Handbook

swissdamed User Guide UDI Devices Module

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List of contents

1 Introduction

This user guide describes how manufacturers (including persons who assemble systems or procedure packs) and their authorised representatives are able to upload, register and manage 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 actors are described in the user manual BW630_40_001e_HB Handbook swissdamed User Guide Actors.

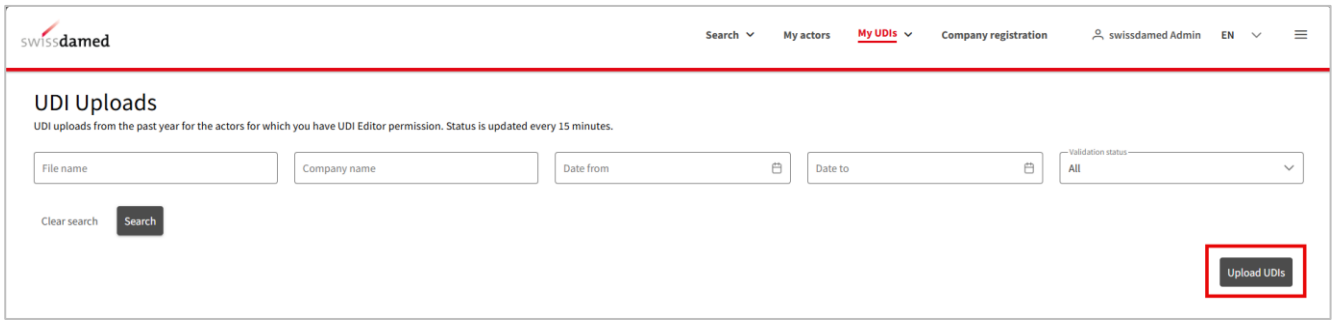
3 Upload UDIs via XML

After an approved registration of the actor, 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.

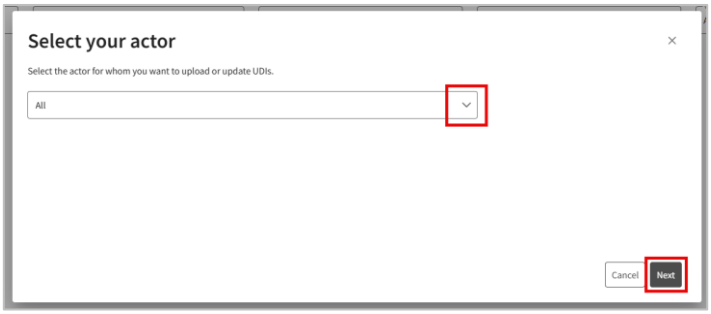
Users with the "UDI Editor" user profile on a manufacturer (MF), person who assembles systems or procedure packs (PR), MF mandate or PR mandate are able to upload UDIs. There are two ways to upload UDIs. One is via the "UDI Upload" / "UDI Management" tab (described in chapter 3.1), the other one is directly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

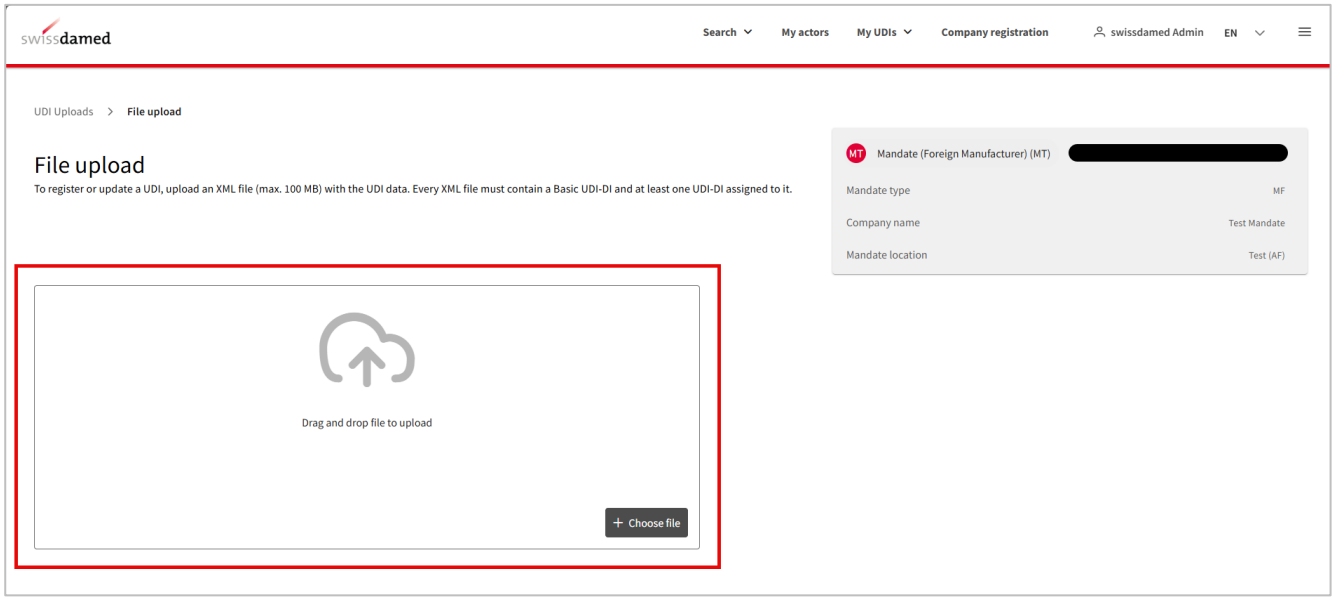


2. Select the actor or mandate from the dropdown for which you want to upload UDIs. There are only actors / mandates shown for which you have the “UDI Editor” user profile. Click “Next” to move on with the upload.

