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Medical Devices – situation in Switzerland

Swiss Medical Device Ordinances and relationship to EU Medical Device Regulations

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

AFDO RAPS

Switzerland not part of the single EU (EEA) market for medical devices…

Since May 2021 no more MRA between EU and Switzerland for medical devices

Brussels, 26 May 2021
NOTICE TO STAKEHOLDERS: STATUS OF THE EU-SWITZERLAND MUTUAL RECOGNITION AGREEMENT (MRA) FOR MEDICAL DEVICES
https://health.ec.europa.eu/document/download/b047f611-20a5-48a0-8d67-e8b4d9d3b8db_en?filename=mdcg_eu-switzerland_mra_en.pdf

Summary for NON-CH manufacturers that want to sell devices in Switzerland

- **Need CE mark**
- **Need a CH-REP** (independent from the nonexistence of MRA), linked to MDR / IVDR – already foreseen in the Swiss Medical Device Ordinance in May 2021 independently from fail in MRA)
  - **Additional cost for CH-REP (use subsidiary or service provider) and for labeling**

Swiss Medical Device Ordinance, section 2 – Authorised Representative

Article 51 – Obligations: (paraphrased)

[1] Manufacturers (incl. PPP) of devices not domiciled in Switzerland need an authorised representative domiciled in Switzerland for placing devices on the market.

CH-REP obligations (MeDOArt. 51 / 52 continued, paraphrased…)

- rights and obligations, scope of the mandate and changes governed by Articles 11 & 12 EU-MDR
- "The manufacturer and authorised representative may contractually agree that **instead of the authorised representative keeping available a copy of the technical documentation, the manufacturer shall, on request, submit the documentation straight to Swissmedic**. The CH-REP must ensure that the documentation is submitted within seven days."
- CH-REP needs PRRC, art. 15 MDR applies for competence, PRRC can be the one of the manufacturer (see section 3.4. of CHRN – Guidance) https://www.swissmedic.ch/dam/swissmedic/en/dokumente/medizinprodukte/mep_urr/bw630_10_003d_mb-chrn-faq.pdf.download.pdf/BW630_10_003e_MB_CHRN_FAQ.pdf

CH-REP obligations (MeDOArt. 59 & 62, paraphrased…)

- CH-REP makes available PMS report to Swissmedic upon request
- CH-REP makes available “saftey report” (PSUR) and for class III and IIb implants PSUR review result from NB available to Swissmedic upon request.

CH-REP obligations (MeDOArt. 64, TPA Art. 47d, paraphrased…)

- CH-REP shall ensure its part of traceability of devices between Importers, distributors and CH-REP (unclear how this should be performed in case of grey import)
- CH-REP needs sufficient financial coverage to compensate damage caused by defective medical devices (Product liability)

CH-REP obligations (MeDOArt. 66, paraphrased…)

- CH-REP is responsible for vigilance reporting to Swissmedic
  - Serious incidents in Switzerland (adverse events / product problems)
  - Recalls, corrections, removals in Switzerland (FSN / FSCA)
- CH-REP responsible for spontaneous trend reporting
  - Reporting of incidents that are not serious incidents (refer to art.88 and art.2 MDR for definitions)

CH-REP obligations must be fixed in a written mandate agreement - summary

- Mandate scope and techdoc modalities, PRRC (art.51 & 52 MedDO)
- PMS and PSUR reports to Swissmedic upon request (art. 59 & 62 MedDO)
- Financial coverage product liability (art. 47d TPA)
- Traceability (art. 64 MedDO)
- Vigilance reporting (art.66 MedDO)

I manufacture a niche product and burden for MedDO compliance is too high for few devices requested by swiss hospitals…

Discuss with your client using MedDO art. 70

- **Any professional who uses a device from a foreign country directly without placing it on the market is responsible for the conformity of that device.**
  - Only possible if client is healthcare professional AND directly putting the device into service (no placing on the market!)
  - Conformity here means “technical conformity” – the device must have a valid CE mark
  - Lot of fear is created by many stakeholders in CH around article 70…

Situation in Switzerland – why such a «Buzz» ?

The real problems are:

- **Burden for Swiss manufacturers** not any more part of single market (same obligations as a US manufacturer, EC-REP, no more Swiss NB – more costly to get to EU market)
- **Expected shortage of medical device supply** for the Swiss healthcare system (MDR / IVDR to blame first…then Swiss MedDO with some add ons)
  - Switzerland is a small market and the cost / burden for Swiss MedDO compliance may be too high for manufacturers and they could drop the swiss market

Pragmatism is a Swiss virtue…

Swiss parliament mandated the Federal Council (government):

- **…to come up with a solution to authorize US FDA cleared / approved devices on the Swiss market** to avoid shortage

  - https://www.parlament.ch/en/ratsbetrieb/amtliches-bulletin/amtliches-bulletin-die-verhandlungen?SubjectId=58905
  - Summary: https://www.swiss-medtech.ch/en/news/politicians-decide-favour-patient-care
  - Summary: https://www.swiss-medtech.ch/en/news/motion-203211

Careful…

- This is not yet done…will take at least until Q4 2024 until legal proposal “on the table”
- Not a side pathway for US manufacturers to EU !

But…

- This is pioneering – many interest groups and stakeholders all over EU / EEA and UK are observing in detail the process
- Finally, all EU / EEA countries and UK are facing a similar problem with risk of device shortage
- For Swiss Medtech manufacturers this may be an important asset – medical devices go US first but still able to serve the home market…depending on how the legal proposal is done…

All you ever wanted to know about Swiss medical device regulations - links

Laws:

TPA https://www.fedlex.admin.ch/eli/cc/2001/422/en

MedDO https://www.fedlex.admin.ch/eli/cc/2020/552/en

IvDO https://www.fedlex.admin.ch/eli/cc/2022/291/en

ClinO-MD https://www.fedlex.admin.ch/eli/cc/2020/553/en

Guidance:

https://www.swissmedic.ch/swissmedic/en/home/medical-devices.html -> click “medical devices”

Help:

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or global -> https://www.veranexsolutions.com/

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