IMDRF International Medical Device Regulators Forum

IMDRF Stakeholder Forum
Regulatory Update, Switzerland

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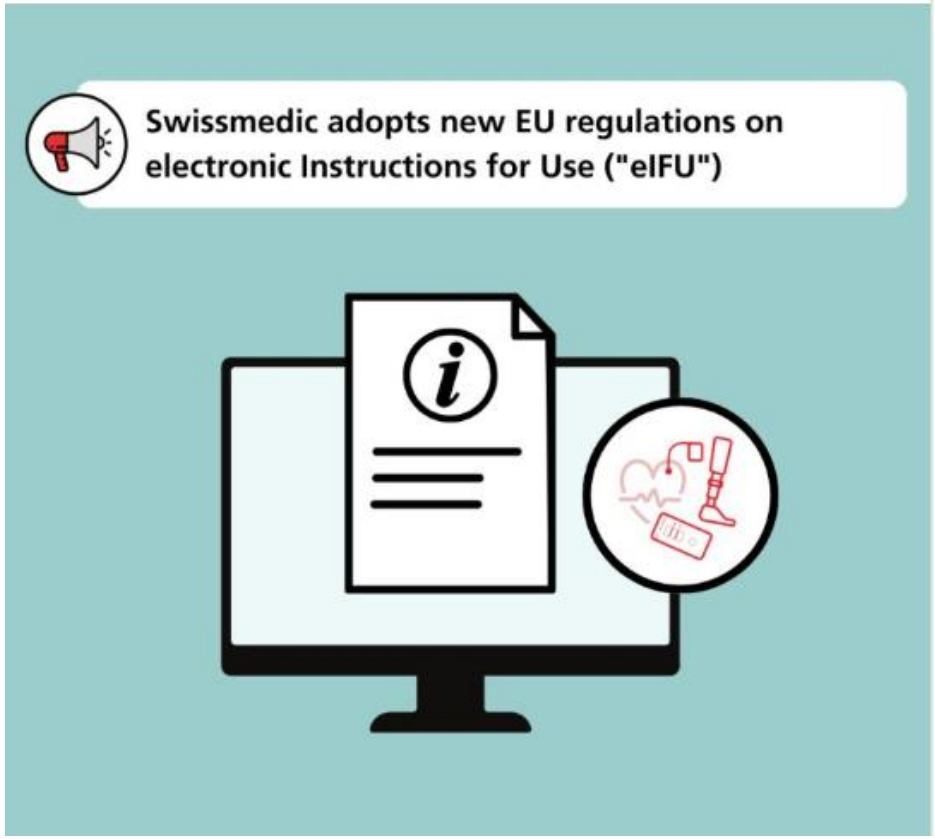
Key changes to regulatory framework

Following the entry into force of the EU's new Implementing Regulation (EU) 2025/1234 on 16 July 2025, Swissmedic is adopting the updated provisions on electronic Instructions for Use (eIFUs).

The regulation extends the scope of electronic IFUs to all medical devices (not IVDs), including legacy devices, their accessories, and products without a medical purpose intended for professional users.



Learn more: [Announcement] / [Website]

Key changes to regulatory framework

Go Live of the UDI Devices Module in swissdamed – a milestone for greater transparency in the Swiss medical device market!

August 2025
Voluntary registration of devices, systems and procedure packs begins