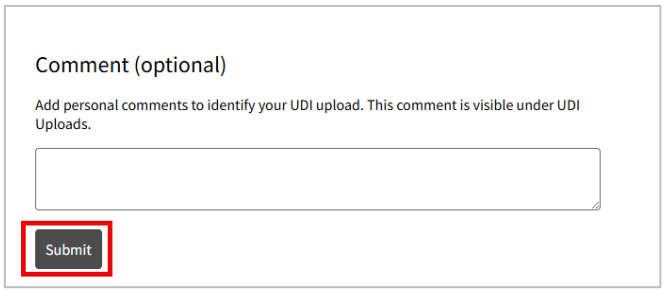


Note: If there is only one actor / mandate for which you have the “UDI Editor” user profile, no dropdown is shown, you get redirected directly to the XML Upload.

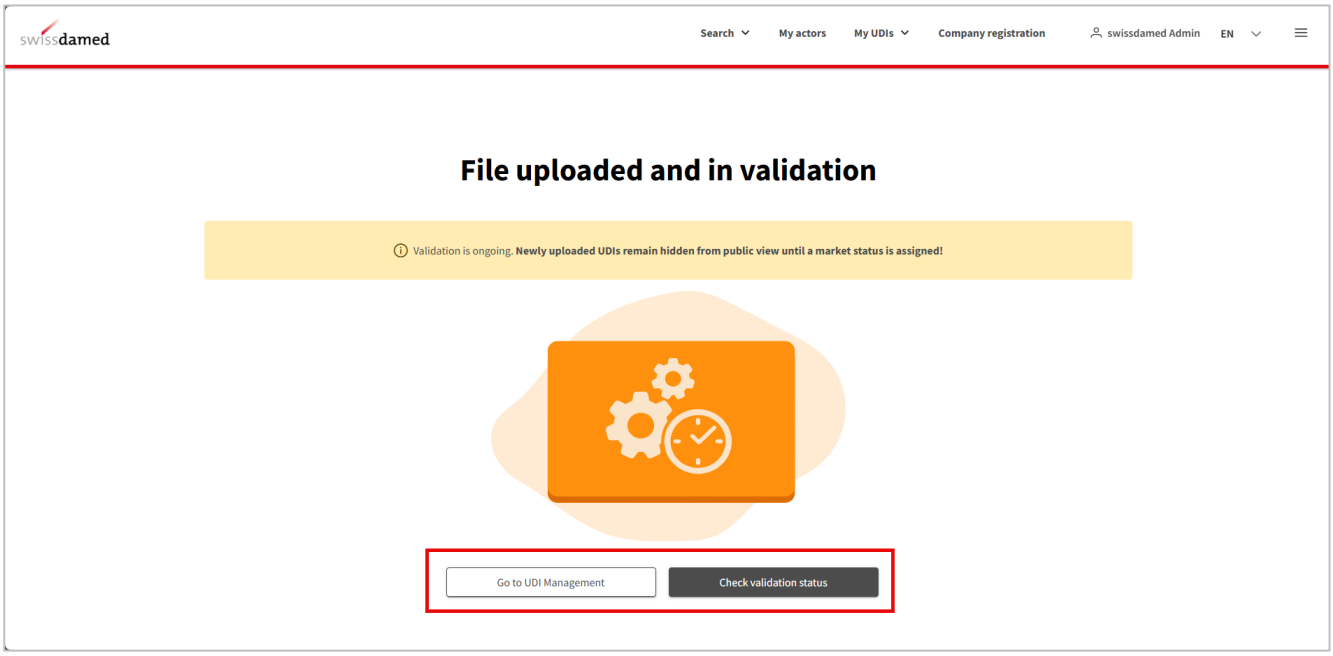
3. Enter the XML via drag and drop or click on the button “+ Choose file”.



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”.



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”.

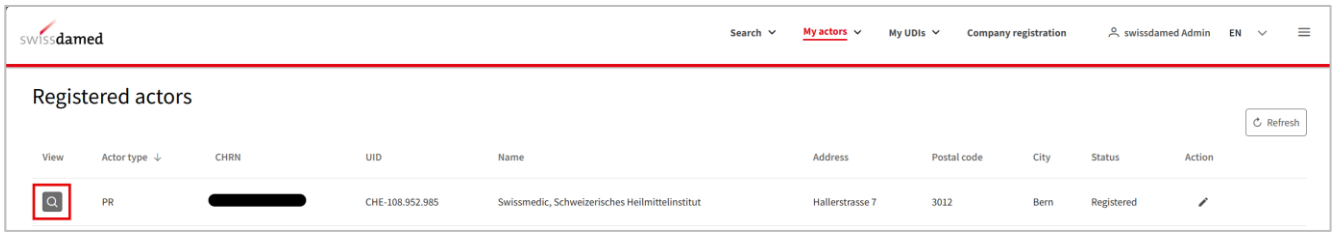


6. By clicking on “Check validation status”, you will get redirected to the “UDI Uploads” tab. There you can see the outcome of the validation (business rules check). The validation may take some time. A page refresh is required to see the result of the validation.

