

Handbook

swissdamed User Guide UDI Devices Module

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1 Introduction

This user guide describes how manufacturers (including persons who assemble systems or procedure packs) and their authorised representatives are able to upload and register UDIs in swissdamed.

For information regarding the Actors Module and how to use swissdamed in general, please see the user manual: [BW630_40_001e_HB Handbook swissdamed User Guide Actors](#).

1.1 Overview

swissdamed is structured around **two modules** and two public search sites:

- **Actors Module** - Company and actor user registration and management
- **UDI Devices Module** - Registration and management of devices
- Public search function for actors and UDIs

2 Who is able to upload / register UDIs in swissdamed?

In order to register UDIs in swissdamed, a user has to have the “**UDI Editor**” user profile.

The users who are part of an actor can have different user rights and profiles. User rights and profiles are designed to ensure that only authorised users can perform specific actions for their actor.

The different user profiles of the economic operators are described in the user manual [BW630_40_001e_HB Handbook swissdamed User Guide Actors](#).

3 Upload UDIs via XML

After an approved registration of the economic operator, UDIs can be registered. Only manufacturers, authorised representatives, or persons who assemble systems or procedure packs can register UDIs. Authorised representatives must register the UDIs at the mandate level.

UDI registration is currently only possible via XML upload. During the upload, two automatic validations are performed, which must be successful for the UDIs to be uploaded to swissdamed. UDIs are only considered registered and are publicly accessible once the market status has been set in swissdamed.

After uploading the XML file, swissdamed first performs a technical validation and checks the following points:

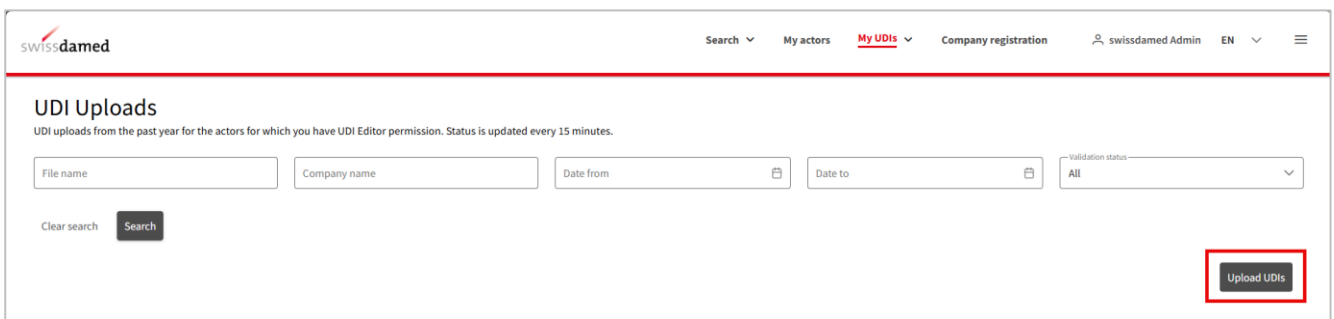
- XSD version
- XML schema (the uploaded XML file is validated against the applicable EUDAMED data exchange format definition)

During the second validation, the content of the XML file is checked. The information contained in the file is reviewed according to the business rules. The applied business rules can be found in the [business rules document](#).

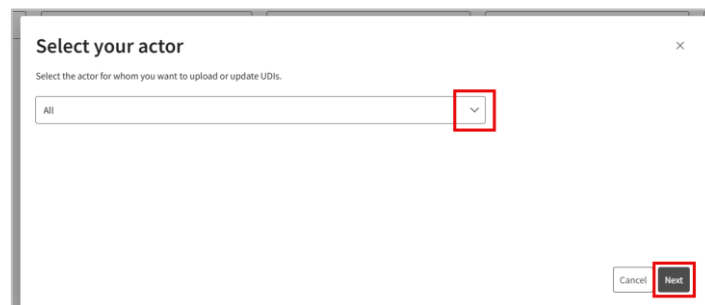
Users with the “UDI Editor” user profile on a manufacturer (MF), person who assembles systems or procedure packs (PR), MF mandate or PR mandate are able to upload UDIs. There are two ways to upload UDIs. One is via the “UDI Upload” / “UDI Management” tab (described in chapter 3.1), the other one is directly via the actor / mandate details (described in chapter 3.2).

3.1 Upload via “UDI Management” or “UDI Uploads”

1. Go to the “UDI Uploads” tab via the “My UDIs” dropdown and click on the button “Upload UDIs”. A pop-up opens.

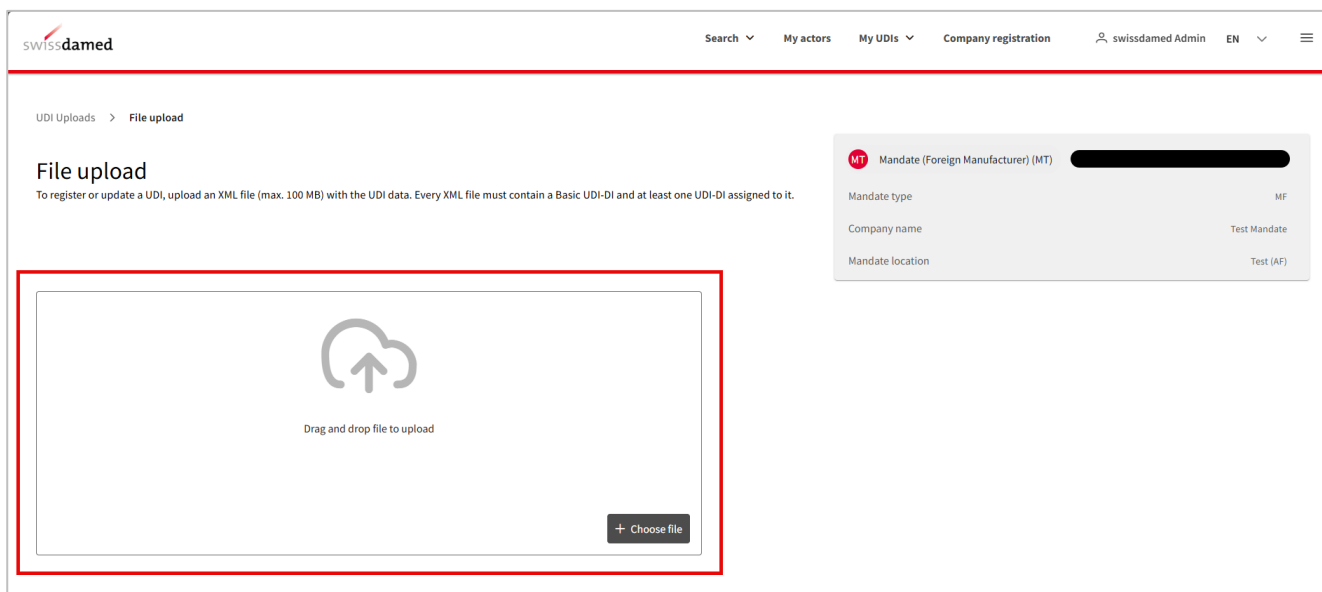


2. Select the actor or mandate from the dropdown for which you want to upload UDIs. There are only actors / mandates shown for which you have the “UDI Editor” user profile. Click “Next” to move on with the upload.



Note: If there is only one actor / mandate for which you have the “UDI Editor” user profile, no dropdown is shown, you get redirected directly to the XML Upload.

3. Enter the XML via drag and drop or click on the button “+ Choose file”.




swissdamed

Search ▾ My actors My UDIs ▾ Company registration swissdamed Admin EN ▾

UDI Uploads > File upload

File upload

To register or update a UDI, upload an XML file (max. 100 MB) with the UDI data. Every XML file must contain a Basic UDI-DI and at least one UDI-DI assigned to it.