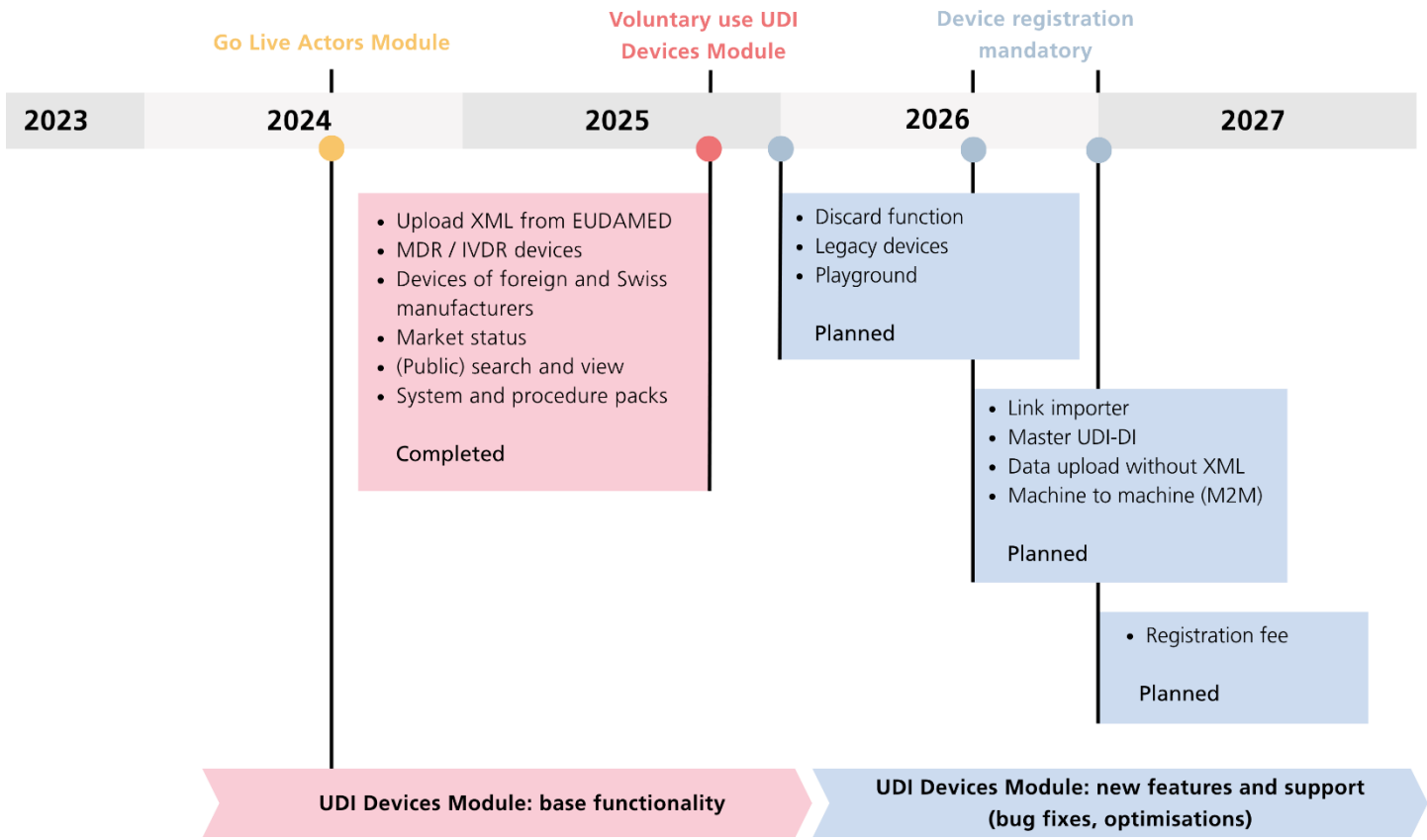
End of 2025
Playground for testing device data available

1 July 2026
Mandatory registration begins, immediate registration for devices with serious incidents

31 December 2026
End of transition period

Learn more: Announcement / Website

swissdamed: roadmap



Learn more: [Announcement](#) / [Website](#) / [technical documentation](#)

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swissdamed: UDI Devices Module: Data Elements

Learn more: [technical docs]

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Outlook on the future regulatory framework

Press release | Published on 30 April 2025

The Federal Council defines guidelines for expanding the supply of medical devices

Bern, 30.04.2025 — At its meeting on 30 April 2025, the Federal Council noted the ongoing efforts to implement Motion 20.3211, which aims to open the possibility for medical devices from non-European regulatory systems to be placed on the Swiss market. In order to ensure adequate supplies of medical devices and to guarantee patient safety, the Federal Council defined guidelines and will assign responsibility for controls to private bodies.

In November 2022, the National Council referred to the Federal Council the motion (20.3211) brought by Damian Müller, a member of the Council of States, calling for measures to enable medical devices from non-European regulatory systems to be placed on the market in Switzerland. The aim of this motion is to expand sources of medical device supplies beyond the European Union (EU), including in particular devices authorised by the US Food and Drug Administration (FDA).

Learn more: Press release / Medical devices legislation

Controls by private bodies

An impartial assessment and effective controls are necessary to ensure the safety of the medical devices concerned. The Federal Council intends to assign responsibility for reviewing the conditions for devices already authorised by the FDA in the US to private bodies. These bodies will review the relevant conditions under a simplified conformity assessment procedure, taking into account elements already performed by the FDA.

Next steps

The Federal Council has therefore requested the Federal Department of Home Affairs (FDHA), in collaboration with the Federal Department of Economic Affairs, Education and Research (EAER) and the Federal Department of Foreign Affairs (FDFA), to explore this approach in more detail.

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Hospital Inspection - Annual Report 2024 - Scope: reprocessing units for MD & endoscopy, maintenance, vigilance

Key weaknesses identified in the areas of:

- **Reprocessing**: understaffed and undertrained teams → infection risk (flexible endoscopes sensitive to heat).
- **Documentation**: inadequate and partly not established lifecycle processes (inventory, preventive maintenance) → device failure risk.
- **Vigilance**: gaps in training and process quality
- Unresolved **cybersecurity** risks in >40% of cases.

