

A collection of light blue squares of various sizes, some solid and some outlined, arranged in a scattered pattern on the left side of the screen.

UDI Guidances



Introduction

Swissmedic is currently developing the Swiss Database SWISSDAMED, which features the ACT module for registering economic operators and a publicly accessible platform, as well as the UDI module for device registration. The Swiss medical device regulatory framework, including the Medical Devices Ordinance (MedDO; SR 812.213) and the Ordinance on In Vitro Diagnostic Medical Devices (IvDO; SR 812.219), incorporates compliance with certain EU legislation aspects, including UDI.



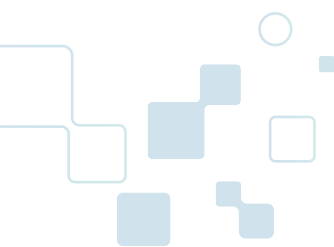
Swissdamed updates

The Actors module has been operational since August 2024. The UDI Devices module has been available voluntarily since August 2025, with mandatory use starting on July 1, 2026, for devices, systems, and procedure packs. After a six-month transition, registration in the UDI Device module will become compulsory on January 1, 2027. If a serious incident, Field Safety Corrective Action, or trend is relevant for a device or system/procedure pack after July 1, 2026, registration will be immediate, with no transitional period.

Swissdamed guidances

On August 15, Swissmedic issued a Swissdamed User Guide for the UDI Devices Module and updated the Swissdamed User Guide for Actors.

#	Guide title	Guide reference
1	Swissdamed User Guide UDI Devices Module	(BW630_40_841)
2	Swissdamed User Guide Actors	(BW630_40_001)



Swissdamed registration guide



Compile UDI Data

- Register the UDI-DIs in EUDAMED.
 - Download the UDI-DIS from EUDAMED as XML file.
- or
- Compile the XML file in EUDAMED POST DEVICE format directly from your system.



Upload UDI Data to swissdamed

- Upload the XML file to swissdamed
- Swiss manufacturers, persons who assemble systems and procedure packs and representatives are responsible to upload UDI-DIS.
- Swiss authorised representatives can delegate the upload to their mandates by assigning UDI Editor roles to mandates.
- Manual and machine-2- machine data entry will be available later.



Register the UDI (set Swiss market status)

- To register, set the market status of the UDI-DI to «On the market»
- UDI-DIS which were uploaded but never registered, can be removed using the «Delete» function.



Manage UDI Data

- To register, set the market status of the UDI-DI to «On the market».
- UDI-DIS which were uploaded but never registered, can be removed using the «Delete» function.

Timeline



Swissdamed Roadmap

