IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

30th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 15 September 2026

Regulatory Update Switzerland

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Medical Devices Surveillance

Swissmedic, Swiss Agency for Therapeutic Products

Key developments

March – September 2026

- swissdamed device registration
- Registration fees introduced
- FDA reliance pathway progressing
- Guidance documents and forms updated

https://www.swissmedic.ch/

Device registration now mandatory

Since 1 July 2026

- Registration now mandatory
- Transition period until 31 Dec 2026
- Immediate registration for:
  - Serious incidents
  - FSCAs
  - Trend reports

https://www.swissdamed.ch/

UDI Devices Module

The registration obligation for devices enters into force in 2026.

Since **1 July 2026**, all devices, systems and procedure packs must be **registered** in swissdamed before they are placed on the market in Switzerland or Liechtenstein. For this registration, a transitional period applies until 31 December 2026.

Immediate registration since 1 July 2026 without a transitional period is required if a serious incident, a field safety corrective action or a trend has to be reported to Swissmedic (vigilance reports at: swissmedic.ch / Medical Devices / Reporting incidents & FSCAs (vigilance)).

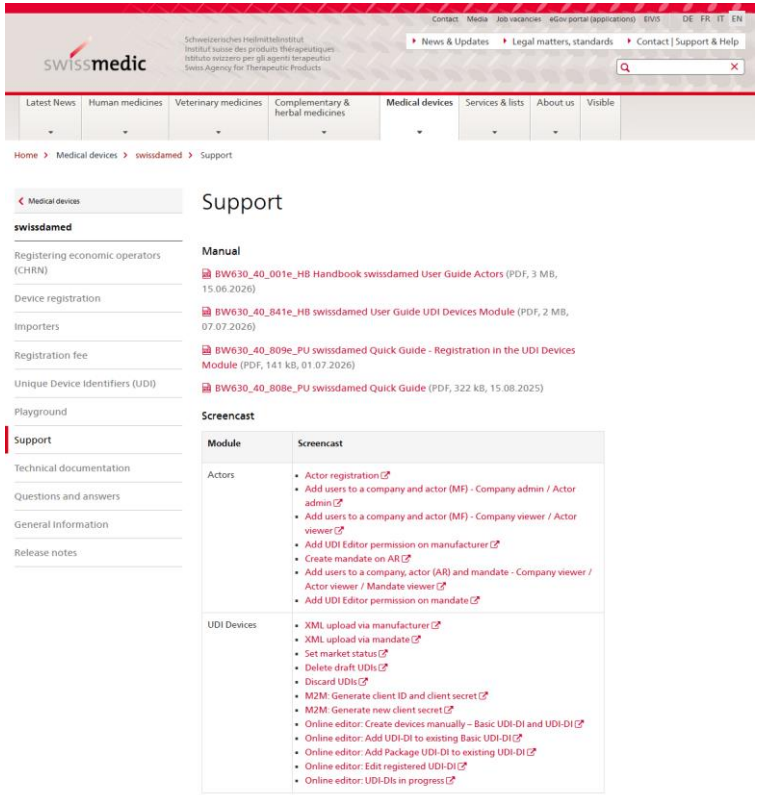
Regarding the reporting procedure in the case of "Old Devices" and for more information, navigate to questions and answers.

Search for UDIs / Devices

swissdamed ready for onboarding

Industry onboarding completed

- User guides published
- Webinar delivered
- Online editor available
- XML upload available
- M2M interface available



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

Training materials are available online

How to register and manage medical device data in swissdamed

Presentation and Recording

Presentation swissdamed Webinar (PDF, 4 MB, 01.06.2026)

Video Recording swissdamed Webinar

Presentation

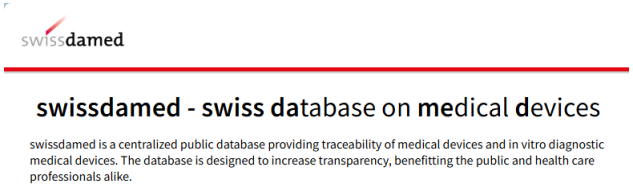
Video Recording

Legal background swissdamed vs EUDAMED
Actors module incl. Q&A
UDI Devices module: • Online Editor • XML Upload • Set Market Status • M2M • Manage UDIs • Registration Fee • Master UDI-DI • Importer Linking
UDI Devices Q&A