Drag and drop file to upload

+ Choose file

MT Mandate (Foreign Manufacturer) (MT) [redacted]

Mandate type	MF
Company name	Test Mandate
Mandate location	Test (AF)

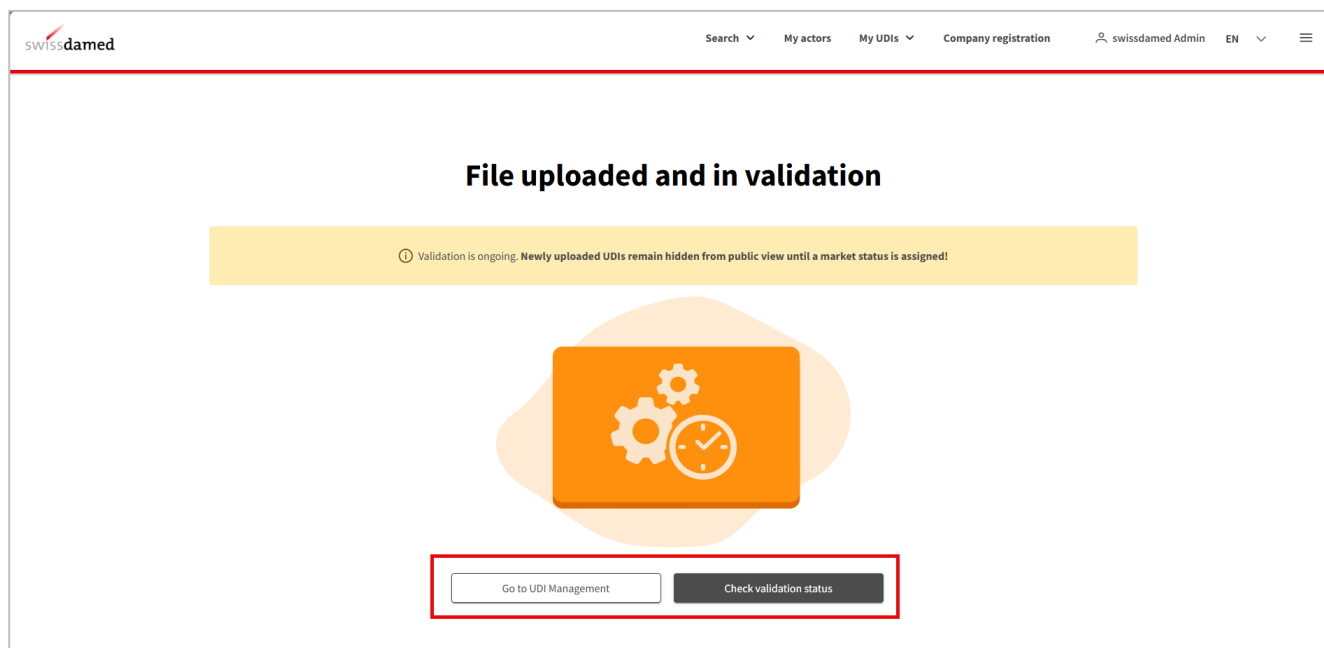
4. Enter a comment if desired (this comment will not be visible to the public, only on the UDI Uploads tab). Click on the button “Submit”.

Comment (optional)

Add personal comments to identify your UDI upload. This comment is visible under UDI Uploads.

Submit

5. The XML will now be validated. To check the validation status, click on the button “Check validation status”. If you want to upload further UDIs, click on the button “Go to UDI Management”.

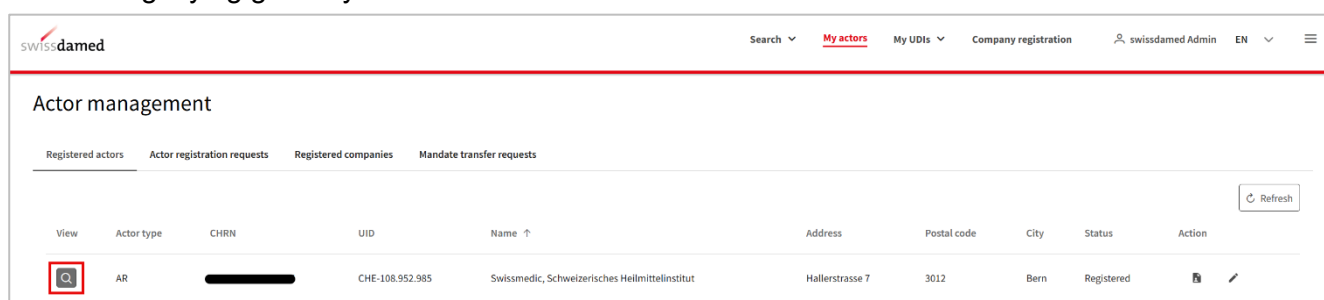


- By clicking on “Check validation status”, you will get redirected to the “UDI Uploads” tab. There you can see the outcome of the validation (business rules check). The validation may take some time. A page refresh is required to see the result of the validation.

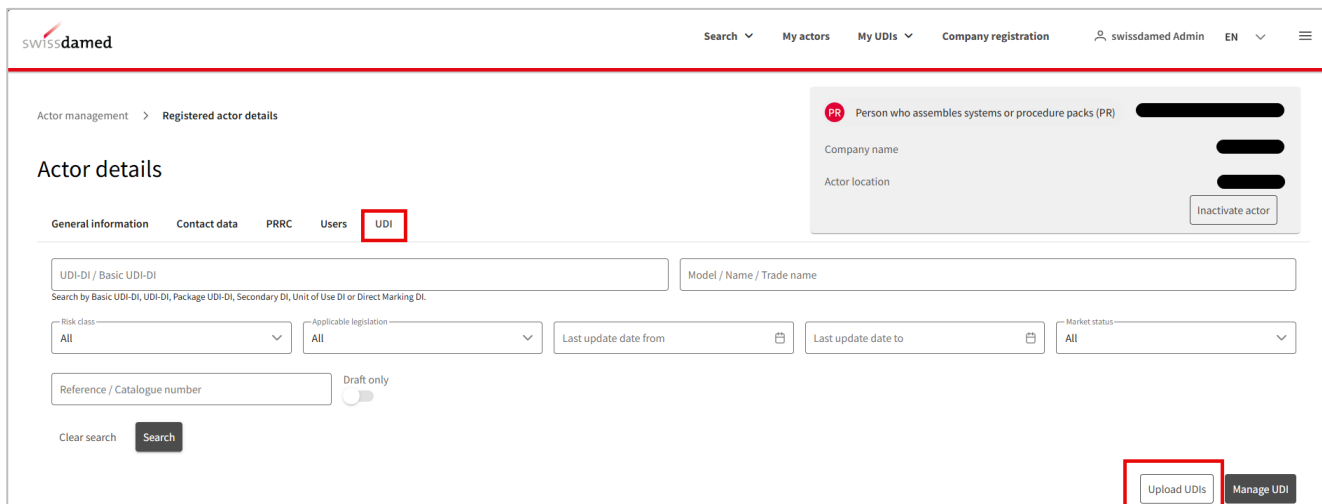
Note: An SPP can only be registered by PR actors / mandates.

3.2 Upload via registered actor / mandate

- Go to the “Registered actors” tab via the “My actors” dropdown.
- Open the detail view of the actor for which you want to upload UDIs by clicking on the magnifying glass symbol.



- If your actor is a manufacturer (MF) or a person who assembles systems or procedure packs (PR) you can see the “UDI” tab directly in the actor details.



SWISSdamed

Search ▾ My actors My UDIs ▾ Company registration swissdamed Admin EN ▾

Actor management > Registered actor details

Actor details

General information Contact data PRRC Users **UDI**

PR Person who assembles systems or procedure packs (PR)

Company name

Actor location

Inactivate actor

UDI-DI / Basic UDI-DI Model / Name / Trade name

Search by Basic UDI-DI, UDI-DI, Package UDI-DI, Secondary DI, Unit of Use DI or Direct Marking DI.

