HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

29th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 10 March 2026

Regulatory Update Switzerland

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Expert Medical Devices Regulation

Swissmedic

Key changes to regulatory framework - swissdamed

Project status

Development is on schedule: Release notes

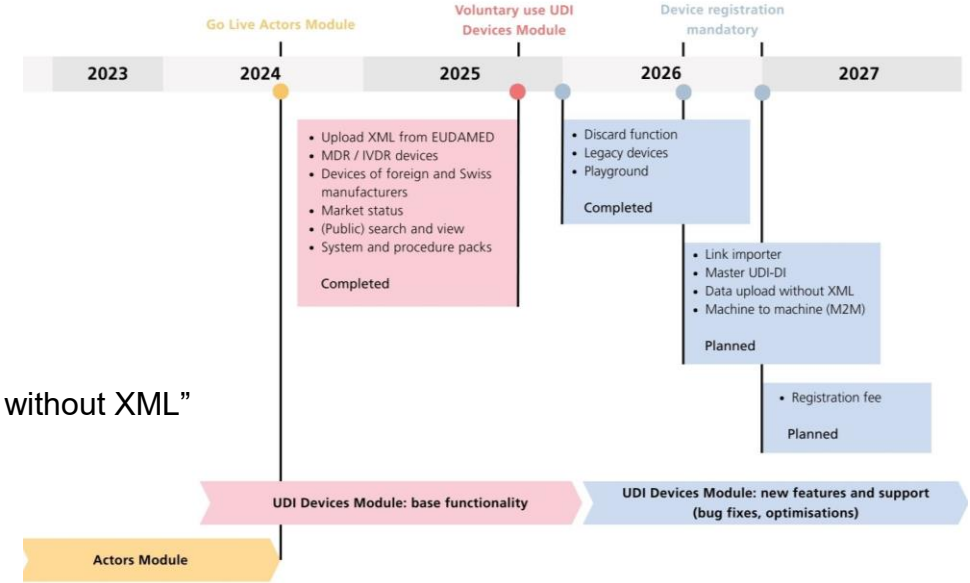
Legacy devices: registration possible & in use

Playground is available & in use

- Publication of M2M specifications: here

Upcoming

- M2M testable on playground
- First version of online editor for “data upload without XML”



Key changes to regulatory framework - swissdamed

System	Mandatory from*	Transition period
swissdamed	**1 July 2026** (device registration)	**31 December 2026** if devices continue to be made available on the market after 1 July 2026. **Exception:** Immediate registration in cases in which a serious incident, field safety corrective action or trend must be reported to Swissmedic.
EUDAMED	**28 May 2026** (first four modules)	**28 November 2026**

* ⚠️ Products, systems and procedure packs which are placed on the market **after the start of the registration requirement** shall be registered before they are placed on the market.

Key changes to regulatory framework - swissdamed

Registration options	No. of devices	EUDAMED experience	IT expertise
M2M connection / upload via REST API • IT support / project required	●●●●●	●●●●●	●●●●●
XML upload • Download XML from EUDAMED & upload in swissdamed • Create XML according to EUDAMED specifications (GET or POST DEVICE)	●●● ●●●	●●●●● ●●●●●	●● (swissdamed part) ●●●●●
Online editor • Manual entry of data elements per UDI-DI	●	●●	●

Key changes to regulatory framework - swissdamed

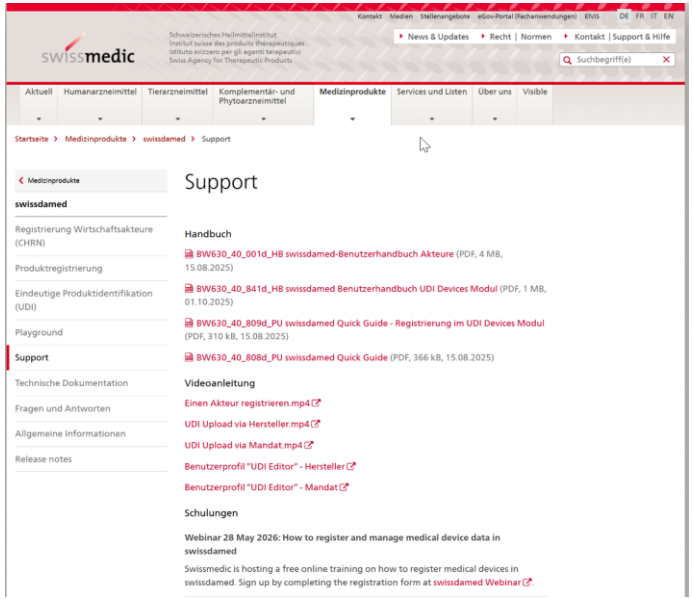
Resources & training

swissdamed.ch
playground.swissdamed.ch
Swissmedic website
Support

swissdamed webinar 28 May 2026

«How to register and manage devices in swissdamed»

Fully booked – recording will be be made available online



Key changes to regulatory framework – delegated acts & standards

Updates on applicable legal acts and harmonised standards

Applicable EU legal acts

- Section updated to include newly adopted delegated regulations
- Clarifies mechanisms for the adoption of EU legal acts in Switzerland

Standards and common specifications

- Latest publications of designated technical standards and EU common specifications used for conformity assessment