Take aways:

- No direct patient harm identified
- Immediate action was taken to guarantee safety and functionality of devices
- Many hospitals still fall short of legal requirements
- Report emphasises root-cause analysis and targeted recommendations

Learn more: Report 2024

Key changes to guidance documents & forms

swissdamed

- Handbook swissdamed User Guide Actors (revised, 15.08.2025)
- Business Rules (initial, 15.08.2025)
- Quick Guides: Public search & UDI Registration & User Guide UDI Devices Module (initial, 15.08.2025)
- Privacy Notice and Terms of Use (revised, 05.08.2025) & Service Agreement (revised, 15.08.2025)

Healthcare institutions*

- Information sheet on In-house Medical Devices (initial, 01.05.2025)

Materiovigilance / Post-Market Surveillance

- Guidance document Incident economic operators (revised, 20.05.2025) – use of EU-MIR form 7.3.1 mandatory from Nov. 2025

Clinical Trials

- FO Application simplified review MD & FO Application simplified review IVD (revised, 09.05.2025)
- FO Form Modifications, notifications, reports MD IVD (revised, 23.05.2025)

Economic Operators

- Information Sheet Systems and procedure packs (initial, 04.08.2025)
- Information sheet derogation MD (revised, 26.03.2025)

Other Guidance

- Products without an intended medical purpose (revised, 30.05.2025)
- Injectable products for wrinkle treatment (revised, 25.06.2025)

*Good practice documents are available only in our national languages: German, French, and Italian.

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

Date	Organizer	Event, Location
14 Mar	Higher Technical School of Medical Technology, Sarnen	Guidelines for the Maintenance of Medical Devices
18 Mar	DIA Europe 2025, Basel	Session 1: How Swissmedic Implements AI Internally Session 2: TRICIA – Using NLP to Enhance Risk Assessment of Incoming Incident Reports Session 3: Panel Discussion
16 Apr, 04 Sep	H+ Education & Swiss Society for Sterile Goods Supply (SGSV)	Reprocessing of Endoscopes – STE Endo
08 May	Swiss Society for Sterile Goods Supply (SGSV)	News from Swissmedic: Findings from Hospital Inspections and Swissmedic's Topic-Specific Expectations for AEMPs Regarding Validation of Packaging Processes
09 May	HF Medi, Training Course "Operating Technique: Assistance, Positioning & Suturing in the OR"	Vigilance Concerning Medical Devices – What It Means for Operating-Room Staff
02-06 Jun	Swissmedic	14th Swissmedic Regulatory Training
06 Jun	Swiss Association of Infrastructure Hospitals (IHS)	Guidelines for the Maintenance of Medical Devices
12 Jun	Swiss Society for Microbiology (SGM)	Requirements for In-house IVDs According to the IvDV and IVDR
16-20 Jun	Informaconnect for MedTech Summit	Combined Studies: The Swiss Approach
18 Jun	SGSV-SSSH, Swiss Society for Sterile Goods Supply	Good Practice for Maintenance in AEMPs
18 Jun	Swissmedic	Guidelines for the Maintenance of Medical Devices
18 Jun	SSSH/SGSV – Swiss Society for Sterile Goods Supply	News from Swissmedic: Reprocessing of Flexible Endoscopes
23 Jun	Swissmedic	Roundtable on Medical Technology (RTMT)
25 Jun	Insel Group	Cyber-security of Medical Devices – What Swissmedic Expects from Hospitals

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

Date	Organizer	Event, Location
27 Jun	University Hospital Zurich	Laboratory Medicine – More Than Machines and Data
25-27 Aug	Interest Group – Re-use in Healthcare	Hospital Inspections by Swissmedic
26 Aug	HF Medi, Training Course “Operating Technique: Assistance, Positioning & Suturing in the OR”	Vigilance Concerning Medical Devices – What It Means for Operating-Room Staff
26 Aug	Swiss Society for Clinical Chemistry (SGKC)	Requirements for In-house IVDs According to the IvDV and IVDR
04 Sep	Swiss Society for Endocrinology and Diabetology (SGED)	Regulatory Framework When Technology Fails
09 Sep	Federal Office of Public Health (FOPH), Department of Communicable Diseases	Requirements for In-house IVDs According to the IvDV and IVDR
10 Sep	Centre for Health Law and Management, University of Bern	Current Medical-Device Regulation: Developments and Insights from Enforcement
11 Sep	MedTech Pharma Platform	Participation in Panel Discussion
20 Sep	H+ Education & Swiss Society for Sterile Goods Supply (SGSV)	News from Swissmedic: Inspection Results in AEMPs
30 Sep	Higher Technical School of Medical Technology, Sarnen	Implementation of the New GPI

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Marketing Authorisation for Global Health Products (MAGHP) in 2025

Visiclor Eye Gel – ophthalmic anesthetic

- Submitted Q1 2024
- Assessment completed
- Active participation of South African Authority SAHPRA
- Product approved by Swissmedic on 21 February 2025
- Approval in South Africa on 13 May 2025

Riamet/Coartem Baby – antimalarial for infants

- Submitted Q1 2024
- Assessment completed
- Close collaboration with authorities from Burkina Faso, Côte d'Ivoire, Kenya, Malawi, Mozambique, Nigeria, Uganda and Tanzania
- Product approved in Switzerland on 3 July 2025
- Submission/national decision phase in targeted countries ongoing

Learn more: Announcement / Website

Thank you/Questions

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