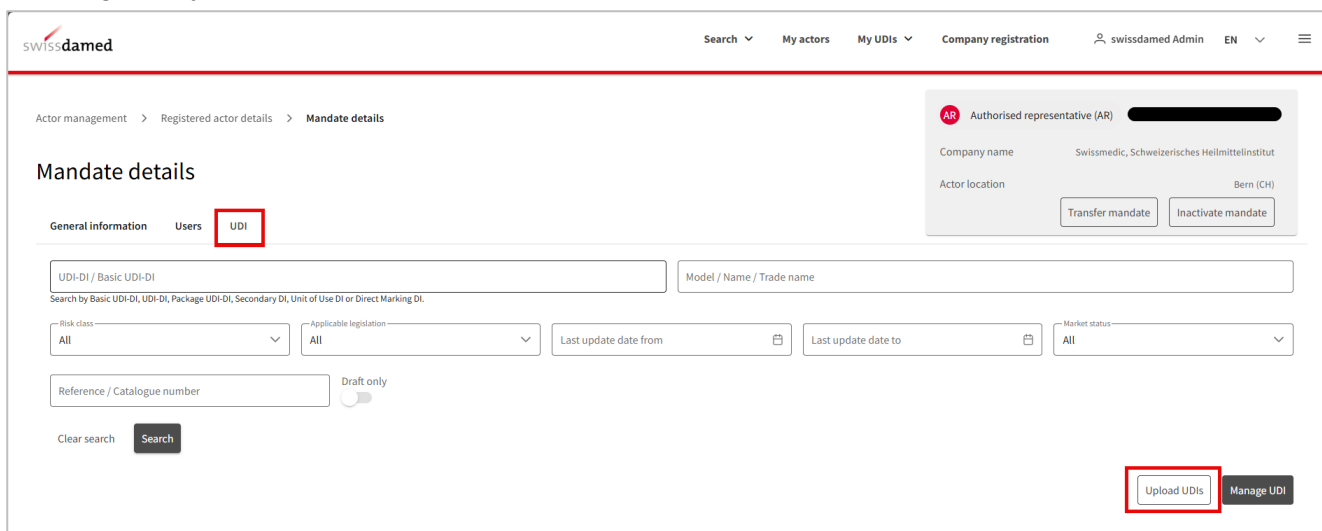
Risk class ▾ All Applicable legislation ▾ All Last update date from Last update date to Market status ▾ All

Reference / Catalogue number Draft only

Clear search Search

Upload UDIs Manage UDI

- If you want to upload UDIs on a mandate, open the “Mandates” tab in the actor details of your Swiss authorised representative (AR). Open the mandate details by clicking on the magnifying glass symbol. Go to the “UDI” tab.



SWISSdamed

Search ▾ My actors My UDIs ▾ Company registration swissdamed Admin EN ▾

Actor management > Registered actor details > Mandate details

Mandate details

General information Users **UDI**

AR Authorised representative (AR)

Company name Swissmedic, Schweizerisches Heilmittelinstitut

Actor location Bern (CH)

Transfer mandate Inactivate mandate

UDI-DI / Basic UDI-DI Model / Name / Trade name

Search by Basic UDI-DI, UDI-DI, Package UDI-DI, Secondary DI, Unit of Use DI or Direct Marking DI.

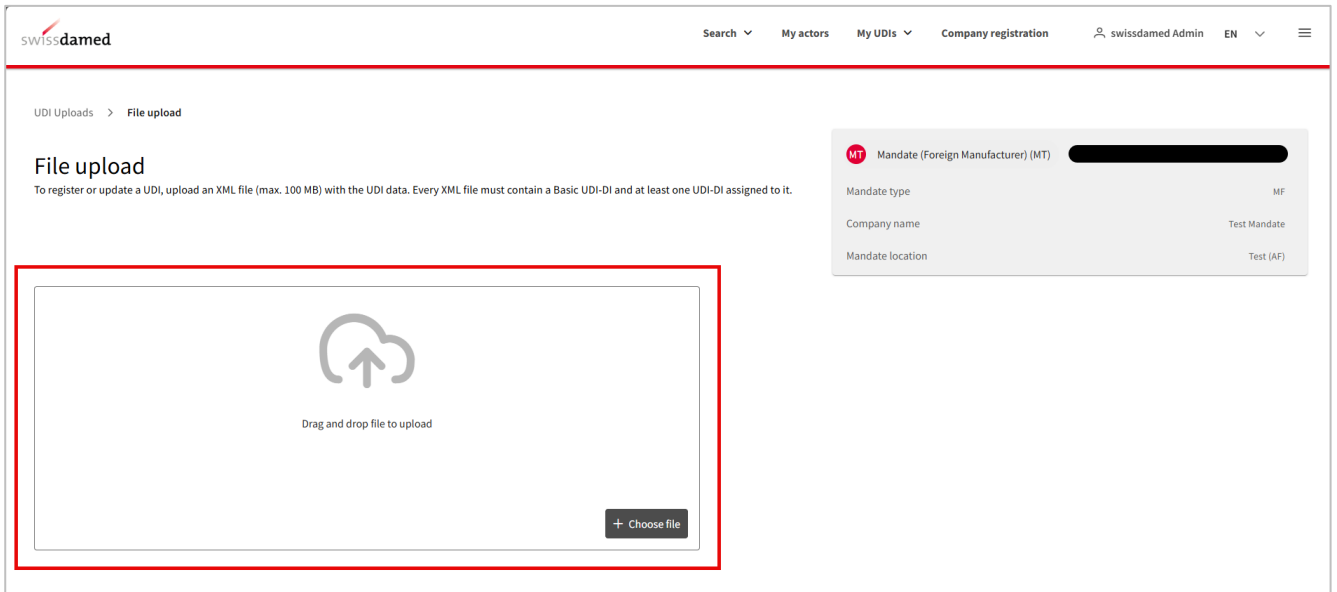
Risk class ▾ All Applicable legislation ▾ All Last update date from Last update date to Market status ▾ All

Reference / Catalogue number Draft only

Clear search Search

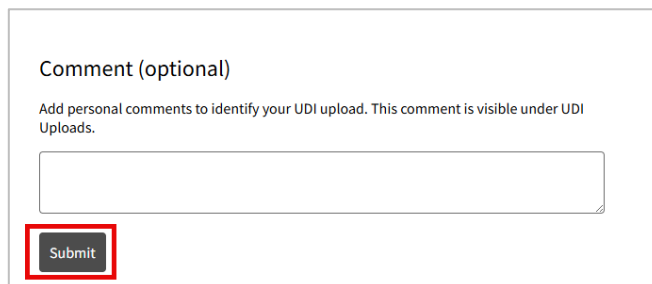
Upload UDIs Manage UDI

- Click on the button “Upload UDIs”.
- Enter the XML via drag and drop or click on the button “+ Choose file”.



