Regulatory Update for Switzerland

André Breisinger
Expert Medical Device Regulation
Swissmedic
March 12, 2024

IMDRF International Medical Device Regulators Forum

Key changes to regulatory framework

Revision of MedDO and IvDO*

The new provisions in the Medical Devices Ordinance (MedDO, SR 812.213) and the Ordinance on In Vitro Diagnostic Medical Devices (IvDO, SR 812.219) entered into force on 1 November 2023. The changes align the Swiss provisions with the EU requirements, restoring equivalence with the EU-MDR and EU-IVDR.

- **Extension of transitional provisions for medical devices and lifting of deadlines**

To ensure continuity of medical device supplies in Switzerland, the transitional period for medical devices certified under the former directives 93/42/EEC and 90/385 EEC can be extended under certain conditions from 26 May 2024 to 31 December 2027 or
31 December 2028. The deadlines for putting into service and placing on the market were lifted.

- **Product groups without an intended medical purpose**

(e.g. cosmetic implants, contact lenses without visual correction, or brain stimulation devices), fall under the scope of the MedDO and have to meet the common specifications set out in the EU Implementing Regulation.

- **Reclassification of certain active products**

without an intended medical purpose, such as equipment for liposuction or hair removal, are reclassified according to the EU Implementing Regulation and have to comply with higher safety standards.

*https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/rev-mepv-und-ivdv-nov23.html

Key changes to guidance documents

Market access

- BW617_00_003e_MB Derogation MEP (revised - 15.12.2023)
- MU600_00_016e_MB **Obligations Economic Operators** CH (revised - 01.11.2023)

Provisions governing special medical devices

- MU600_00_007e_MB **Products without an intended medical purpose** (new - 08.12.2023)
- BW630_30_007e_Information sheet **Medical Device Software** (revised – available soon)

Clinical Trials

- BW600_00_015e_**MB Clinical investigations** with medical devices (revised - 27.12.2023)
- BW600_00_016e_MB **Performance studies with IVD** (revised - 27.12.2023)