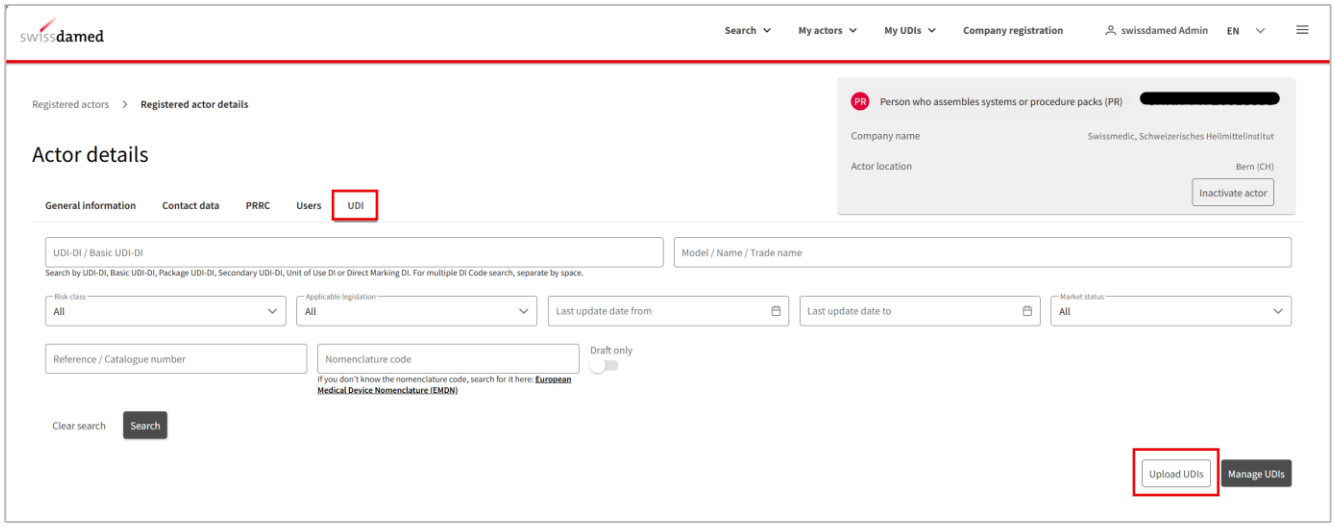
Note: An SPP can only be registered by PR actors / mandates.

3.2 Upload via registered actor / mandate

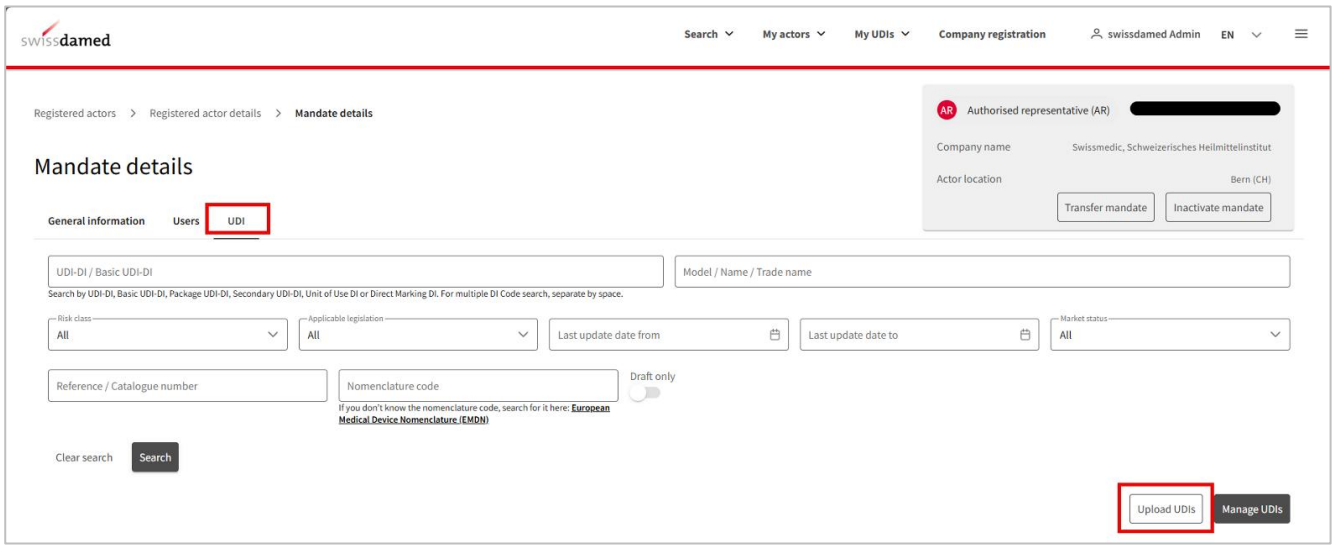
1. Go to the “Registered actors” tab via the “My actors” dropdown.
2. Open the detail view of the actor for which you want to upload UDIs by clicking on the magnifying glass symbol.



