



Webinar swissdamed Swiss Database on Medical Devices

28. May 2026

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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

- Communication exclusively via Slido
- Two Q&A sessions with selected questions
- Questions team in background will address as many questions as possible
- Recording will be available in a few days on our website
- Short feedback survey at the end



Join Q&A:
slido.com
#1833 827

Videos

- Videos are not embedded in this .pdf file (only placeholders)
- Access the videos on the swissdamed support page [Support](#)

Background

Legal background Comparison swissdamed - EUDAMED

swissdamed

- 2021: MRA not updated for MDR/IVDR
 - European regulation largely adopted into MedDO / IvDO
 - No access to EUDAMED

➔ decision to build  swissdamed

Guiding principles

- swissdamed = single source of truth for the Swiss market
- All devices to be placed on the Swiss market need to be registered
- No interface swissdamed – EUDAMED
- Minimal registration effort

Regulation

- Underlying regulation very similar: MedDO/IvDO refer to EU-MDR/IVDR
- MDR Art. 27/29 and Annex VI: directly referenced and applicable
- Delegated acts declared directly applicable: MDR and IVDR, e.g.
 - Commission Delegated Regulation (EU) 2023/2197 of 10 July 2023 amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for **contact lenses**
 - Commission Delegated Regulation (EU) 2025/1920 amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for **spectacle frames, spectacle lenses and ready-to-wear reading spectacle**

swissdamed ↔ EUDAMED

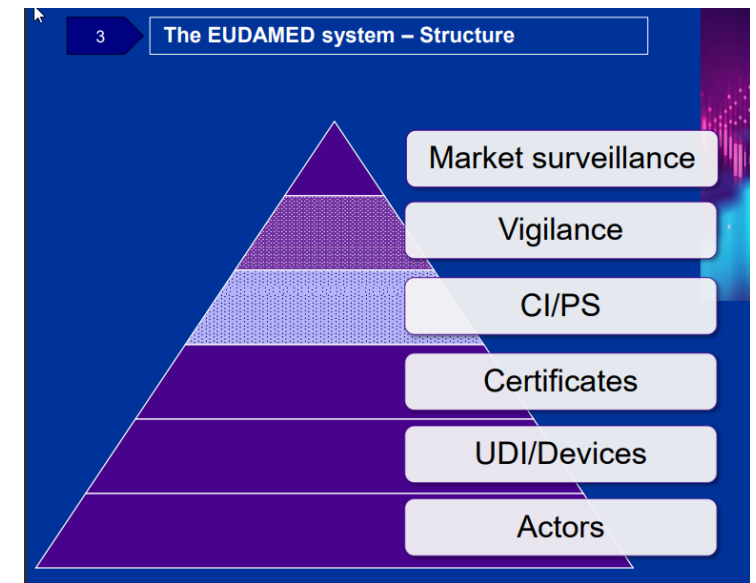
swissdamed ↔ EUDAMED

Similarities

- Largely equivalent data model and business rules
- Registration possible through
 - Manual entry
 - Bulk upload of XML files
 - M2M upload
- Production environment and playground for release/testing of new functionality

Differences

- swissdamed includes only two modules
- Different timelines
- Own / in-house programming, different user interface



From: health.ec.europa.eu


SWISSdamed

UDI Devices

Actors

swissdamed specific data elements:

- Swiss market status
- Swiss single registration number (CHRN)
- Swiss authorised representative
- versioning of records

Common data elements swissdamed - EUDAMED:

Basic UDI-DI Data

- Basic UDI-DI/EUDAMED DI, issuing entities
- applicable regulation
- kits, SPP, special device type
- medical purpose
- risk class
- device model/name
- device characteristics (implantable, measuring, reusable surgical instrument, active, administer/remove medicinal product, companion diagnostic, near patient testing, self testing, reagent, instrument, professional testing)
- single registration number (SRN)
- presence of tissues and cells/derivatives

UDI-DI Data

- UDI-DI/EUDAMED ID, unit of use DI, type of UDI-PI, direct marking DI, secondary UDI-DI, Package UDI-DI, issuing entity
- device name, trade name, reference/catalogue number
- product description
- nomenclature code
- intended purpose
- storage/handling warnings/contraindications
- information on sterilization, reuse, single use
- list of substances (CMR, latex, medicinal product, endocrine disruptors)
- clinical sizes
- quantity
- product original manufacturer

EUDAMED specific data elements:

- clinical investigations, performance studies
- certificate information
- market status in EU member states
- member state of placing on the EU market
- device substatus (recalls, field safety corrective actions)
- reprocessed single use
- versioning of records

Details on website:

[Device registration](#)

Data Model: Minimal Differences

swissdamed only

CHRN (Swiss single registration number)