Market surveillance – focus campaigns on 30 Swiss importers

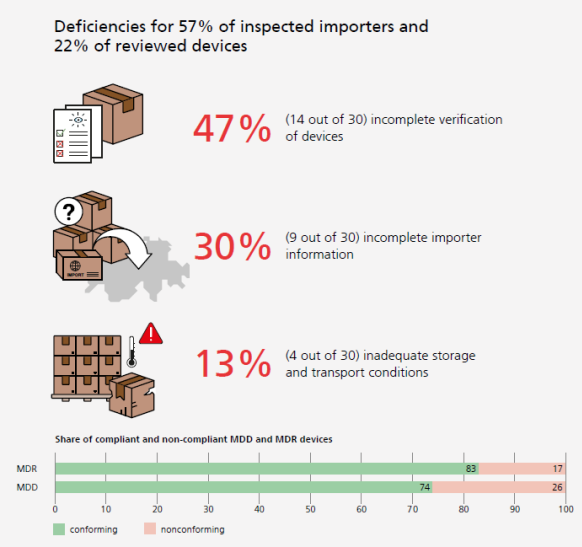
Scope of the campaign

- Compliance assessed based on 232 devices

Key focus areas

- Formal product conformity
- Evidence of conformity (incl. docs. for MDR/MDD transitional periods)
- Labelling, including importer information
- Storage and transport conditions
- Product sourcing → verification through targeted sampling

Want to know more? Results of a focus campaign of importers



Key changes to guidance documents & forms

Clinical Trials

- Performance studies with IVD (revised, 18.02.2026)
- Combined studies (revised, 27.10.2025)

Free Sales Certificates (FSC)

- Export Certificates (revised, 01.12.2025)

Materiovigilance / Post-Market Surveillance

- Guidance document CH Guide Manufacturer Incident Report (MIR) (revised, 20.11.2025)

Economic Operators

- Systems and procedure packs (revised, 31.10.2025)

Healthcare institutions

- "Swiss Good Practice for the Maintenance of Medical Devices (GPM)" (revised, 30.01.2026)*
- "Swiss Good Practices for the Reprocessing of Flexible, Thermolabile Endoscopes" (revised, 01.09.2025)*

*Good practice documents are not available in English

Meetings, Workshops and Training (Link) – since the last IMDRF MC 1/2

Date	Organiser	Event
15-17.09.	Swissmedic for the GSRS25 in Lausanne, Switzerland	Advancing regulatory science with tomorrow's technologies.
01.10.	Higher Technical School of Medical Technology, Sarnen	Quality management in medical technology of healthcare institutions
02.10.	ARATH (Romandy Association of Hospital Technical Agents), Yverdon Hospital	Swiss Good Practice for the Maintenance of Medical Devices (GPM)
15.10.	Swiss Medtech, National Regulatory Conference	swissdamed: Transparency for the Swiss device market
22.10.	Centre for Health Law and Management in Healthcare, University of Bern	Organisation and operation of pharmaco- and materiovigilance in Switzerland
27.10.	Swissmedic	Roundtable on Medical Technology (RTMT)
01.11.	H+ Education / Swiss Society for Sterile Supply (SGSV), Aarau	News from Swissmedic: inspection results of Swissmedic Swiss Good Practices for the Reprocessing of Flexible, Thermolabile Endoscopes» (GPAE)
11.-14.11.	African Union Development Agency (AUDA-NEPAD) and the WHO, Mombasa, Kenya	Plenary IV: Implementing International Standards – Best Practices for Regulatory Convergence
13.11.	SGORL – Swiss Society of Oto-Rhino-Laryngology, Head and Neck Surgery, Kursaal Interlaken	Presentation of “Swiss Good Practices for the Reprocessing of Flexible, Thermolabile Endoscopes"
21.11.	H-CSC Conference, Secure Networking of Medical Devices: Success Factors for Collaboration Between Clinical Engineering and CISOs, Berne	Swissmedic expectations for hospitals regarding cooperation between medical technology and ICT

Meetings, Workshops and Training (Link) – since the last IMDRF MC 2/2

Date	Organiser	Event
27.11.	FAMH – Association of Medical Laboratories in Switzerland, online	Requirements for in-house IVDs in accordance with IvDV and IVDR
06.12.	H+ Education / Swiss Society for Sterile Supply (SGSV), Aarau	News from Swissmedic: inspection results of Swissmedic Swiss Good Practices for the Reprocessing of Flexible, Thermolabile Endoscopes» (GPAE)
08.12.	COFEPRIS – Federal Commission for the Protection against Sanitary Risks, online	Quality Meeting: Best Practices in Quality Management Systems and Regulatory Strengthening
23.12.	ZHAW School of Management and Law	Swissmedic's mandate and placing devices on the Swiss market
13.01.	Swissmedic and H+, “ERFA” Exchange of experience on Materiovigilance	Collaborating for safe medical devices
24.01.	Swiss Society of Pathology, Bern	Requirements for In-house IVDs under the IvDO and the EU-IVDR
06.02.	Clinical Trial Unit Basel, Department of Clinical Research, University of Basel	Clinical Trials with Medical Devices
27.02.	Higher Technical School of Medical Technology, Sarnen	Swiss Good Practice for the Maintenance of Medical Devices (GPM)
02.03.	Swissmedic	Roundtable on Medical Technology (RTMT)
06.03.	H+ Education / Swiss Society for Sterile Supply (SGSV), Aarau	Reprocessing of endoscopes & inspection results of Swissmedic’s Swiss Good Practices for the Reprocessing of Flexible, Thermolabile Endoscopes» (GPAE)
16.03.	University of Berne, Switzerland	Up-to-date: materiovigilance in practice

Thank You!

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