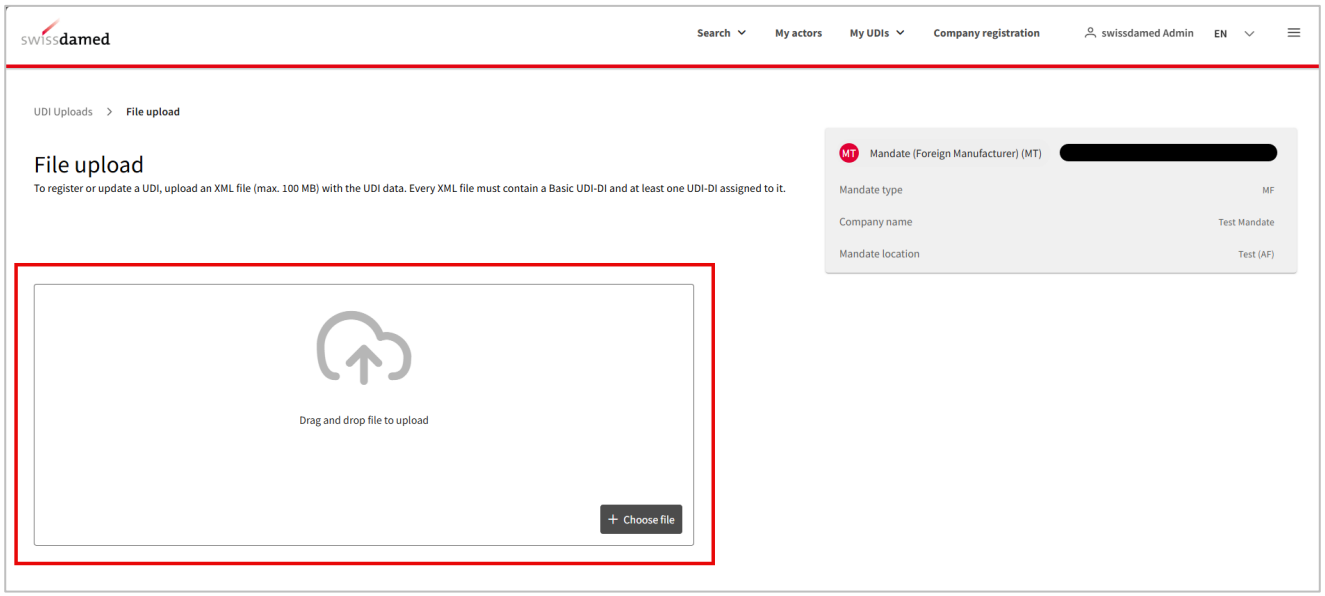
3. If your actor is a manufacturer (MF) or a person who assembles systems or procedure packs (PR) you can see the “UDI” tab directly in the actor details.



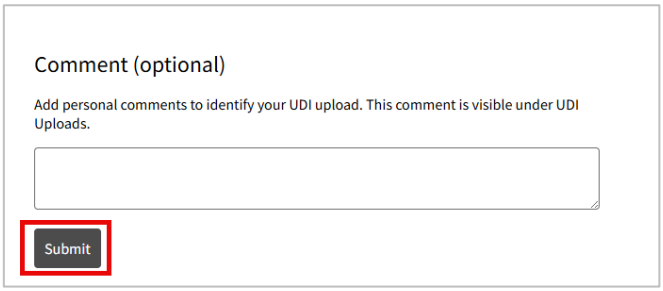
4. If you want to upload UDIs on a mandate, open the “Mandates” tab in the actor details of your Swiss authorised representative (AR). Open the mandate details by clicking on the magnifying glass symbol. Go to the “UDI” tab.



