



IMDRF International Medical Device
Regulators Forum



25 YEARS AND BEYOND

30th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 15 September 2026

Regulatory Update Switzerland

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Key developments

March – September 2026

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

<https://www.swissmedic.ch/>



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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](https://www.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>

The screenshot shows the swissmedic website interface. At the top, there is a navigation bar with links for Contact, Media, Job vacancies, eGov portal (application), ETVS, and language options (DE, FR, IT, EN). Below this is a search bar and a menu with categories like Latest News, Human medicines, Veterinary medicines, Complementary & herbal medicines, Medical devices, Services & lists, About us, and Visible. The main content area is titled 'Support' and includes a sidebar with a list of topics: Registering economic operators (CHRN), Device registration, Importers, Registration fee, Unique Device Identifiers (UDI), Playground, Support (highlighted), Technical documentation, Questions and answers, General information, and Release notes. The main content area under 'Support' is divided into 'Manual' and 'Screencast' sections. The 'Manual' section lists three PDF documents: 'BW630_40_001e_HB Handbook swissdamed User Guide Actors' (3 MB, 15.06.2026), 'BW630_40_041e_HB swissdamed User Guide UDI Devices Module' (2 MB, 07.07.2026), and 'BW630_40_009e_PU swissdamed Quick Guide - Registration in the UDI Devices Module' (141 kB, 01.07.2026). The 'Screencast' section contains a table with two columns: 'Module' and 'Screencast'.

Module	Screencast
Actors	• Actor registration 🔗 • Add users to a company and actor (MF) - Company admin / Actor admin 🔗 • Add users to a company and actor (MF) - Company viewer / Actor viewer 🔗 • Add UDI Editor permission on manufacturer 🔗 • Create mandate on AR 🔗 • Add users to a company, actor (AR) and mandate - Company viewer / Actor viewer / Mandate viewer 🔗 • Add UDI Editor permission on mandate 🔗
UDI Devices	• XML upload via manufacturer 🔗 • XML upload via mandate 🔗 • Set market status 🔗 • Delete draft UDIs 🔗 • Discard UDIs 🔗 • M2M: Generate client ID and client secret 🔗 • M2M: Generate new client secret 🔗 • Online editor: Create devices manually – Basic UDI-DI and UDI-DI 🔗 • Online editor: Add UDI-DI to existing Basic UDI-DI 🔗 • Online editor: Add Package UDI-DI to existing UDI-DI 🔗 • Online editor: Edit registered UDI-DI 🔗 • Online editor: UDI-DIs in progress 🔗



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](https://www.swissmedic.ch)
- [Support](#)



swissdamed - swiss database on medical devices

swissdamed is a centralized public database providing traceability of medical devices and in vitro diagnostic medical devices. The database is designed to increase transparency, benefitting the public and health care professionals alike.

10th November 2026

Save the date

2nd webinar

- How to register and manage medical devices in swissdamed
- Importer linking
- Invoicing for registration fee