Additional stakeholder support planned

Other Ressources & Training

- swissdamed.ch
- playground.swissdamed.ch
- Swissmedic website
- Support



10th November 2026

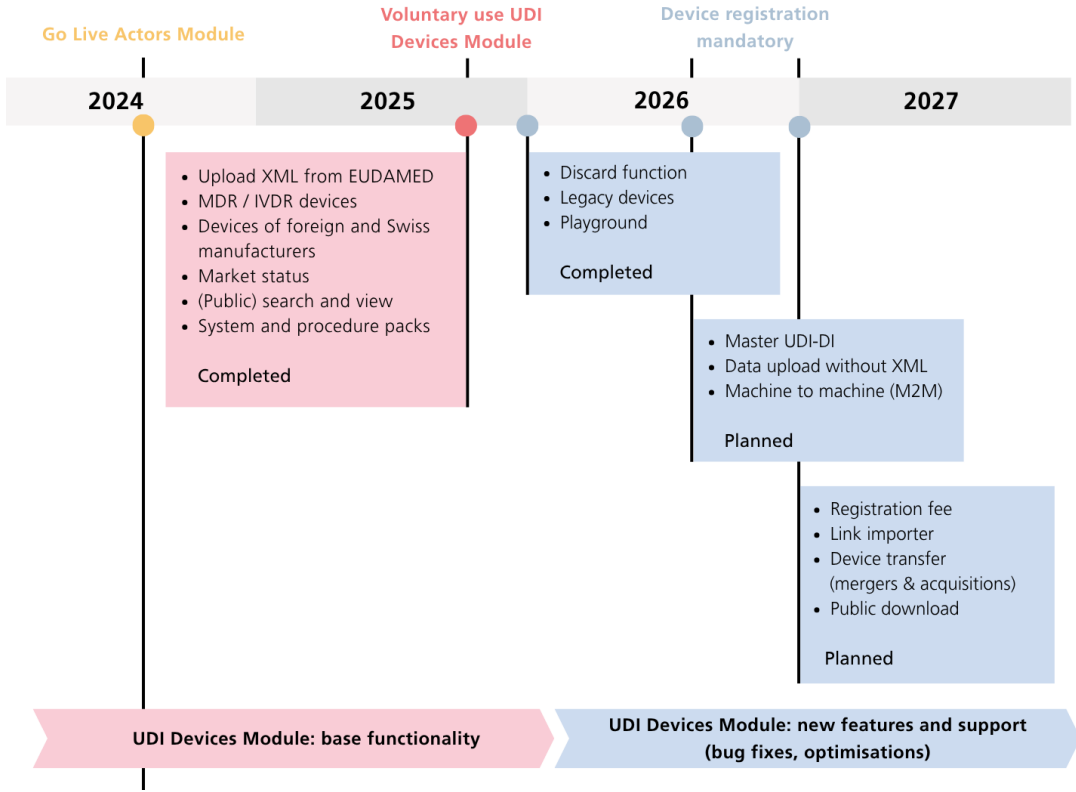
Save the date
2nd webinar
- How to register and manage medical devices in swissdamed
- Importer linking
- Invoicing for registration fee

Booking not open yet

More Features coming

Until the end of 2026:

- Registration fee
- Importer linking
- Device transfer (M&A)
- Public download



Registration fees are now in place

A simple fee model has been introduced for devices registered in swissdamed and placed on the Swiss market. The model is directly linked to UDI-DI registrations.

Registration trigger

- Fees apply to registered UDI-DIs placed on the Swiss market.

No fee for updates

- Updates to existing registrations are not charged.

Integrated model

- Fees are embedded in the swissdamed registration process.

Registration fees remain predictable

The fee structure combines a one-time registration charge with a transparent annual fee cap.