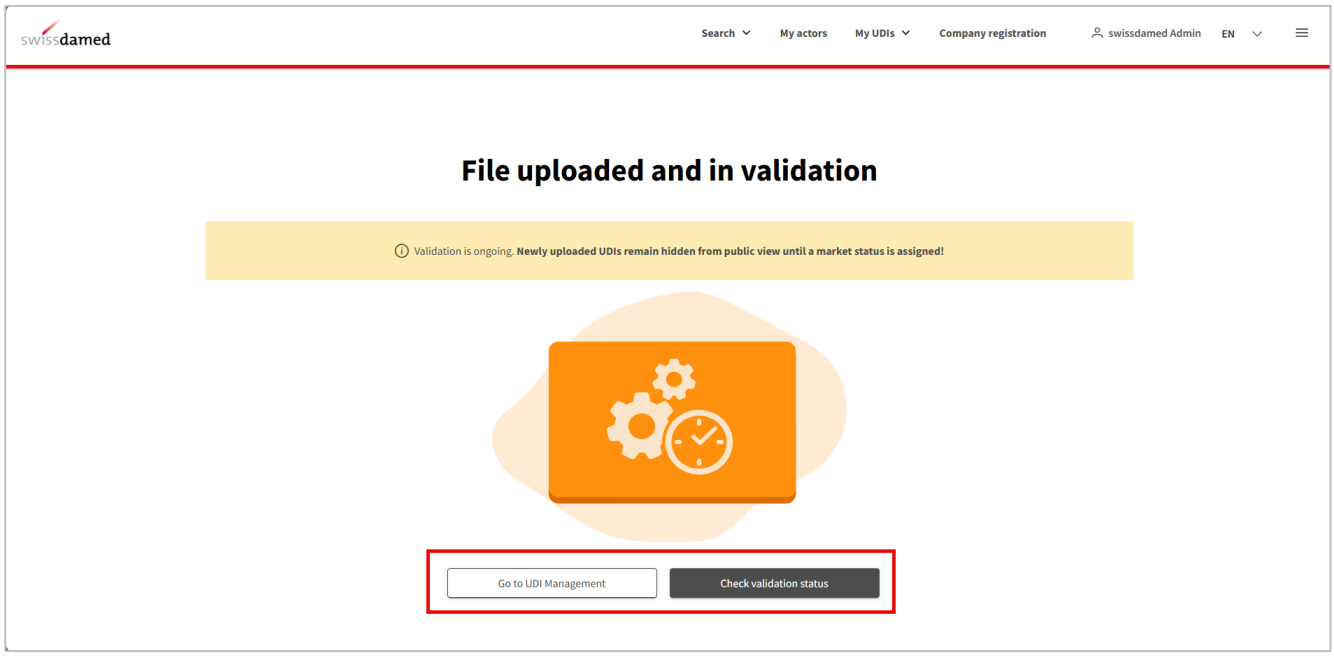
5. Click on the button “Upload UDIs”.
6. Enter the XML via drag and drop or click on the button “+ Choose file”.



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.



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”.



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.

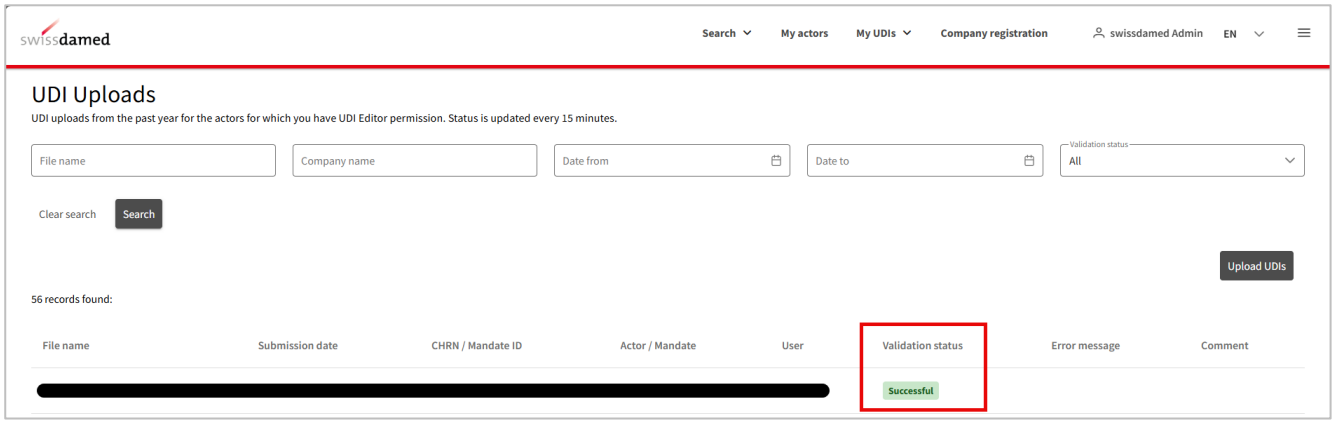
Note: An SPP can only be registered by PR actors / mandates.

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.