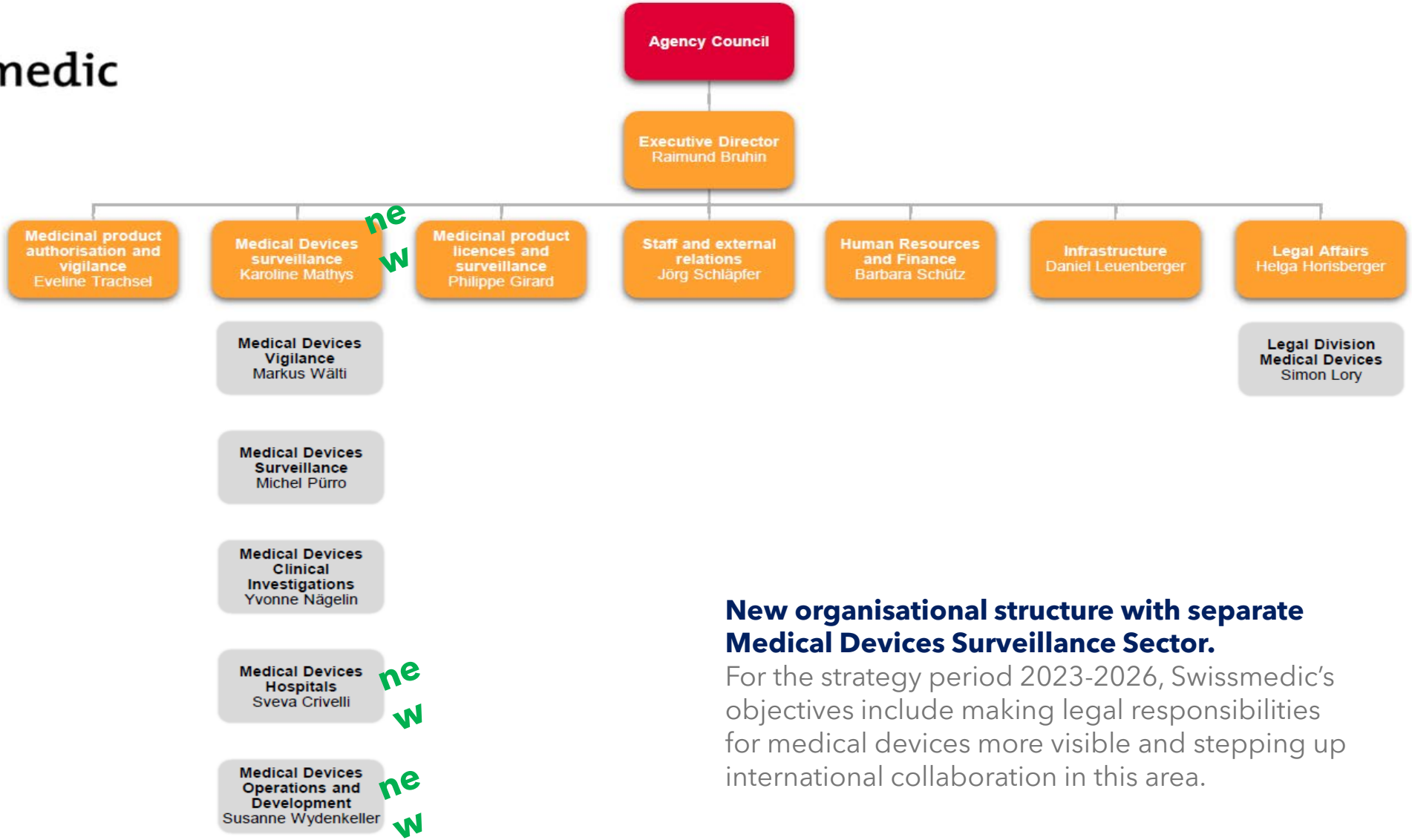
Healthcare institutions

- "Checklist the annual validation reports of instrument for washer disinfectors and trolley washer disinfectors" * (new - 08.01.2024)
- "Checklist for the verification of a report on the performance qualification (PQ) of a steam steriliser" * (new - 25.10.2023)
- "Swiss guideline for the transport of contaminated and reprocessed medical devices for reprocessing units" * (new - 25.09.2023)
- MU600_00_006e_MB **Procurement of medical devices in health institutions** (revised - 01.11.2023)

*not available in English

Swissmedic sets the course for the future (Link)

swissmedic



New organisational structure with separate Medical Devices Surveillance Sector.

For the strategy period 2023-2026, Swissmedic's objectives include making legal responsibilities for medical devices more visible and stepping up international collaboration in this area.

Market surveillance

Focus campaign on economic operators

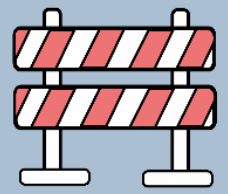
FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF International Medical Device Regulators Forum

Swissmedic inspected 27 medical device manufacturers in Switzerland

Implementation of the new medical device requirements and market surveillance for medical devices in the lowest risk class



11 %
of the products did not have proof of compliance with the new requirements and therefore could not be marketed.

39 %
of the devices and

14 %
of the manufacturers were not correctly registered.

70 %
of the documentation on surveillance of the devices on the market did not meet the new requirements.

Link: *Announcements on market control issues*

Swissmedic inspected 20 Swiss authorised representatives

70 %

of CH-REPs with NCs

65 %

NC - Mandate requirements

55 %

NC - Vigilance reporting obligations

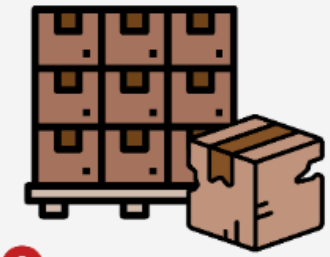
Link: *Announcements on market control issue*

CH | REP

Swissmedic reviewed 30 Swiss importers

18 out of 30 importers performed incomplete product checks.

For **8 out of 30** importers the importer information was incomplete.



At **8 out of 30** importers, the storage and transport conditions were inadequate.

3 out of 30 importers had deficiencies in the recording and forwarding of complaints.

Link: *Announcements on market control issues*

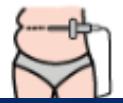
Product conformity under the Medical Devices Ordinance

Risk classification

Classification is subject to Annex VIII EU-MDR, taking account of the implementing acts listed in Annex 5a MedDO, which define specific rules of classification for the (active) product groups 4 to 6 in Annex 1 MedDO.