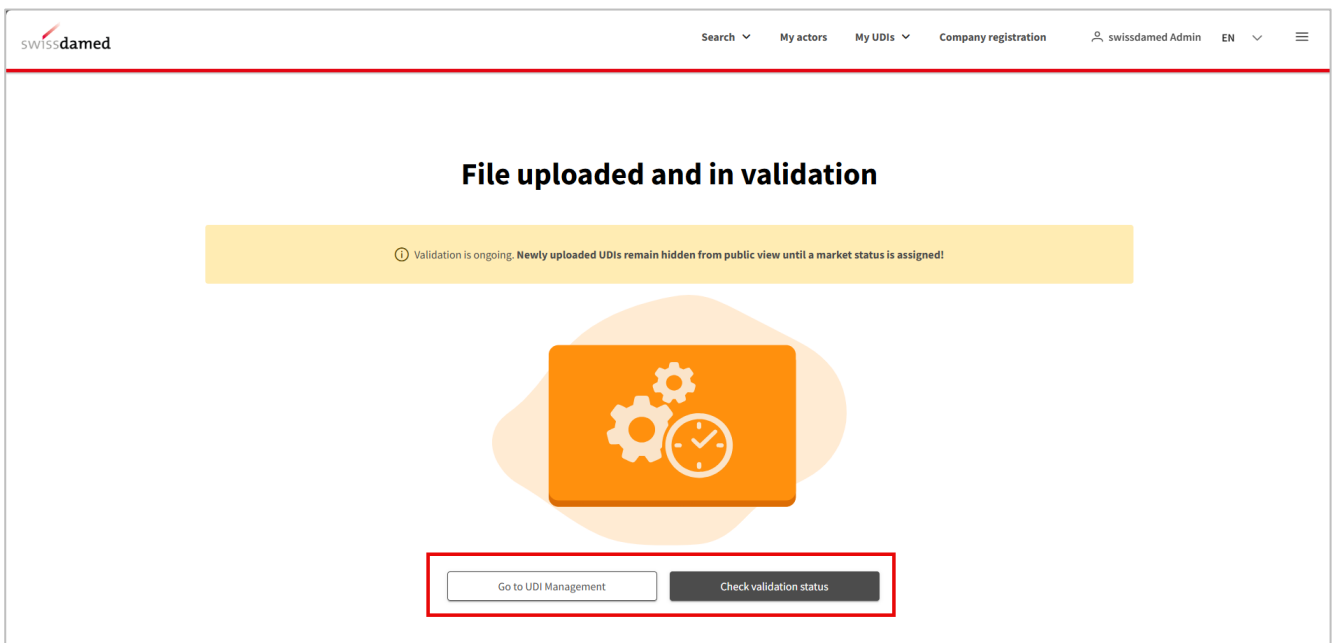
The screenshot shows the 'File upload' page in the SWISSdamed system. The page title is 'File upload' with a subtitle: 'To register or update a UDI, upload an XML file (max. 100 MB) with the UDI data. Every XML file must contain a Basic UDI-DI and at least one UDI-DI assigned to it.' A large red rectangle highlights the file upload area, which contains a cloud icon with an upward arrow and the text 'Drag and drop file to upload'. Below this is a '+ Choose file' button. On the right side, there is a sidebar with a 'Mandate (Foreign Manufacturer) (MT)' section and a table with columns for 'Mandate type', 'Company name', and 'Mandate location'. The table contains rows for 'MF', 'Test Mandate', and 'Test (AF)'.

7. Enter a comment if desired (this comment will not be visible to the public, only on the UDI Upload tab). Click on the “Submit” button.



The screenshot shows the 'Comment (optional)' section. It includes a text input field with the placeholder text 'Add personal comments to identify your UDI upload. This comment is visible under UDI Uploads.' Below the input field is a 'Submit' button, which is highlighted with a red rectangle.

8. The XML will now be validated. To check the validation status, click on the button “Check validation status”. If you want to upload any further UDIs, click on the button “Go to UDI Management”.



The screenshot shows the 'File uploaded and in validation' page in the SWISSdamed system. The page title is 'File uploaded and in validation'. Below the title is a yellow banner with a warning icon and the text: 'Validation is ongoing. Newly uploaded UDIs remain hidden from public view until a market status is assigned!'. In the center of the page is a large orange graphic with a gear and a clock icon. At the bottom, there are two buttons: 'Go to UDI Management' and 'Check validation status'. The 'Check validation status' button is highlighted with a red rectangle.

9. By clicking on “Check validation status” you will get redirected to the “UDI Upload” tab. There you can see the outcome of the validation (business rules check). The validation may take some time. A page refresh is required to see the result of the validation.

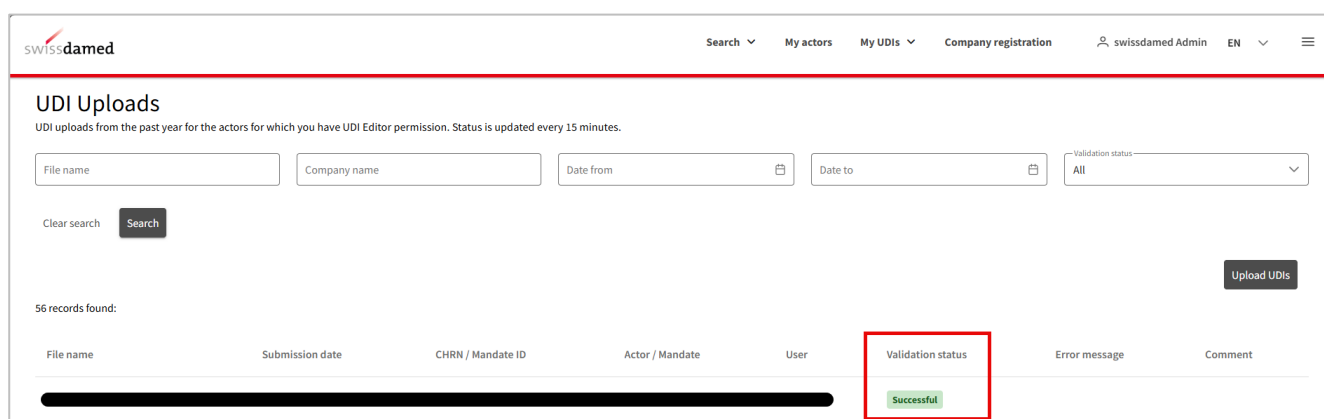
Note: An SPP can only be registered by PR actors / mandates.

3.2.1 XSD / XML validation failed

If the XSD validation fails, please check the XSD version and the XML schema (the uploaded XML file is validated against the applicable EUDAMED data exchange format definition).

3.2.2 Upload outcome: Successful

If the “Validation status” is “Successful”, your UDI Upload was successful.

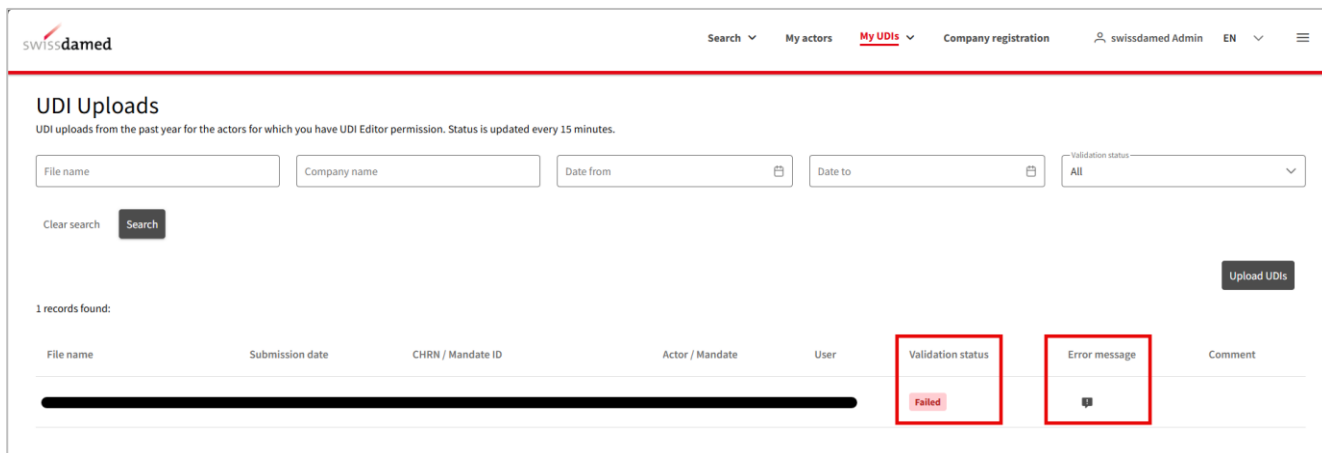


The screenshot shows the 'UDI Uploads' section of the SWISSdamed interface. At the top, there is a navigation bar with 'Search', 'My actors', 'My UDIs', 'Company registration', and 'swissdamed Admin'. Below this, the 'UDI Uploads' title is followed by a subtitle: 'UDI uploads from the past year for the actors for which you have UDI Editor permission. Status is updated every 15 minutes.' There are search filters for 'File name', 'Company name', 'Date from', 'Date to', and 'Validation status' (set to 'All'). A 'Search' button is present. Below the filters, it says '56 records found:'. A table with columns 'File name', 'Submission date', 'CHRN / Mandate ID', 'Actor / Mandate', 'User', 'Validation status', 'Error message', and 'Comment' is shown. The 'Validation status' column for the first record is highlighted with a red box and contains the word 'Successful' in a green box.