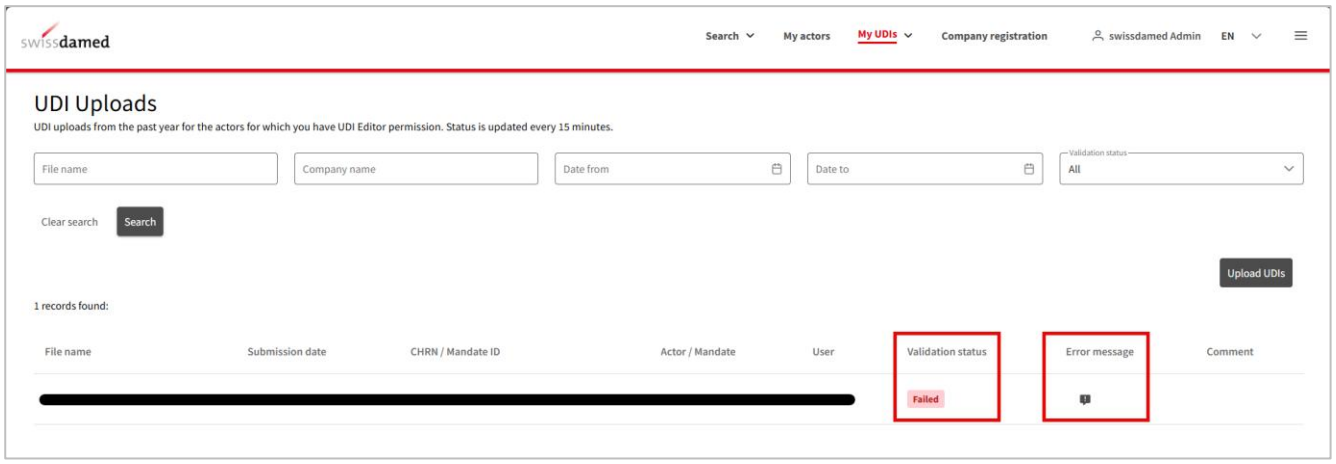


The uploaded UDIs are now listed under the “UDI Management” tab. They are marked as “draft” and therefore not publicly visible. For instructions on how to register the UDIs and set the market status,

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.

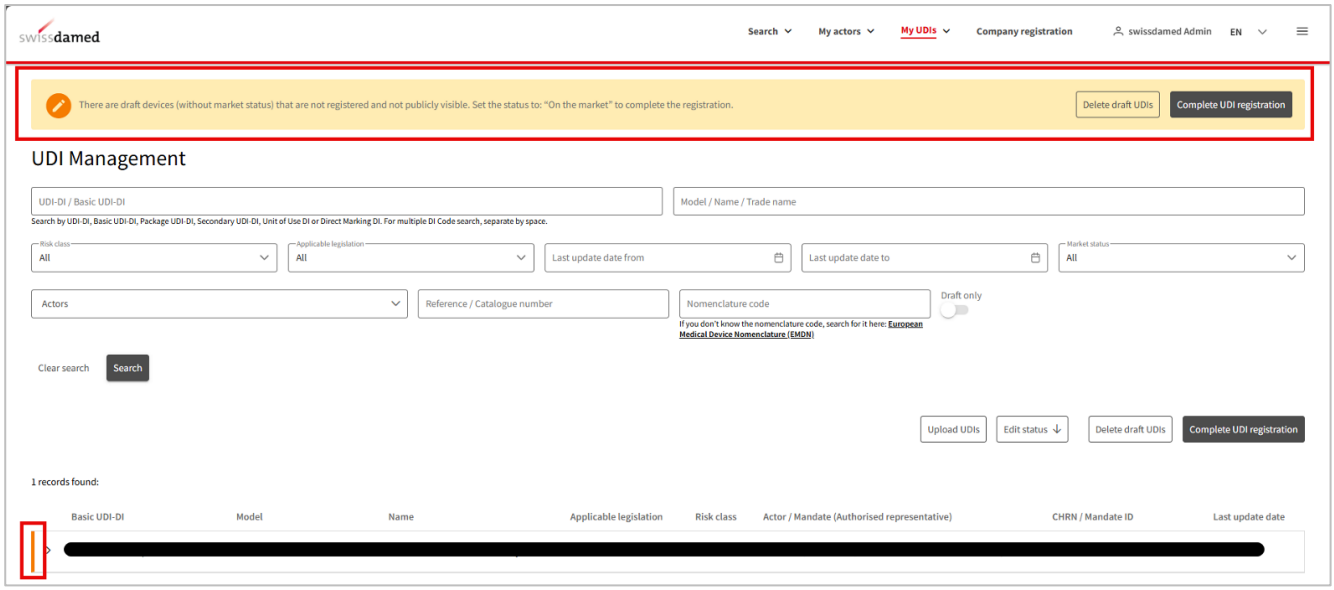
Respect the non-updatable fields and further relevant business rules. An overview of the non-updatable fields can be found in the Data dictionary UDI Devices.

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 market status set.

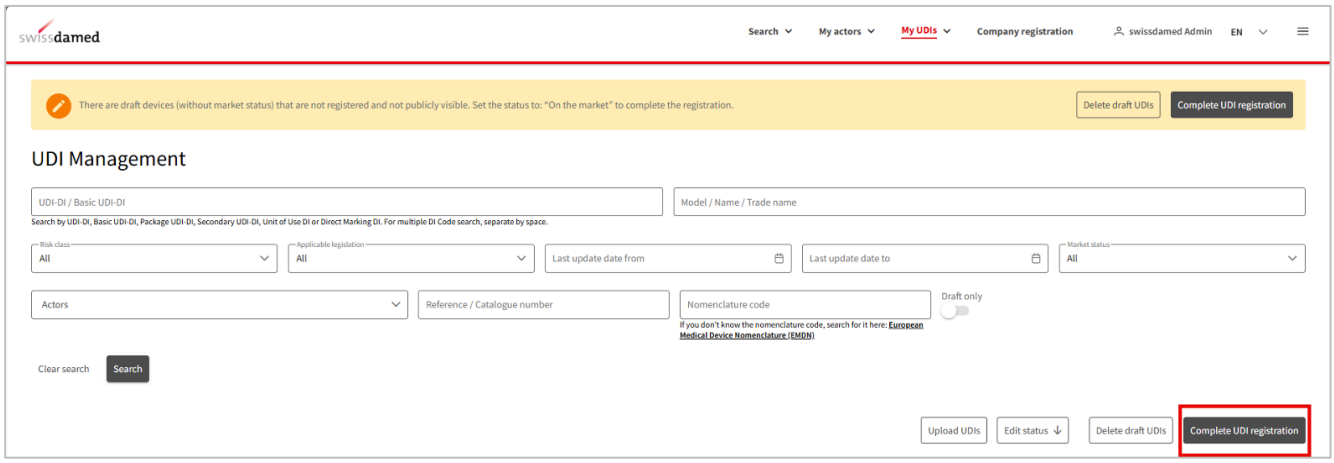


The “UDI Editor” can individually assign a market status to UDI-DIs and Package UDI-DIs flagged as “draft”.