- Swiss manufacturers
- Swiss authorised representatives
- Swiss importers

Foreign manufacturers: mandate ID

Swiss market status

Link between Swiss importer and the imported UDI-DIs

EUDAMED only

Clinical investigations, performance studies

Certificate information

Market status in EU member states

Member state of placing on the EU market

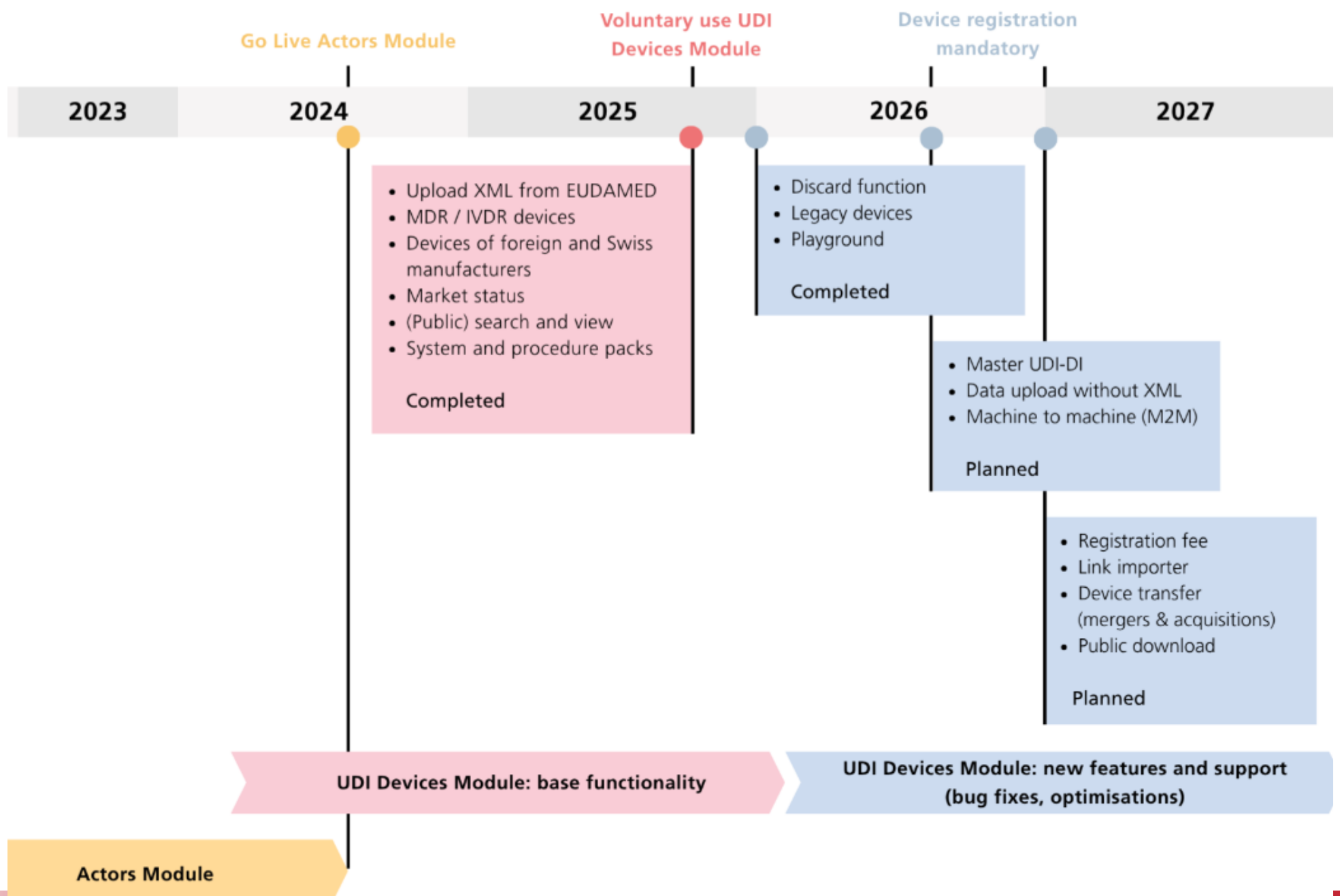
Device substatus (recall, FSCA)

Reprocessed single use

Link between EU importer and foreign manufacturer

List shortened/abbreviated. Details on website: [Device registration](#)

Roadmap



swissdamed ↔ EUDAMED

Registration obligation

swissdamed UDI Devices:

01.07.26 registration obligation, transition period until **31.12.26**

EUDAMED UDI Devices:

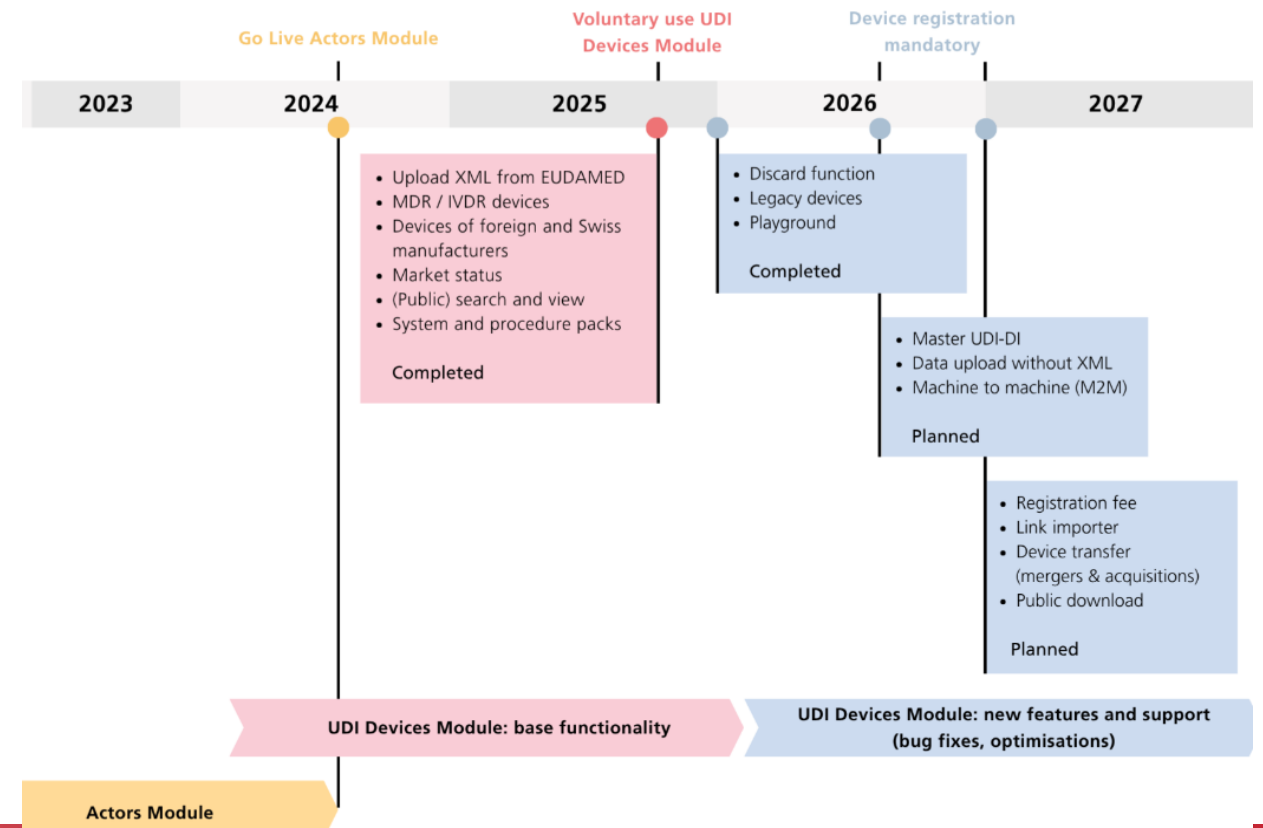
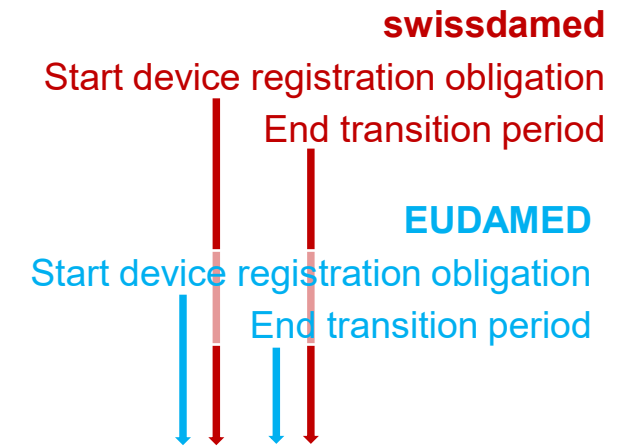
28.05.26 registration obligation, transition period until **27.11.26**