First UDI-DI

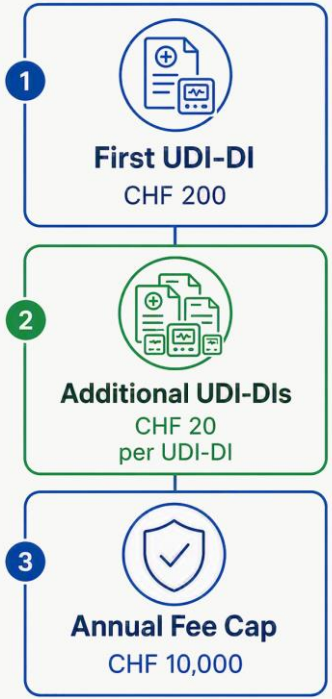
- CHF 200

Additional UDI-DIs

- CHF 20 per UDI-DI

Annual fee cap

- CHF 10,000 per manufacturer and calendar year



FDA-based reliance will complement existing pathways

Objective

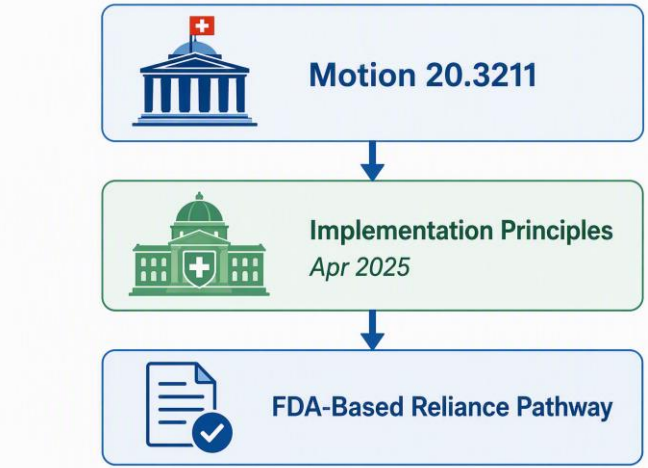
- Access to innovative medical devices
- Supply resilience
- High patient safety standards

Basis

- Motion 20.3211 from Swiss Parliament
- Additional pathway alongside EU-based access route

Key message

- Reliance complements existing pathways.



The proposal is taking shape

Current Status

- Draft legislation completed
- Extensive engagement with industry and authorities
- Technical discussions completed
- Interagency review ongoing
- Federal Council consultation planned for December 2026

Lesson learned

- Close collaboration between legal and technical experts is essential

Public consultation comes next

Next Steps

- Q4 2026
  - Launch of public consultation
- Q1 2027
  - 3-month consultation period
- Thereafter
  - Finalise legislation
  - Prepare implementation

Key message

- Building trust through a practical reliance framework

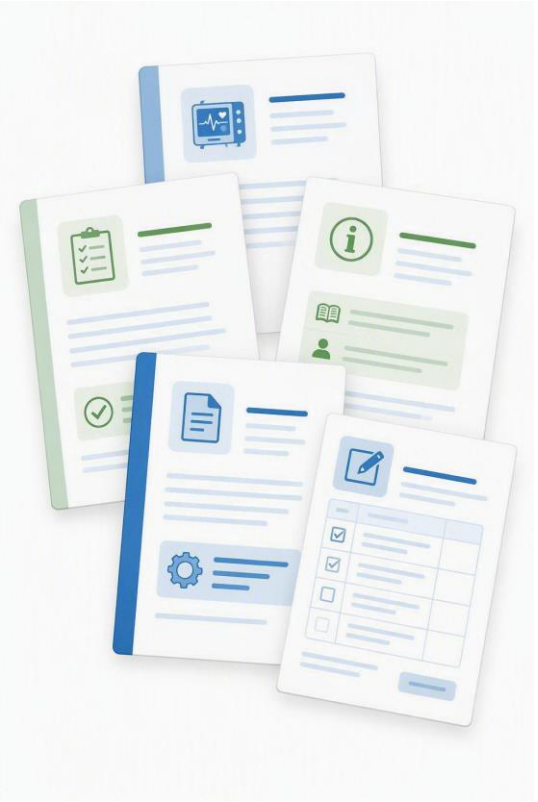
Guidance continues to evolve

Clinical Trials
- Clinical investigations with medical devices (revised, 10.07.2026)
- Performance studies with IVD (revised, 10.07.2026)
- Updated clinical trial application and reporting forms (01.07.2026)

Device Registration / swissdamed
- swissdamed User Guide UDI Devices Module (new, 07.07.2026)
- swissdamed Service Agreement (new, 17.07.2026)
- Medical device registration fee (new, 13.07.2026)

Materiovigilance / Post-Market Surveillance
- Incident economic operators (revised, 26.03.2026)
- FSCA economic operators (revised, 26.03.2026)

Healthcare Institutions *(not available in English)*
- Checklist for inspection of vigilance in hospitals (new, 17.07.2026)
- Maintenance of sterilisation containers (updated, 18.06.2026)
- Maintenance of medical devices obligations (new, 28.07.2026)



Thank You!