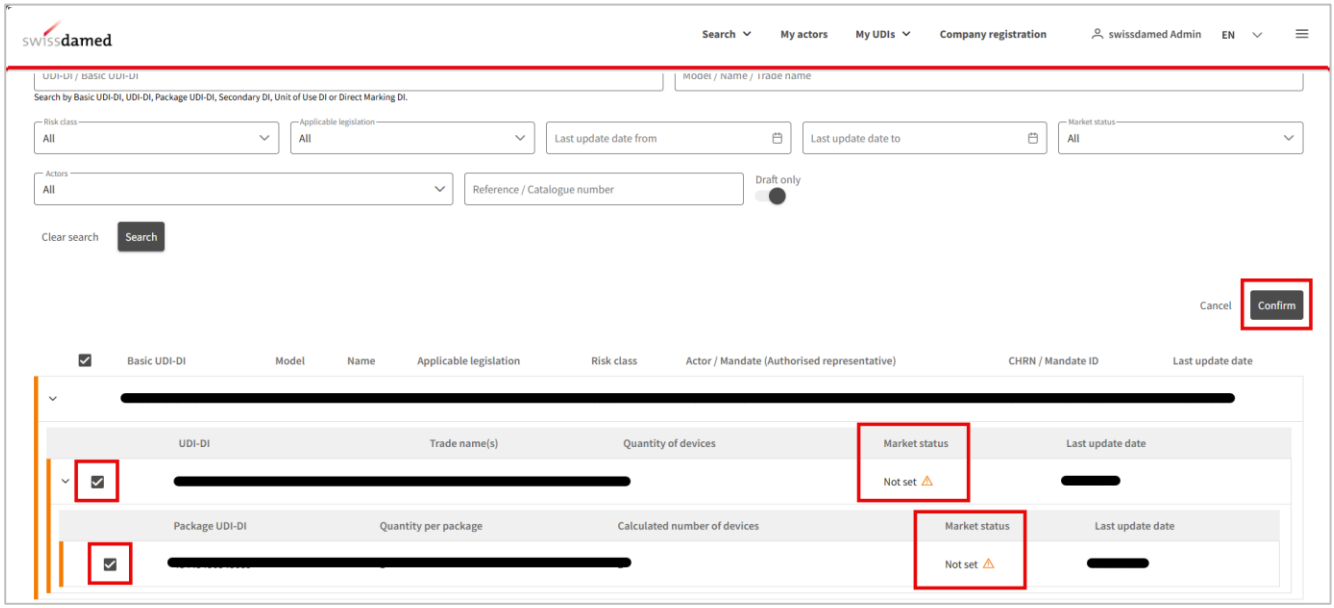
Note: UDIs marked as “draft” will not cause any fees.

4.1 Complete UDI registration

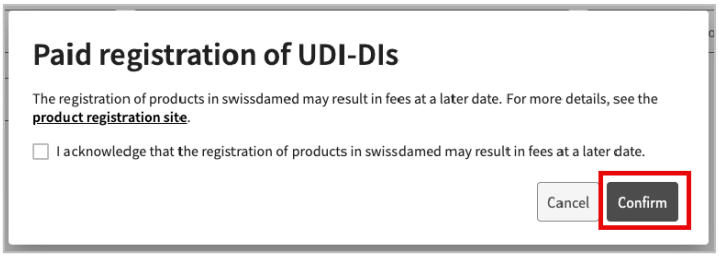
1. Go to the “UDI Management” tab via the “My UDIs” dropdown.
2. Click on the button “Complete UDI registration”.



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”.



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.