→ registration obligation >1 month later in swissdamed than in EUDAMED

Legal basis:

[SR 812.213 - MepV | Fedlex](#)

Alle Fassungen			
● 01.07.2026	HTML	XML	PDF DOC
● 01.11.2023	HTML	XML	PDF DOC
● 01.09.2023	HTML	XML	PDF DOC
● 26.05.2022	HTML	XML	PDF DOC



Device registration

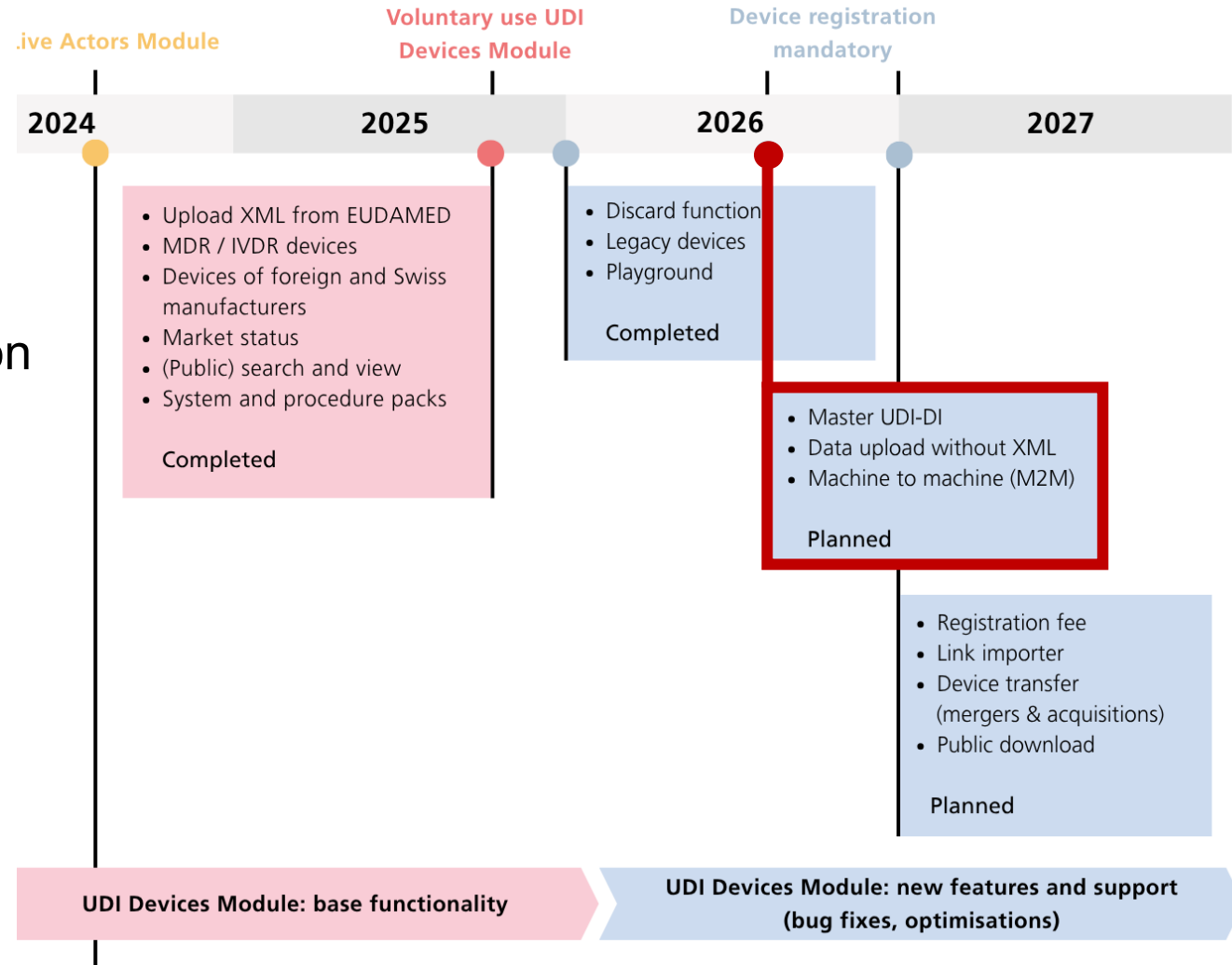
- Registration in swissdamed is mandatory for devices / systems and procedure packs:
 - For which individual sales units are placed on the Swiss market as of 1. July 2026
 - Regulation and legacy devices
 - Registration to be completed until 31. December 2026
 - Immediate registration in case of a required report to Swissmedic due to an incident, FSCA or trend
 - As of 1.1.2027: registration before placing on the market

Roadmap

Coming next:

- Master UDI-DI
- Online editor 'Upload data without XML' on productive environment
- M2M on productive environment