Furthermore, the "Borderline Manual" must be observed, which places facial and other dermal and mucous membrane fillers under the highest risk class of III.

Table: Classification in accordance with the EU Commission's implementing acts listed in Annex 5a MedDO:

Group	Description (short form)	Class
	Reduction, removal or destruction of adipose tissue	IIb

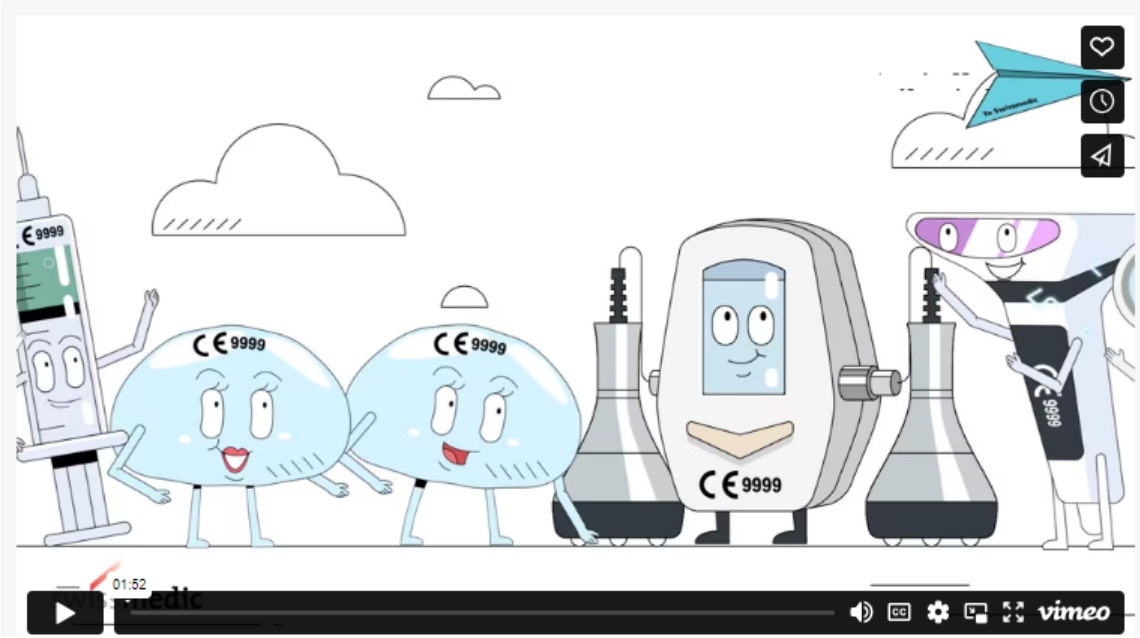
Actions required of the manufacturer*

- Determine whether your device falls under one of the six product groups listed in Annex 1 MedDO[1] and whether you are thus affected by the new requirements.
- Familiarise yourself with the legal requirements under the MedDO, the EU-MDR and the common specifications for product groups without an intended medical purpose. See also the Explanatory report [not available in English] of the FOPH for background information on the MedDO.
- Make a note of 1 May 2024. The devices must have been marketed in Switzerland by this date in order to benefit from the transitional rules .
- Based on the intended purpose, determine the risk class (Art. 15 MedDO) for your devices under Annex VIII EU-MDR, taking account of the exceptions for the active product groups under Annex 5a MedDO.
- Prepare technical documentation in accordance with Annexes II/III EU-MDR to provide evidence of conformity with the general safety and

new website (link)

New explanatory clips available (Link)

Products without a medical purpose: procurement and use



Products without a medical purpose – What are they?

More clips:

-What is a medical device?
-How do medical devices come onto the market?
-What are the tasks of Swissmedic in the area of medical devices?
…more to come soon

swissdamed

Swissmedic website | Terms of service | Contact Swissmedic | Support | DE FR IT EN

Home | Search for Actors | Actor Management | Companies | LOGIN

Swissdamed - Swiss database on medical devices

Goals | Actors | Devices

One of the main goals of the new Medical Device Regulation is to increase transparency and to ensure the complete traceability of products throughout the entire supply chain. In the event of problems, appropriate measures can thus be taken quickly. swissdamed, as a centralised system, was designed for this purpose and serves to collect and process the information on Swiss Economic Operators and Medical Devices. The public and professionals benefit equally from access to published information.