The uploaded UDIs are now listed under the “UDI Management” tab. They are marked as “draft” and therefore not publicly visible. For instructions on how to register the UDIs and set the market status, go to chapter 4.1. You will also receive an email confirming that the upload was successful, along with a direct link for assigning the market status.

3.2.3 Upload outcome: Failed

If the “Validation status” is “Failed”, your UDI Upload has failed and no UDIs were uploaded. In the column “Error message” you can click on the symbol, in order to open the information as to why the upload failed.



You will also receive an email informing you that the upload has failed, along with a direct link for viewing the error message.

The error message is built as follows:

UDI-1124: The Basic UDI-DI 012345678910 cannot be uploaded because an implantable device cannot be classified as risk class I.

- Business rule No.
- Basic UDI-DI
- Error description

The applied business rules can be found in the [business rules document](#).

3.3 Update UDIs

If you need to update your UDIs, you can do so by uploading the updated XML. The process is the same as for uploading UDIs for the first time. Please see chapter 3.1 or 3.2.

Respect the non-updatable fields and further relevant business rules. They can be found in the [business rules document](#).

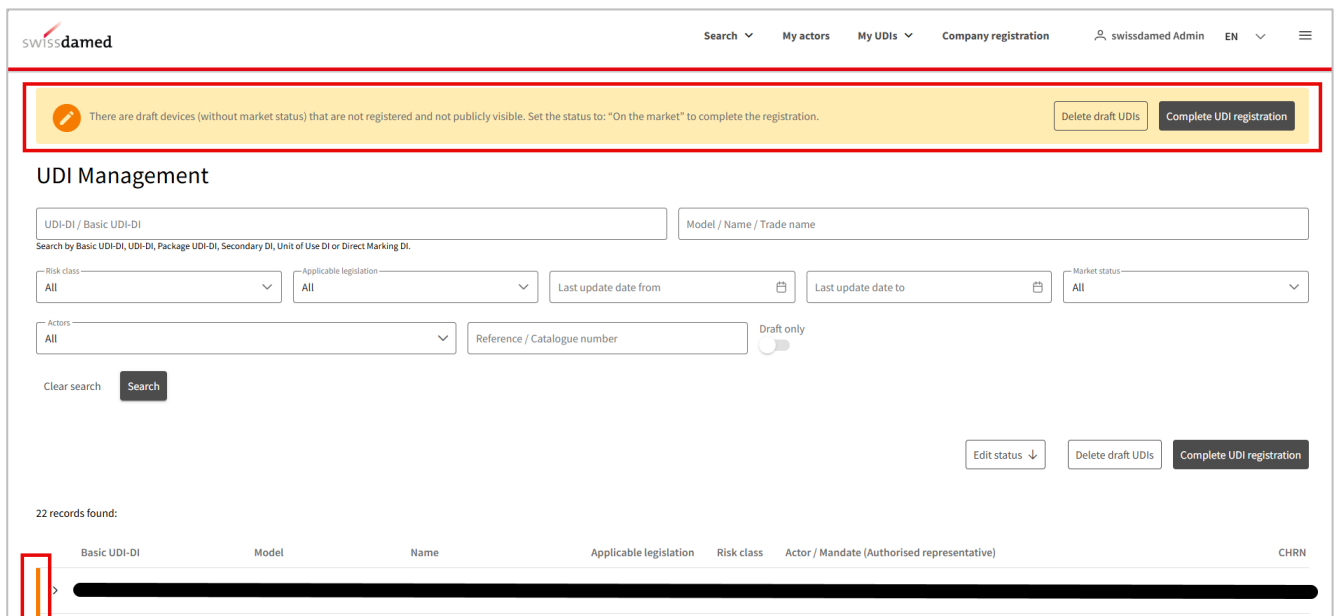
A **new version** of the UDI is created.

Note: The market status is maintained for the updated UDIs. However, any newly uploaded Package UDI-DIs will be flagged as “draft”, even if they are added to an existing UDI-DI with an assigned market status → the market status will not be inherited!

4 Market status

UDIs are only considered registered and are publicly accessible once the market status has been set in swissdamed. UDIs without a market status are stored in the “UDI Management” tab and are marked

as “draft” with an orange bar. There is also an info banner, which is visible as soon as there is at least one UDI-DI or Package UDI-DI without a set market status.

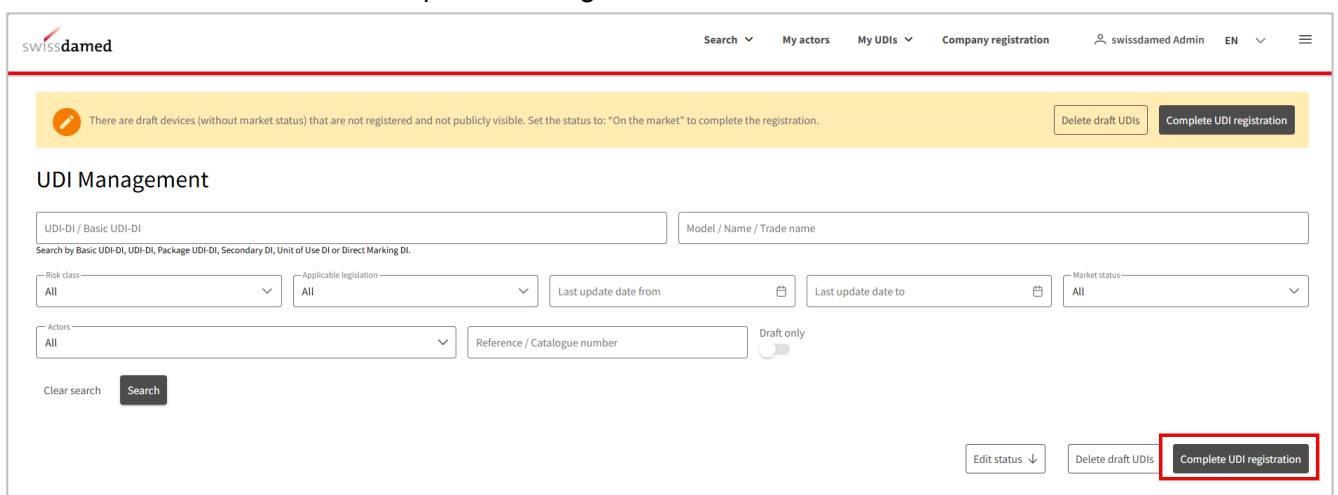


The “UDI Editor” can individually assign a market status to UDI-DIs and Package UDI-DIs flagged as “draft”. But the market status will not be inherited.