Release notes

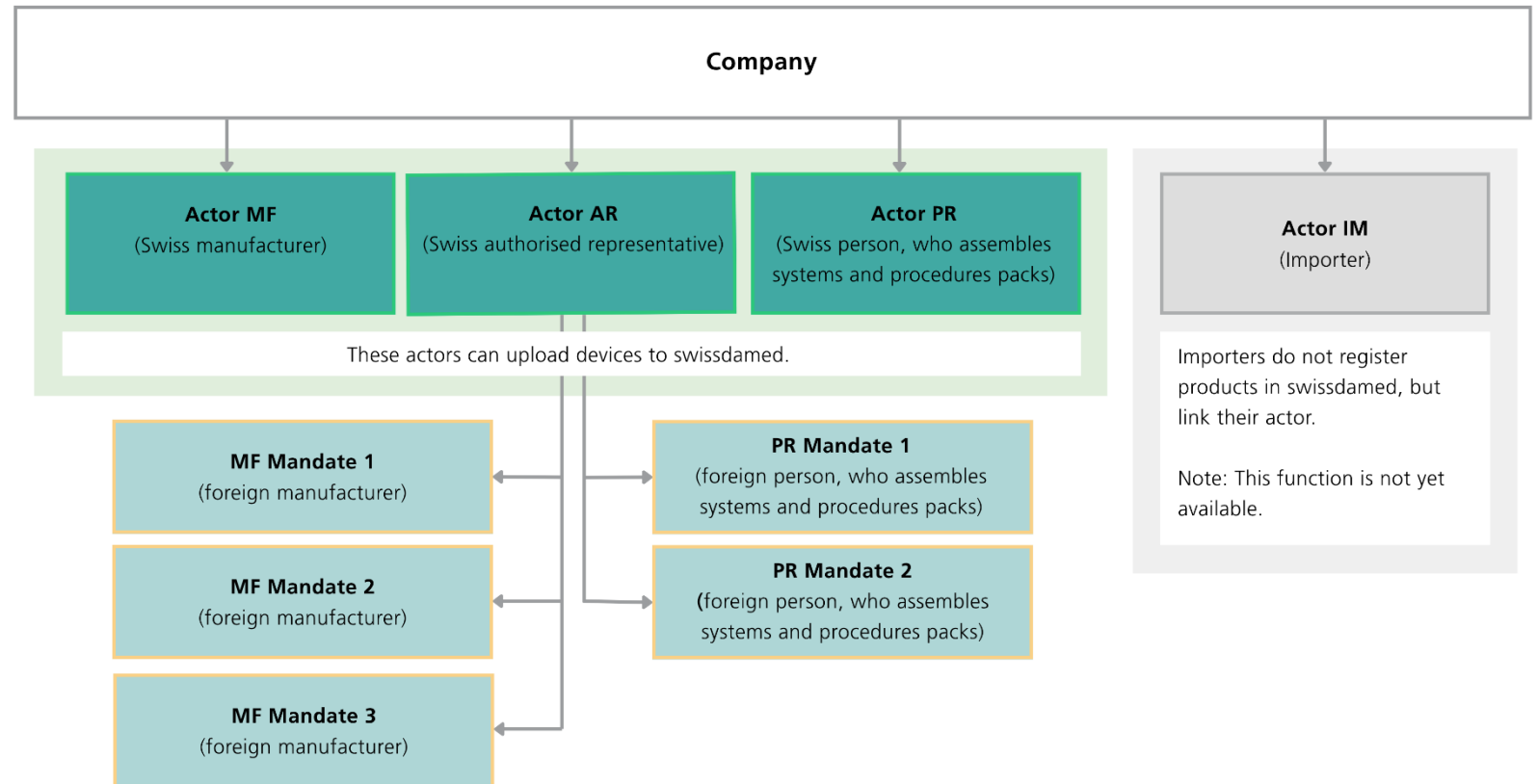


Actors module

- Actor type
- Mandate management
- User management
- Inactivation
- Mandate transfer

Different actor roles

- Economic operators specific for Switzerland
 - Swiss manufacturer (MF)
 - Swiss Person, who assembles... (PR)
 - Swiss authorized representative (AR) → responsible for mandates of foreign manufacturers
 - Swiss importer (IM)



Create and manage mandates (foreign manufacturer)

- Authorized representative (AR) must create / manage mandates with a foreign manufacturer or a foreign person who assembles systems and procedures packs

Required information

- SRN: Must be entered if available. Validation has been tightened
- Address of the mandate
- Email address for direct contact from Swissmedic to the foreign manufacturer. Email address is not publicly accessible
- Upcoming change: Only the AR admin is allowed to change the attributes 'valid from...' and 'valid until...'. The address attributes may also be managed by a mandate admin



Create mandate on AR

User permissions

Manage user permission of an actor or mandate

- Level company: Onboard a user in the company registration menu and assign permissions
 - Admin
 - Viewer
- Level actor in swissdamed:
 - Detailed permissions can be assigned per actor → see [User Guide Actor](#)
 - Admin
 - Viewer
 - UDI Editor:
 - UDI Editor permission are required to manage devices
 - authorised representative can assign UDI Editor permissions to foreign manufacturer staff



**Add users to a company, actor (AR) and mandate
Company viewer / Actor viewer / Mandate viewer**

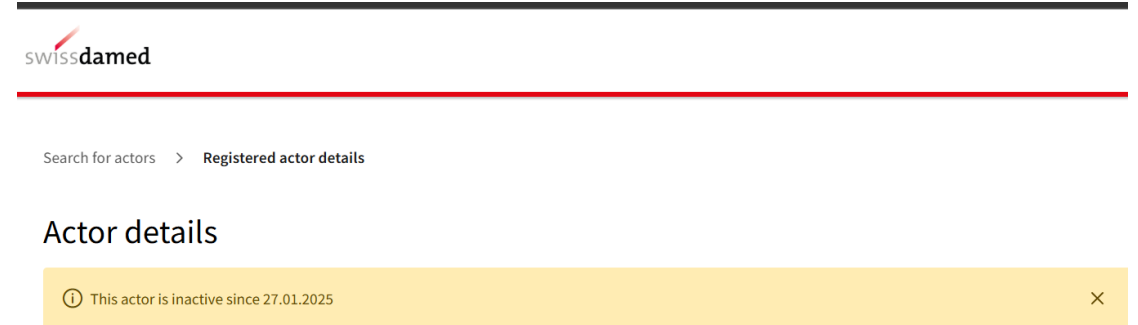


Add UDI Editor permission on mandate

Inactivation of an actor / mandate and mandate transfer

Inactivation of an actor / mandate

- An actor or a mandate can be inactivated
 - All users of an inactivated actor lose write permissions
 - The status of the products of an actor/mandate is changed to “No longer placed on the market”
- How an actor is inactivated:
 - Manually by the actors themselves
 - Automatically when the commercial register entry is deleted
 - Manually by Swissmedic according to an official decision



Not valid mandate (coming functionality)

- A foreign manufacturer requires a Swiss authorised representative to market products in the Swiss market
- If a Swiss authorised representative becomes inactive, all their mandates are considered not valid
- A mandate becomes “not valid” if the mandate's data has expired or has not yet started
- A “not valid” mandate can no longer set the status of their devices to “on the market”
- The status of products already “On the market” is lost after 30 days
 - If the mandate is to remain active, the mandate must be transferred

Transfer mandates

- A foreign manufacturer can change the authorised representative (AR). For this, there is the mandate transfer function.
- Workflow is started by the current AR
 - The date of the change can be defined
- What happens during the change:
 - Entry of the mandate is transferred to the new AR
 - Mandate receives a new mandate ID
 - Permissions on the mandate are all deleted and must be reassigned by the new AR
 - Registered devices are moved along
- Do not inactivate a mandate if the AR changes → inactivation will also set all devices to status “No longer placed on the market”

Questions Background / Actors

Q&A

Join Q&A:



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UDI Devices

UDI Devices module: submission methods background

Options for registration

	Number of products	Familiarity with EUDAMED	Required IT expertise
M2M connection / upload via REST API <ul style="list-style-type: none"> IT support / project required 	●●●●●	●●●●●	●●●●●
XML upload <ul style="list-style-type: none"> Download XML from EUDAMED / upload in swissdamed Create XML according to EUDAMED specifications 	●●● ●●●	●●●●● ●●●●●	●● (swissdamed part) ●●●●●
Online editor <ul style="list-style-type: none"> Manual entry of data elements per UDI-DI 	●	●●	●