Support

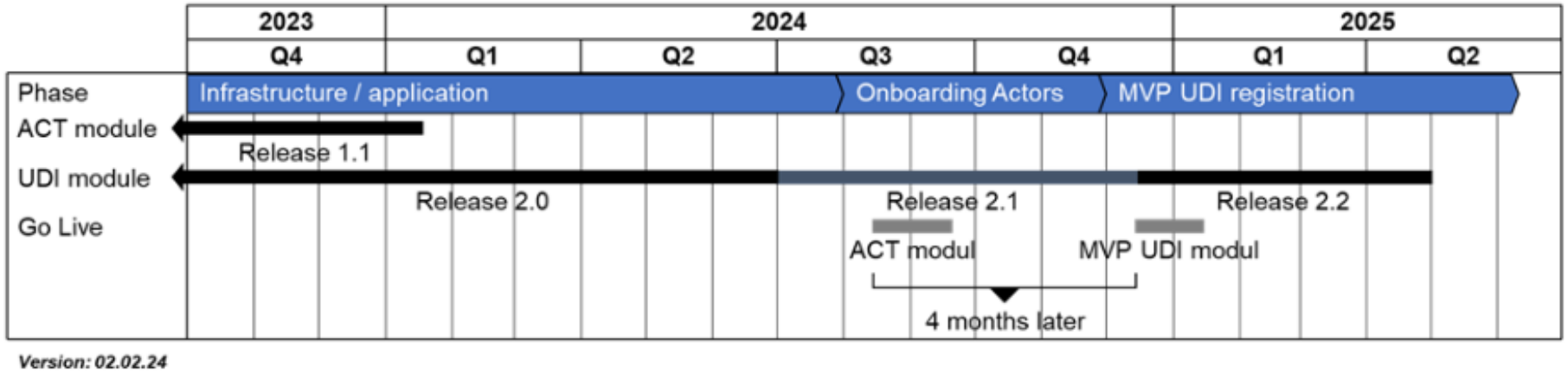
Find relevant documents and information about swissdamed.

GO TO SUPPORT

Search for Actors an

Development

- **ACT module (Release 1.1) has been completed in functional terms.**
- **U**



Version: 02.02.24

MVP: Minimum Viable Product

Swissmedic Website (Link)

IMDRF 2024 Chair

IMDRF International Medical Device Regulators Forum

Swissmedic's commitment to IMDRF WGs

Adverse Event Terminology

Harmonize terminology for reporting adverse events related to medical devices, and further harmonize adverse event reporting datasets to improve signal detection.

Artificial Intelligence/Machine Learning-enabled

Seeking to harmonize internationally principles to help promote the development of safe and effective AI/ML enabled medical devices

Good Regulatory Review Practices

Develop good review practices for pre-market reviews and evaluations.

Software as a Medical Device

Promote consistency in regulatory assessment for Software as a Medical Device to reach patients more efficiently.

Personalized Medical Devices (PMD)

Harmonize the regulatory requirements for medical devices that are intended for a particular individual, considering unique characteristics and risks associated with each type of device.

Quality Management Systems

Ensure alignment of IMDRF QMS and risk management documents with current international standards

Regulated Product Submission

Harmonize the format and content of regulatory submissions.

IMDRF AE WG F2F Meeting in Bern, CH

International Medical Device Regulators Forum (IMDRF)
AET WG F2F Meeting
23 to 26 April 2024, Bern, Switzerland

It is an honour for Swissmedic, the Swiss Agency for Therapeutic Products, to host the next meeting as a new, young member of the AET WG. We are very much looking forward to it.