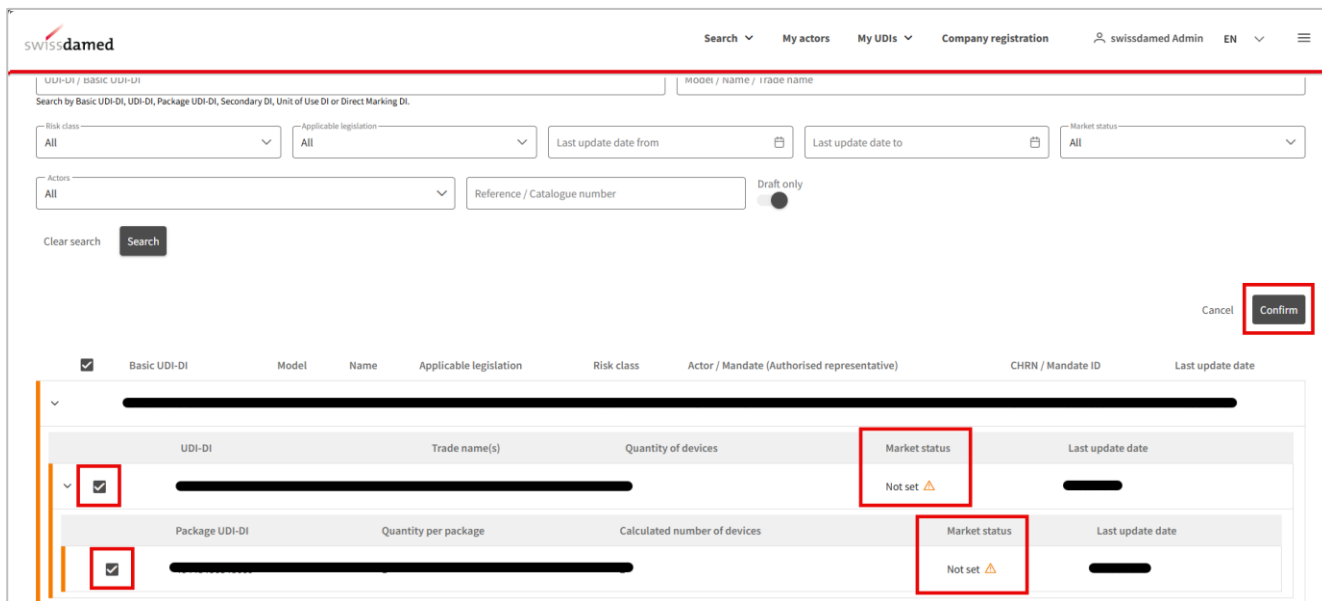
Note: UDIs marked as “draft” will not cause any fees.

4.1 Complete UDI registration

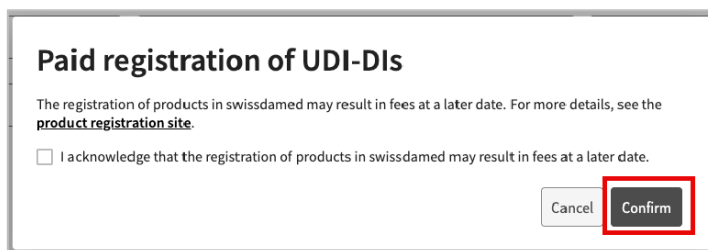
1. Go to the “UDI Management” tab via the “My UDIs” dropdown.
2. Click on the button “Complete UDI registration”.



3. Select the UDIs for which you want to set the market status to “On the market”. You can filter the list by entering data. As default the filter “Draft only” is applied, therefore only UDIs without a market status are shown (market status is “Not set”). It is not possible to select a Package UDI-DI if the connected UDI-DI is not selected. Click on the button “Confirm”.



- A pop up opens, where you need to acknowledge and confirm, that the registration of products in swissdamed may result in fees at a later date.

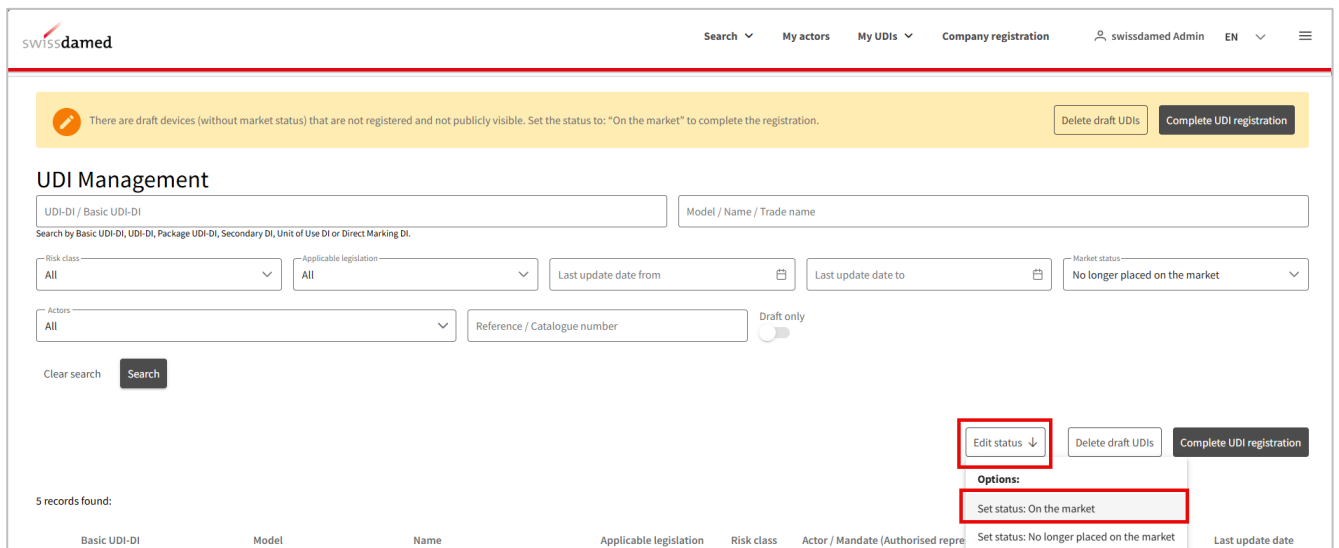


- The selected UDIs now have the market status “On the market” and are therefore publicly visible. The **initial version** of the corresponding UDI is created.

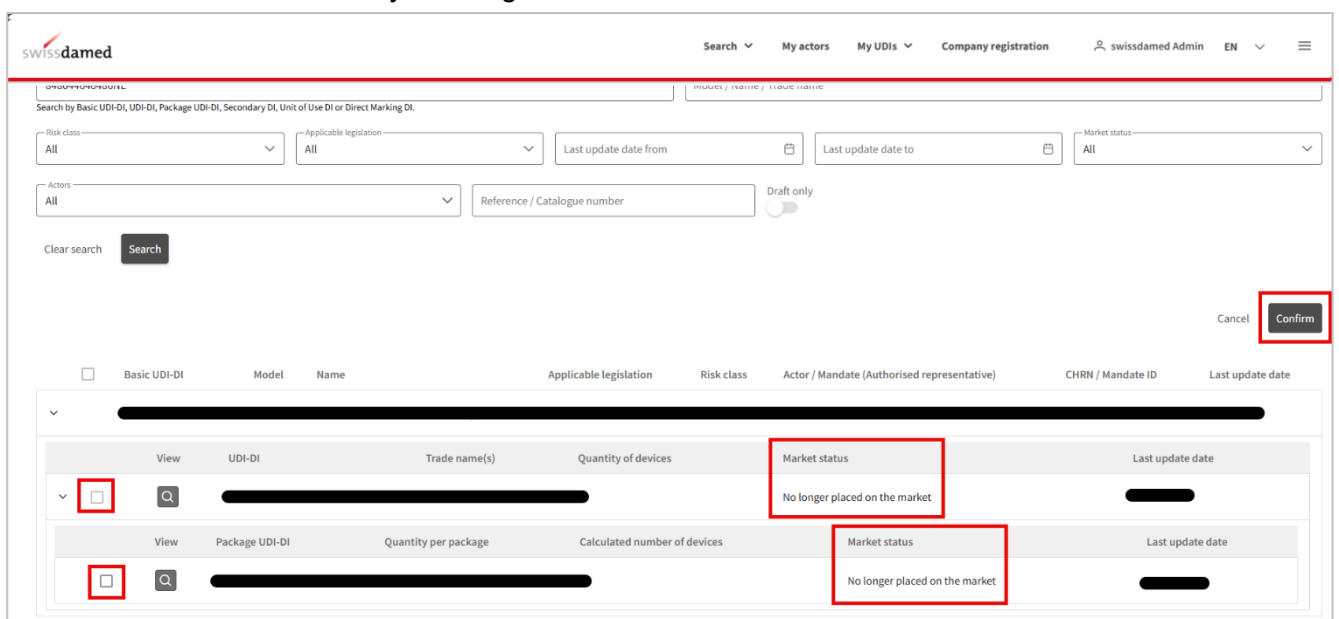
4.2 Edit status: Set status to “On the market”

If your UDIs have the market status “No longer placed on the market” you can change it to “On the market”.