UDI Devices

UDI Devices: online editor demo and timelines

Current status online editor

- Guided entry of data elements
- Available for MDR devices (not Master UDI-DI) for testing on playground
- First on playground, then on the production environment
- All device information on one page





Online editor: Create devices manually – Basic UDI-DI and UDI-DI



Online editor: Add UDI-DI to existing Basic UDI-DI



Online editor: Edit registered UDI-DI



Online editor: Add Package UDI-DI to existing UDI-DI



Online editor: UDI-DIs in progress

UDI Devices

UDI Devices: XML Bulk Upload

XML Bulk Upload

- XML according to EUDAMED XSD specifications: GET DEVICE or POST DEVICE
 - Download from EUDAMED (private search). [UDI user guide](#)
 - Create according to XSD specifications from own system. [Specifications](#)
- Two validations:
 - XSD format
 - Business rules
- XSD format limits size to 300 UDI-DIs
- Same process for initial upload and later update (consider: non-updateable fields)
- No Excel XML bulk upload template

```
1 <?xml version="1.0" encoding="UTF-8" standalone="yes"?>
2 <message:PullResponse version="3.0.16" xmlns:msuobj="https://ec.europa.eu/tools/eudamed/dtx/datamodel/Entity/MsuProcedures/Measure/Objection/v1" xmlns:device="http://www.w3.org/2001/XMLSchema-instance"
3   ....<message:correlationID>APP-DTX-000064989</message:correlationID>
4   ....<message:creationDateTime>2025-09-09T14:01:06.863+02:00</message:creationDateTime>
5   ....<message:messageID>ec89086f-6032-4b41-ac0a-c7db8b26c331</message:messageID>
6   ....<message:recipient>
7     ....<message:node>
8       ....<service:nodeActorCode>BE-MF-000000001</service:nodeActorCode>
9     ....</message:node>
10    ....<message:service>
11      ....<service:serviceID>DEVICE</service:serviceID>
12      ....<service:serviceOperation>GET</service:serviceOperation>
13    ....</message:service>
14  ....</message:recipient>
15  ....<message:payload>
16    ....<device:Device xsi:type="device:MDEUDeviceType" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
17      ....<device:MDEUData>
18        ....<e:state>REGISTERED</e:state>
19        ....<e:version>1</e:version>
20        ....<e:versionDate>2025-09-09T13:21:53.693+02:00</e:versionDate>
21        ....<udidi:identifier>
22          ....<commondevice:DIcode>15236984500003</commondevice:DIcode>
23          ....<commondevice:issuingEntityCode>GS1</commondevice:issuingEntityCode>
24        ....</udidi:identifier>
25        ....<udidi:status>
26          ....<commondevice:code>ON_THE_MARKET</commondevice:code>
27        ....</udidi:status>
28        ....<udidi:additionalDescription>
29          ....<lngs:name>
30            ....<lngs:language>EN</lngs:language>
31            ....<lngs:textValue>Additional product description EN</lngs:textValue>
32          ....</lngs:name>
33        ....</udidi:additionalDescription>
34        ....<udidi:basicUDIIdentifier>
35          ....<commondevice:DIcode>B-15236984500003</commondevice:DIcode>
36          ....<commondevice:issuingEntityCode>EUDAMED</commondevice:issuingEntityCode>
37        ....</udidi:basicUDIIdentifier>
38        ....<udidi:MDNCodes>J0190010104</udidi:MDNCodes>
```



XML upload via manufacturer

Registered actors

Refresh

View	Actor type	CHRN	UID	Name ↑	Address	Postal code	City	Status	Action
	MF	CHRN-MF-20019079	CHE-108.952.985	Swissmedic, Schweizerisches Heilmittelinstitut	Hallerstrasse 7	3012	Bern	Registered	
	PR	CHRN-PR-20018893	CHE-108.952.985	Swissmedic, Schweizerisches Heilmittelinstitut	Hallerstrasse 7	3012	Bern	Registered	
	AR	CHRN-AR-20017737	CHE-108.952.985	Swissmedic, Schweizerisches Heilmittelinstitut	Hallerstrasse 7	3012	Bern	Registered	

UDI Devices

UDI Devices: Set market status

Set market status = Register devices

- Registration obligation is only fulfilled when market status is set
- Status
 - On the market
 - No longer placed on the market
- Market status to be set for all registration methods:
 - M2M: API endpoint '3 Set Market Status'
 - Manually after XML upload and online data entry
- Market status
 - remains unchanged, even if UDI data is updated
 - is removed when UDI-DI is discarded



Set market status

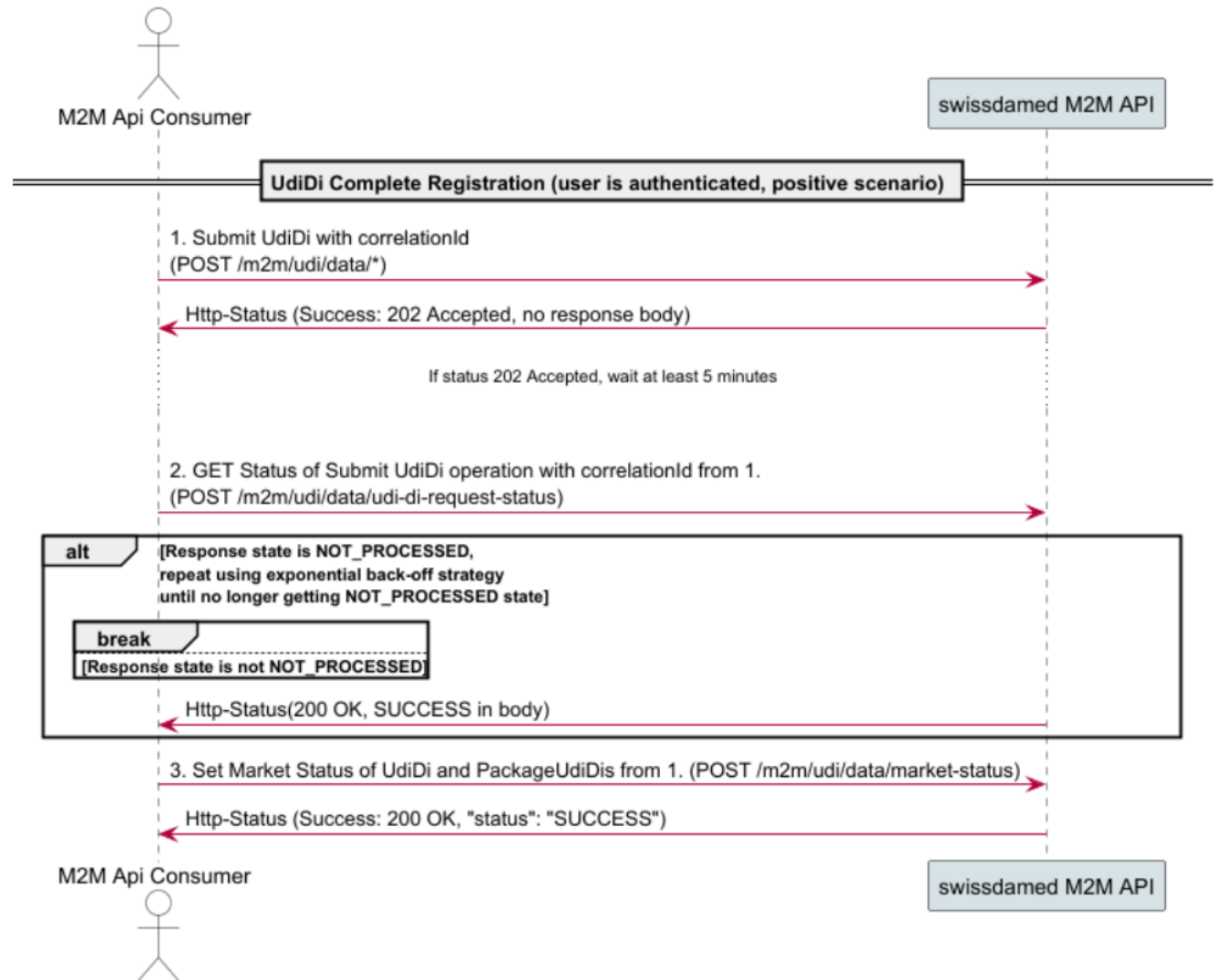
UDI Devices: Machine-to-Machine (M2M)