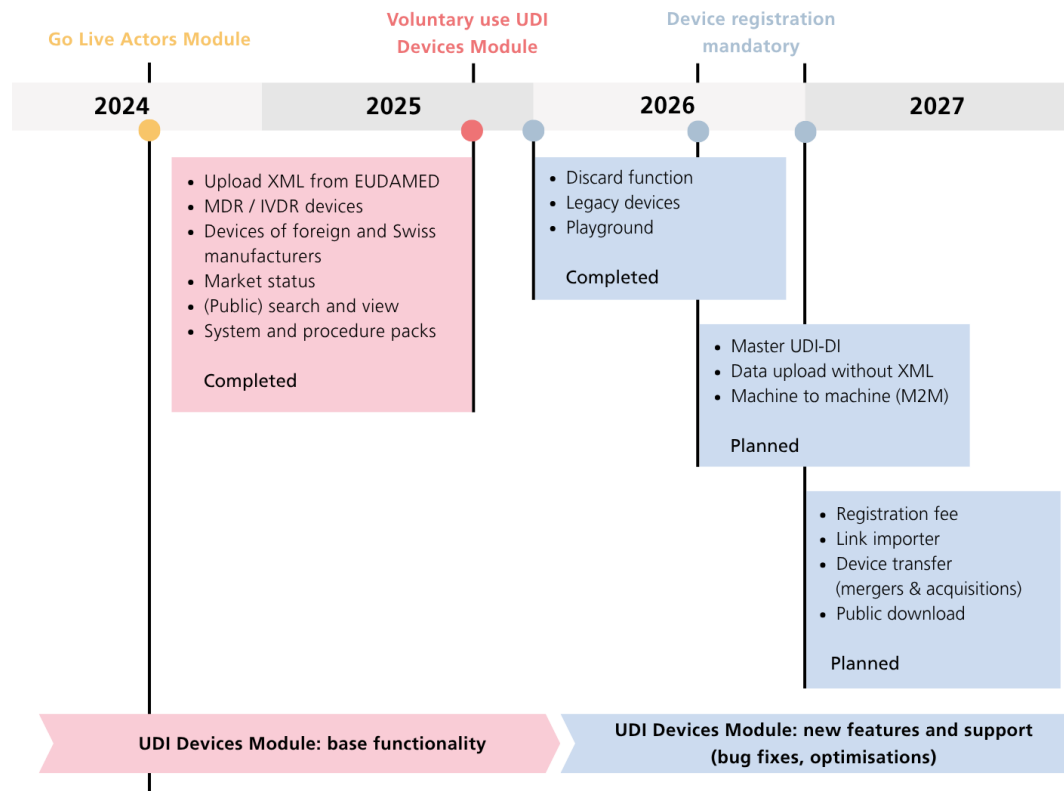
Booking not open yet



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

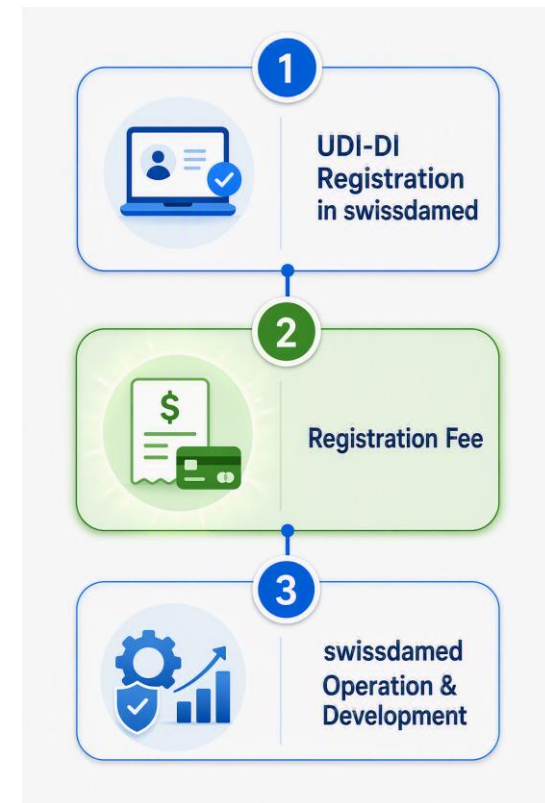
- Fees apply to registered UDI-DIs placed on the Swiss market.

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

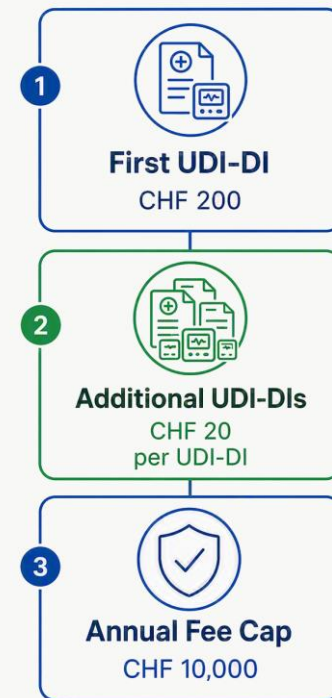
- CHF 200

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

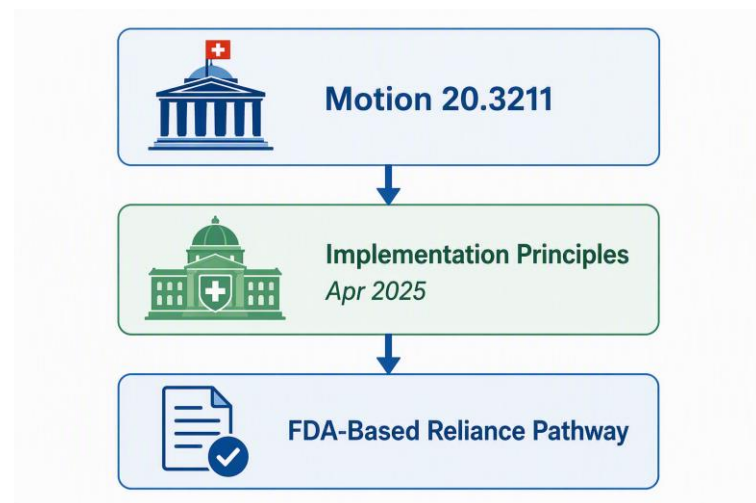
- Access to innovative medical devices
- Supply resilience
- High patient safety standards

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

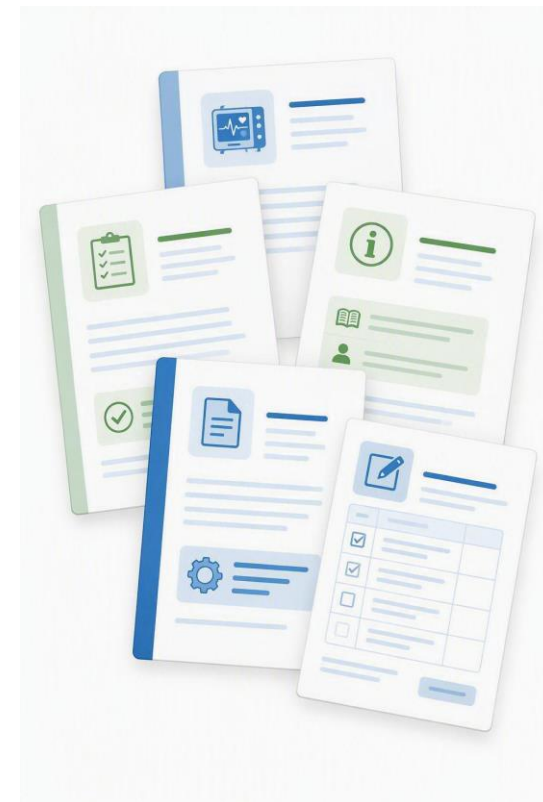
- swissdamed User Guide UDI Devices Module ([new, 07.07.2026](#))
- swissdamed Service Agreement ([new, 17.07.2026](#))
- Medical device registration fee ([new, 13.07.2026](#))

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!



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THE 30TH IMDRF 2026
WILL BE A VIRTUAL EVENT
HOSTED BY THE
HEALTH SCIENCES AUTHORITY
OF SINGAPORE.