The meeting will be at Swissmedic's headquarter, Hallerstrasse 7, Bern, Switzerland. We are looking forward to welcoming you.

swissmedic IMDRF

Register now!
www.swissmedic.ch/imdrf

Venue

FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF International Medical Device Regulators Forum

Meetings, Workshops and Training (Link)

Date	Organiser	Event, venue
27.-28. Sep. 2023	U.S. Food & Drug Administration (FDA)	Global Summit of Regulatory Sciences 2023, Parma, IT
27. Sep. 2023	Medtech & Pharma Platform (MPP)	MPP Annual Conference, Basel, CH
18. Oct. 2023	University of Bern	Master of Science in Pharmacy, University of Bern (M Sc Pharm) As part of the curriculum, Swissmedic teaches the organisation and operation of pharmacovigilance and Materiovigilance, Bern, CH
23. - 27. Oct. 2023	Swissmedic-WHO	Regulatory training course for regulatory authorities, Bern, CH
18. Oct. 2023	Swiss Medical Technology Association (Swiss Medtech)	National Regulatory Conference, Bern, CH
13. Nov. 2023	Swissmedic	Roundtable on Medical Technology (RTMT), Bern, CH
26. Jan. 2024	ZHAW School of Management and Law	"CAS Health Systems and Politics, Bern", CH Certificate of Advanced Studies
02. Feb. 2024	Clinical Trial Unit Basel, Department of Clinical Research, University of Basel	CAS Clinical Research I (Clinical Trial Planning and Conduct) Certificate of Advanced Studies, Module 1, Basel, CH
02. Feb. 2024	«Swiss Association for the Supply of Sterile Goods" (SSSH/SGSV)	Training day: Swissmedic's requirements for hospital sterilisation centres and its strategic objectives on reprocessing of reusable medical devices, followed by a Q&A session, Lausanne, CH
12. Feb. 2024	Swissmedic	Roundtable on Medical Technology (RTMT), Bern, CH

Link collection (in chronological order)

https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/rev-mepv-und-ivdv-nov23.html

https://www.swissmedic.ch/dam/swissmedic/en/dokumente/medizinprodukte/mep_urr/bw617_00_003d_mb-ausnahmebewilligung-mep.pdf.download.pdf/BW617_00_003e_MB Derogation MEP.pdf

https://www.swissmedic.ch/dam/swissmedic/en/dokumente/medizinprodukte/mep_urr/mu600_00_016d_mb_pflichten_wirtschaftsakteure_ch.pdf.download.pdf/MU600_00_016e_MB_Obligations_Economic_Operators_CH.pdf

https://www.swissmedic.ch/dam/swissmedic/en/dokumente/medizinprodukte/mep_urr/mu600_00_007d_mb_produkte_ohne_medizinische_zweckbestimmung.pdf.download.pdf/MU600_00_007e_MB_Devices_without_an_intended_medical_purpose.pdf

https://www.swissmedic.ch/dam/swissmedic/en/dokumente/medizinprodukte/mep_urr/bw630_30_007d_mbmedizinprodukte-software.pdf.download.pdf/BW630_30_007e_MB Medical Device Software.pdf

https://www.swissmedic.ch/dam/swissmedic/en/dokumente/medizinprodukte/mep_urr/bw600_00_015d_mb_klinische_versuche_mep.pdf.download.pdf/BW600_00_015e_MB_Clinical investigations with medical devices.pdf

https://www.swissmedic.ch/dam/swissmedic/en/dokumente/medizinprodukte/mep_urr/bw600_00_016e_mb_performance_studies_with_ivd.pdf.download.pdf/BW600_00_016e_MB_Information_performance_studies_IVD_KlinVMEP.pdf

https://www.swissmedic.ch/dam/swissmedic/en/dokumente/medizinprodukte/mep_urr/mu600_00_006d_mb_beschaffung_mep.pdf.download.pdf/MU600_00_006e_MB_Procurement_of_medical_devices_in_health_institutions.pdf

https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/neue-organisationsstruktur-mit-bereich-ueberwachung-mep.html

https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-surveillance-of-medical-devices/announcements-on-market-control-issues.html

https://www.swissmedic.ch/swissmedic/en/pomz/produktkonformitaet-mepv.html

https://www.swissmedic.ch/swissmedic/en/home/about-us/publications/video/mep-video.html

https://www.swissmedic.ch/swissmedic/en/home/medical-devices/medizinprodukte-datenbank/swissdamed-ueberblick.html

https://www.swissmedic.ch/swissmedic/en/home/services/veranstaltungen/speaking-engagement.html

https://www.swissmedic.ch/swissmedic/en/home/medical-devices/regulation-of-medical-devices/roundtable-medizintechnik-rtmt.html


IMDRF
International Medical Device
Regulators Forum
United States
of America
2024