Machine-to-Machine (M2M)

- swissdamed provides a Machine-to-Machine interface.
- Most commonly used via third-party providers
- Four endpoints are available:
 - API endpoint '1 Submit UdiDi': Used for submitting **one** UdiDi (incl. associated PackageUdiDis) with its related BasicUdi
 - API endpoint '2 GET Status': Used for checking the status of **one** Submit UdiDi operation
 - API endpoint '3 Set Market Status': Used for setting the market status of a UdiDi and/or PackageUdiDis
 - API endpoint '4 Get UdiDi': Used for obtaining the data of **one** UdiDi (incl. associated PackageUdiDis) and its related BasicUdi, and the current market status.

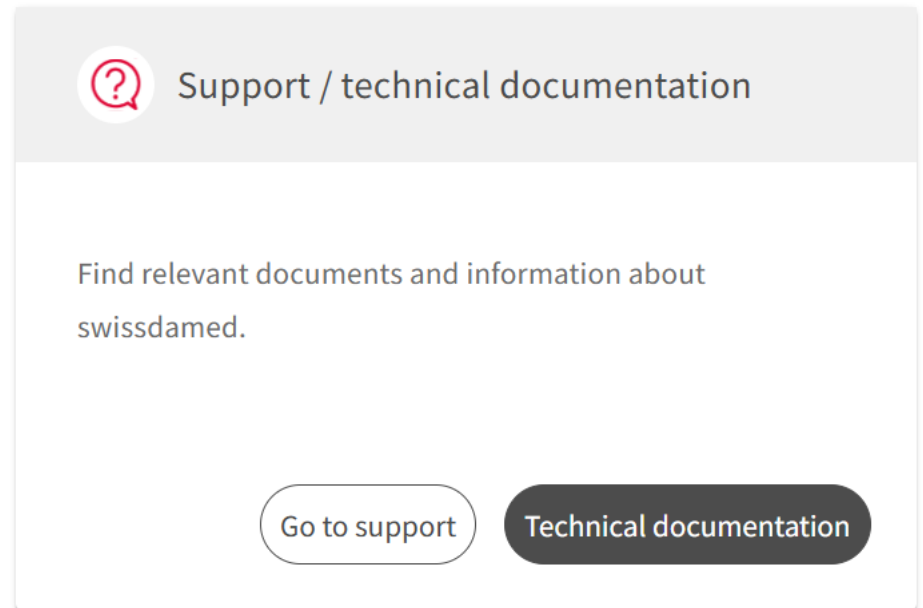
M2M – Endpoints stories

- Example:
Register and set market status of new UdiDi with or without PackageUdiDi



How to use Machine-to-Machine (M2M)

- Test in playground is mandatory
 - Get your client ID and the secret → demo later
 - Obtain a token (URL is documented in the specification)
 - Upload your devices formatted according to the OpenAPI specification
-
- On production environment M2M will be available in June
 - M2M Specifications can be found in the technical documentation





Generate client ID and client secret



Generate new client secret

UDI Devices

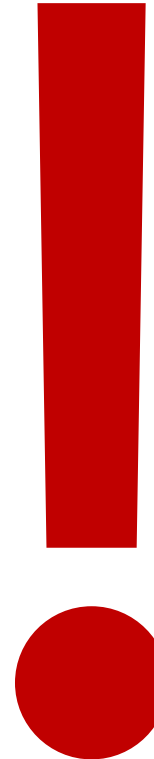
Manage UDIs

swissdamed – single source of truth

Please keep in mind:

Manufacturers are responsible to upload the correct data and to control the uploaded data.

The data from swissdamed will be used in various contexts in the future. We will make the device data available for public download by 2027 at the latest.



UDI Management – «database – housekeeping» functionality

- Change device status to «no longer on market»
- Delete uploaded drafts
- Discard device

Coming up:

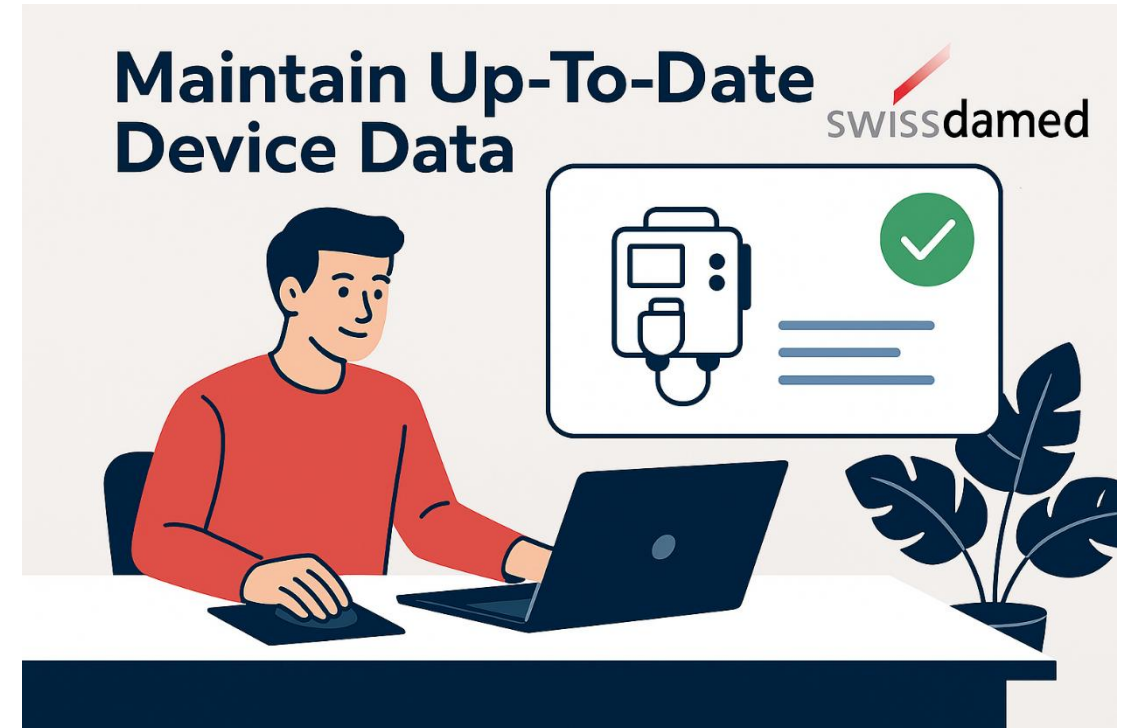
- Retrieve / export of your data



Set market status “No longer placed on the market” for multiple UDI-DIs

Delete UDI-DI

- Deletion of UDI-DIs **without** market status (Draft)
 - manually
 - automatic deletion 30 days after last update





Delete draft UDIs

Discard UDI-DI

- Discard of UDI-DIs
 - In case of submission errors and fields are non-updateable
 - Discard of last UDI-DI discards the Basic UDI-DI
 - Only available through interface, not M2M
 - Reason for discard needs to be indicated



Discard UDIs

UDI Devices

Registration fee

Registration fee for Medical Devices (SR 812.214.5)

- New FeeO-Swissmedic, SR 812.214.5 adopted by Swissmedic (Agency Council) and approved by the Federal Council; commencement date 01.07.2026.

What will be charged:

- Every UDI-DI that has been registered (market status “On the market”)
- No fee for uploaded devices that were deleted or are in status “draft”
- No fee for new versions/updates of a UDI-DI

Amount of the fee:

- First device of an actor or a foreign manufacturer registered in the calendar year: 200 CHF
- Each additional device registered in the calendar year: 20 CHF
- Fee cap per calendar year: 10'000 CHF (491 devices)

Registration fee for Medical Devices (SR 812.214.5)

How we will proceed

- Fee will be charged for the first time on 31.12.2026 for all devices which will be / have the status "On the market" at this time
- From 31.01.2027 at the end of each month a fee will be charged for all devices registered for the current month
- The invoice will be sent to the actor
- Fee for devices of foreign manufacturers will be sent to the authorised representative

UDI Devices

Master UDI-DI

- Timelines

swissdamed ↔ EUDAMED

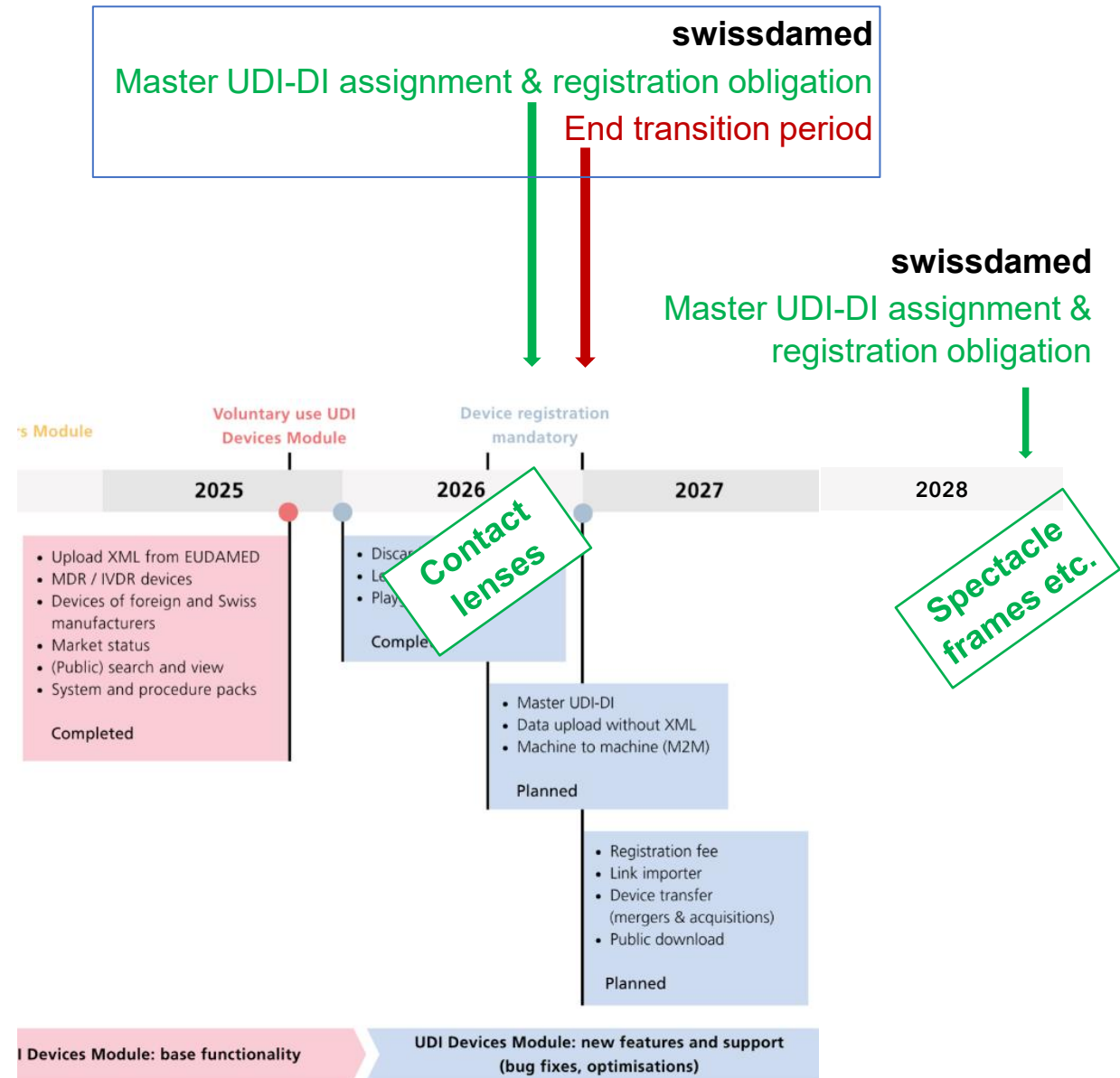
Device registration obligation: Master UDI-DI

swissdamed UDI Devices:
09.11.26 registration obligation, transition
period until **31.12.26**