- Go to the “UDI Management” tab via the “My UDIs” dropdown.
- Click on the button “Edit status” and select “Set status: On the market”.



3. Search and select the UDIs for which you want to set the market status to “On the market”. You can filter the list by entering data. Click on the button “Confirm”.



4. A pop up opens, where you need to acknowledge and confirm, that the registration of products in swissdamed may result in fees at a later date.

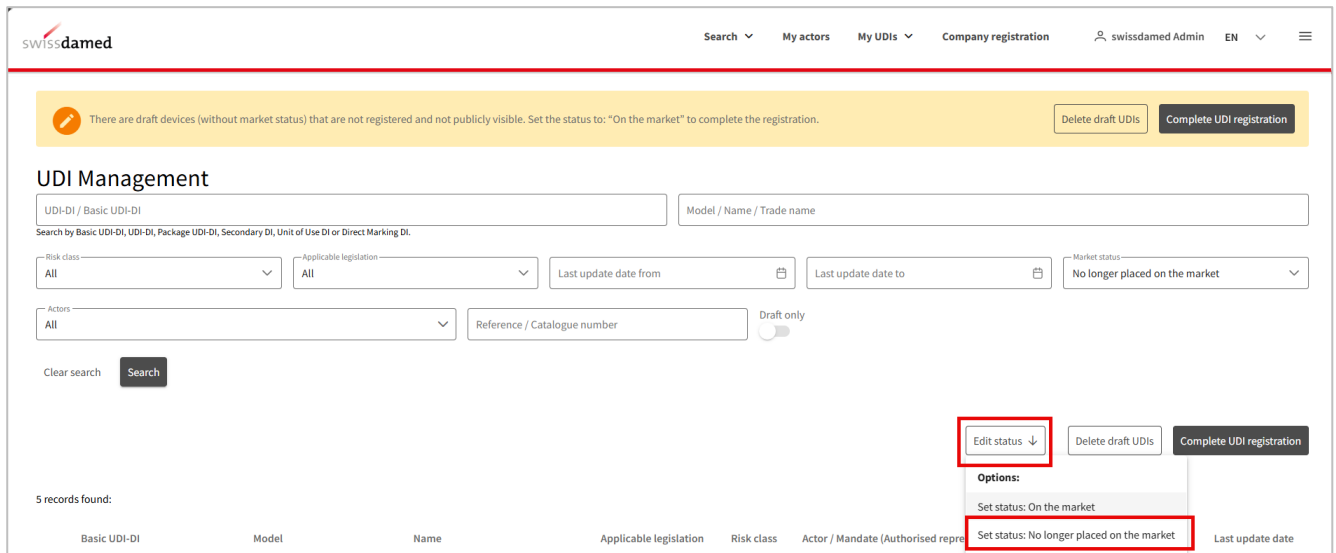
product registration site.' Below this is a checkbox labeled 'I acknowledge that the registration of products in swissdamed may result in fees at a later date.' The 'Confirm' button is highlighted with a red box." data-bbox="281 751 729 862"/>

5. The selected UDIs now have the market status “On the market” and stay publicly visible. A **new version** of the corresponding UDI is created.

4.3 Edit status: Set status to “No longer placed on the market”

If your UDIs have the market status “On the market” you can change it to “No longer placed on the market”. To be able to set the status to “No longer placed on the market”, the UDIs need to have the status “On the market” set first. It is not possible to set the status to “No longer placed on the market” for UDIs marked as “draft”.

1. Go to the “UDI Management” tab via the “My UDIs” dropdown.
2. Click on the button “Edit status” and select “Set status: No longer placed on the market”.

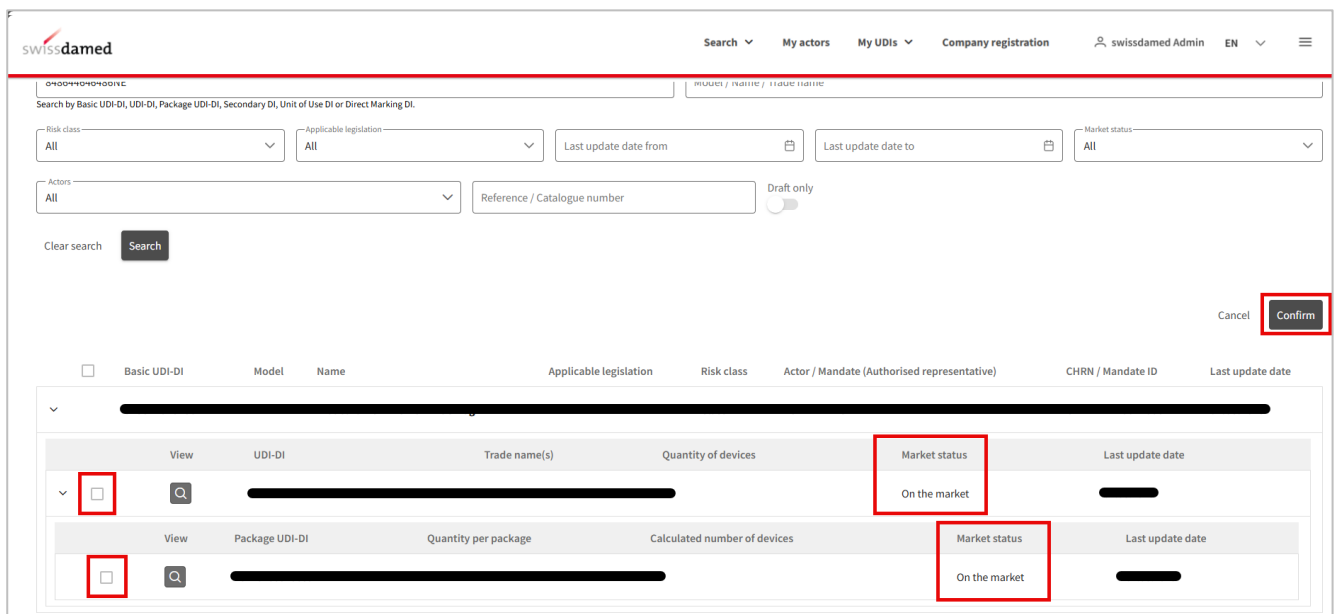


The screenshot shows the SWISSmedic UDI Management interface. At the top, there is a navigation bar with 'Search', 'My actors', 'My UDIs', 'Company registration', and 'swissdamed Admin'. Below the navigation bar, there is a yellow banner with a message: 'There are draft devices (without market status) that are not registered and not publicly visible. Set the status to: "On the market" to complete the registration.' with buttons 'Delete draft UDIs' and 'Complete UDI registration'.

The main section is titled 'UDI Management'. It contains search filters for 'UDI-DI / Basic UDI-DI', 'Model / Name / Trade name', 'Risk class', 'Applicable legislation', 'Last update date from', 'Last update date to', 'Market status', 'Actors', and 'Reference / Catalogue number'. A 'Draft only' toggle is also present. A 'Search' button is located below the filters.

Below the search filters, there is a table with 5 records found. The table has columns: 'Basic UDI-DI', 'Model', 'Name', 'Applicable legislation', 'Risk class', 'Actor / Mandate (Authorised representative)', and 'Last update date'. A dropdown menu is open next to the 'Edit status' button, showing options: 'Set status: On the market' and 'Set status: No longer placed on the market'.

3. Search and select the UDIs for which you want to set the market status to “No longer placed on the market”. You can filter the list by entering data. Click on the button “Confirm”.



