN**

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