EUDAMED UDI Devices:
09.11.26 registration obligation, transition
period until 27.11.26

Master UDI-DI assignment and registration
obligation until **01.11.28** for:

- spectacle frames
- spectacle lenses
- ready-to-wear reading spectacles

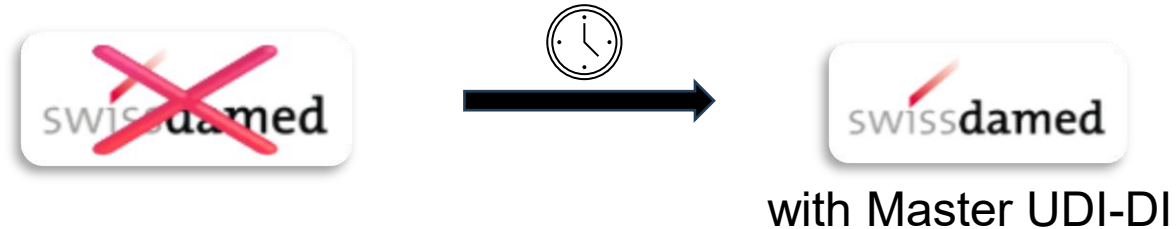


Master UDI-DI

- Legacy devices which would require a Master UDI-DI



- Regulation devices, which have not yet been assigned a Master UDI-DI

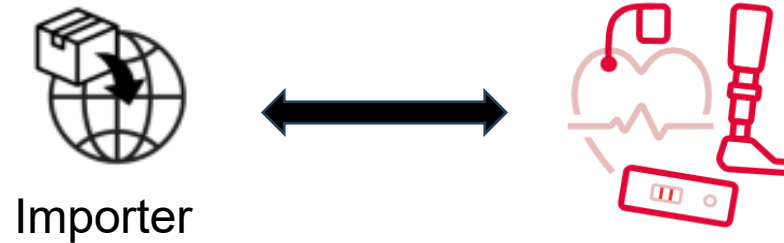


- Master UDI-DI registration in swissdamed currently not available
 - ➔ Directly on production environment: before the entry into force of the registration obligation

swissdamed - UDI Devices

Importer linking

Importer linking



importers **do not** register product themselves !



functionality available from **autumn 2026**

Once in place importers have till the 1st of April 2027 to link themselves to the products

swissdamed - UDI Devices

Coming features

Coming features

Until the end of 2026:

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

Go Live Actors Module

Voluntary use UDI Devices Module

Device registration mandatory



Completed

- Upload XML from EUDAMED
- MDR / IVDR devices
- Devices of foreign and Swiss manufacturers
- Market status
- (Public) search and view
- System and procedure packs

Completed

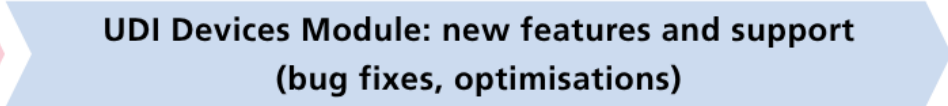
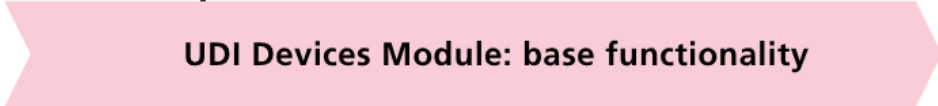
- Discard function
- Legacy devices
- Playground

Planned

- Master UDI-DI
- Data upload without XML
- Machine to machine (M2M)

Planned

- Registration fee
- Link importer
- Device transfer (mergers & acquisitions)
- Public download



Ressources & Training

- [swissdamed.ch](https://www.swissdamed.ch)
- playground.swissdamed.ch
- [Swissmedic website](https://www.swissmedic.ch)
- [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

The screenshot shows the Swissmedic website interface. At the top, there is a navigation bar with the Swissmedic logo and the text 'Schweizerisches Heilmittelinstitut Institut suisse des produits thérapeutiques Istituto svizzero per gli agenti terapeutici Swiss Agency for Therapeutic Products'. There are also links for 'Contact', 'Media', 'Job vacancies', 'eGov portal (applications)', 'ELVIS', and language options 'DE FR IT EN'. A search bar is located on the right side of the header.

Below the header is a main navigation menu with categories: 'Latest News', 'Human medicines', 'Veterinary medicines', 'Complementary & herbal medicines', 'Medical devices', 'Services & lists', 'About us', and 'Visible'. The 'Medical devices' category is currently selected.

The breadcrumb trail reads: 'Home > Medical devices > swissdamed > Support'. The page title is 'Support'. On the left side, there is a sidebar menu with the following items: 'Medical devices', 'swissdamed', 'Registering economic operators (CHRN)', 'Device registration', 'Unique Device Identifiers (UDI)', 'Playground', 'Support' (which is highlighted), 'Technical documentation', 'Questions and answers', 'General Information', and 'Release notes'.

The main content area under 'Support' is divided into two sections: 'Manual' and 'Screencast'. The 'Manual' section contains three links to PDF documents: 'BW630_40_001e_HB Handbook swissdamed User Guide Actors (PDF, 3 MB, 15.08.2025)', 'BW630_40_841e_HB swissdamed User Guide UDI Devices Module (PDF, 1 MB, 01.10.2025)', and 'BW630_40_809e_PU swissdamed Quick Guide - Registration In the UDI Devices Module (PDF, 215 kB, 15.08.2025)'. The 'Screencast' section contains four links to video files: 'Actor registration.mp4', 'UDI upload via manufacturer.mp4', 'UDI upload via mandate.mp4', 'User profile "UDI Editor" - manufacturer', and 'User profile "UDI Editor" - mandate'.

Useful links

EU:

- [Unique Device Identifier - UDI - Public Health - European Commission](#)
- [Welcome to EU UDI Helpdesk](#)

Questions UDI Devices

Q&A

Join Q&A:



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Use swissdamed now!
And increase
transparency in the Swiss
market