The screenshot shows the SWISSmedic UDI Management interface. It contains the same search filters as the previous screenshot. Below the search filters, there is a table with 5 records found. The table has columns: 'Basic UDI-DI', 'Model', 'Name', 'Applicable legislation', 'Risk class', 'Actor / Mandate (Authorised representative)', 'CHRN / Mandate ID', and 'Last update date'. A dropdown menu is open next to the 'Edit status' button, showing options: 'Set status: On the market' and 'Set status: No longer placed on the market'.

Below the table, there is a 'Confirm' button. The table shows two rows of data. The first row has a checkbox selected, and the second row has a checkbox selected. The 'Market status' column for both rows is 'On the market'.

4. The selected UDIs now have the market status “No longer placed on the market” and stay publicly visible. A **new version** of the corresponding UDI is created.

5 Versioning of UDI

If updates were made, the versions of the UDI are visible in the device / system or procedure pack details.

1. Open the “UDI Management” tab via the “My UDIs” dropdown.
2. Search for the UDI
3. Open the device / system or procedure pack details by clicking on the magnifying glass in front of the Basic UDI-DI, the UDI-DI or, if available, the Package UDI-DI.

1 records found:

Basic UDI-DI	Model	Name	Applicable legislation	Risk class	Actor / Mandate (Authorised representative)	CHRN / Mandate ID	Last update date
View	UDI-DI	Trade name(s)	Quantity of devices	Market status	Last update date		
View	Package UDI-DI	Quantity per package	Calculated number of devices	Market status	Last update date		

4. Click on the “View older version” button and select the date of the version that you want to view.

swissdamed

Search My actors My UDIs Company registration swissdamed Admin EN

UDI Management > UDI details

UDI details

Basic UDI-DI details

Certificate details

UDI-DI details

Package UDI-DI details

Product original manufacturer details

View older version

Back to UDI overview

Manufacturer (MF)

Company name

Actor location

Actor details of manufacturer

Last update date

Applicable legislation

Basic UDI-DI / Issuing entity

System or procedure pack which is a device in itself

Special device type

Risk class

Implantable

Is the device a suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip or connector?

Measuring function

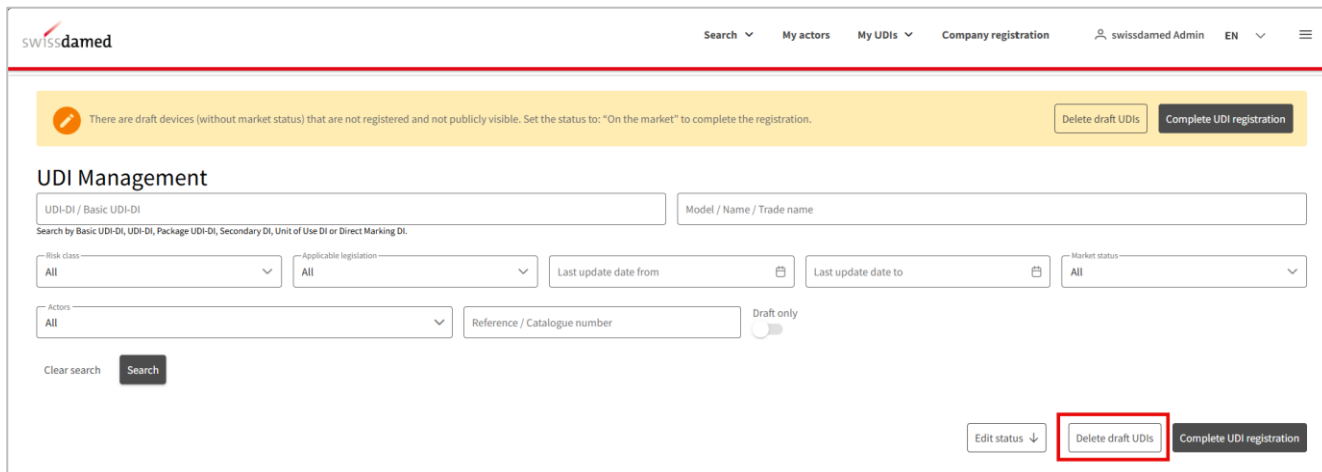
5. A new tab opens with the version / last update date selected.

Note: This is only possible for UDIs with a set market status. UDIs marked as “draft” do not have versions.

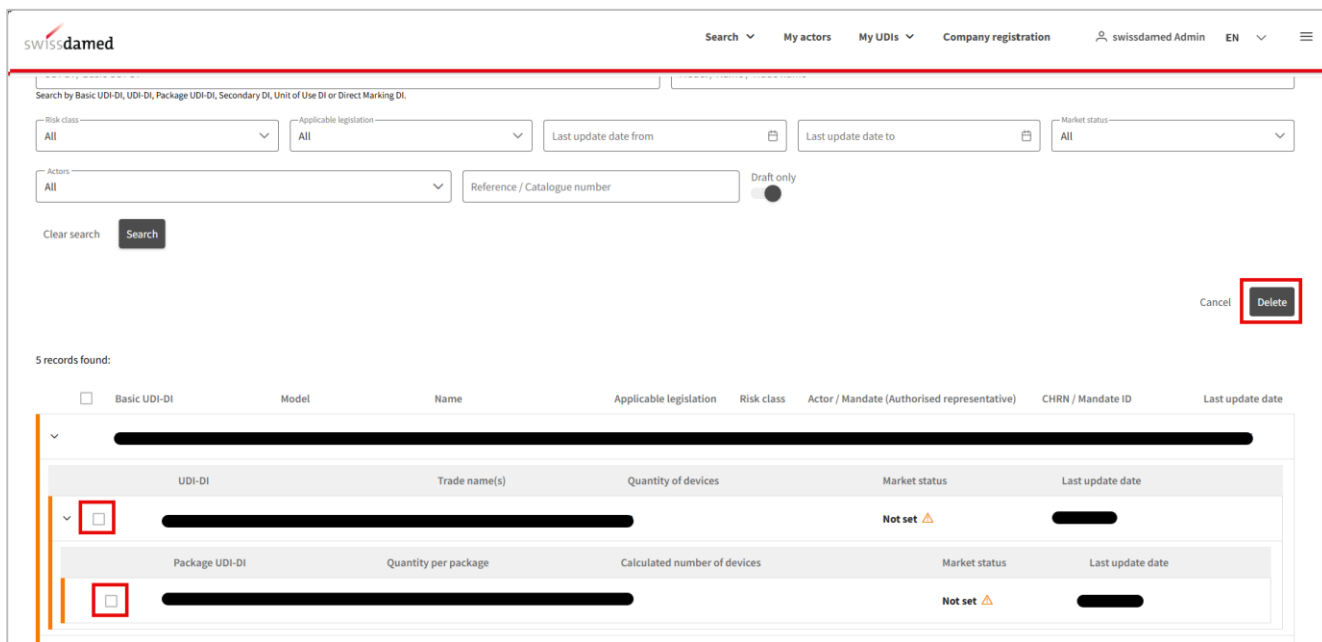
6 Delete draft UDIs

If there are UDIs uploaded by the actor that are still marked as “draft” and are not intended to be registered, the “UDI Editor” can delete them. It is **not** possible to delete UDIs with a market status assigned.

1. Open the “UDI Management” tab via the “My UDIs” dropdown.
2. Click on the button “Delete draft UDIs”.



3. Select the UDIs that you want to delete. You can filter the list by entering data. As default, the filter “Draft only” is applied, therefore only UDIs without a market status are shown.



4. Confirm the deletion by clicking on the button “Delete”.
5. The selected UDIs are deleted.

7 Transfer UDIs by transferring a mandate

If a mandate is transferred and it has registered UDIs attached, both the mandate and the UDIs will be transferred to the new Swiss authorised representative.

The procedure for transferring a mandate is described in the user manual [BW630_40_001e_HB Handbook swissdamed User Guide Actors](#).

8 Change history

Version	Change	sig
1.0	Initial version	stj