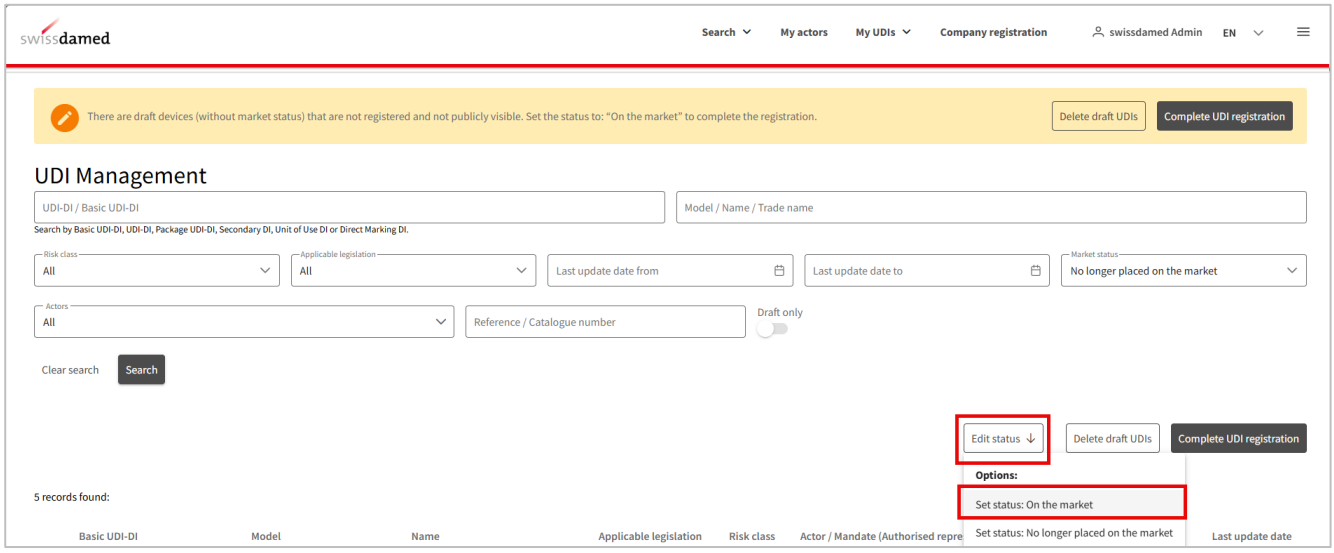


5. The selected UDIs now have the market status “On the market” and are therefore publicly visible. The **initial version** of the corresponding UDI is created.

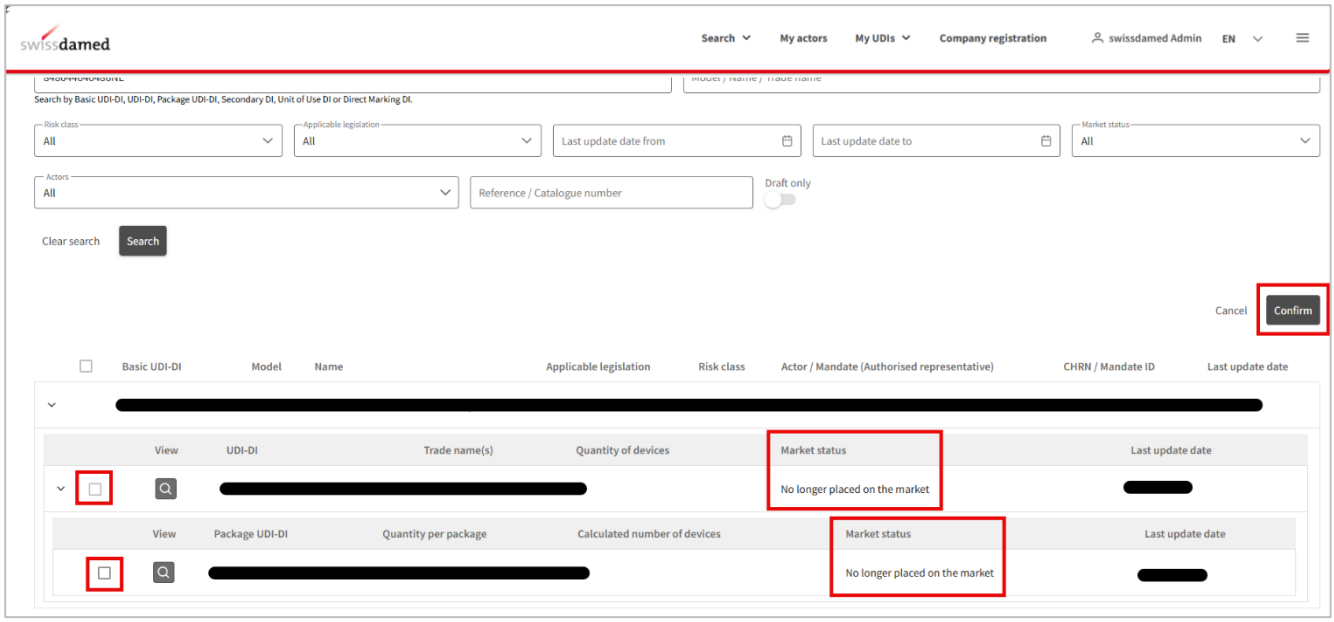
4.2 Edit status: Set status to “On the market”

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

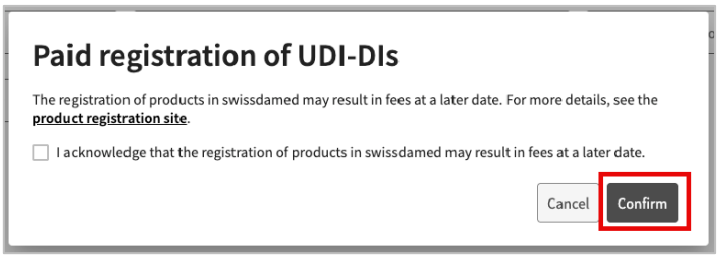
1. Go to the “UDI Management” tab via the “My UDIs” dropdown.
2. Click on the button “Edit status” and select “Set status: On the market”.



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.

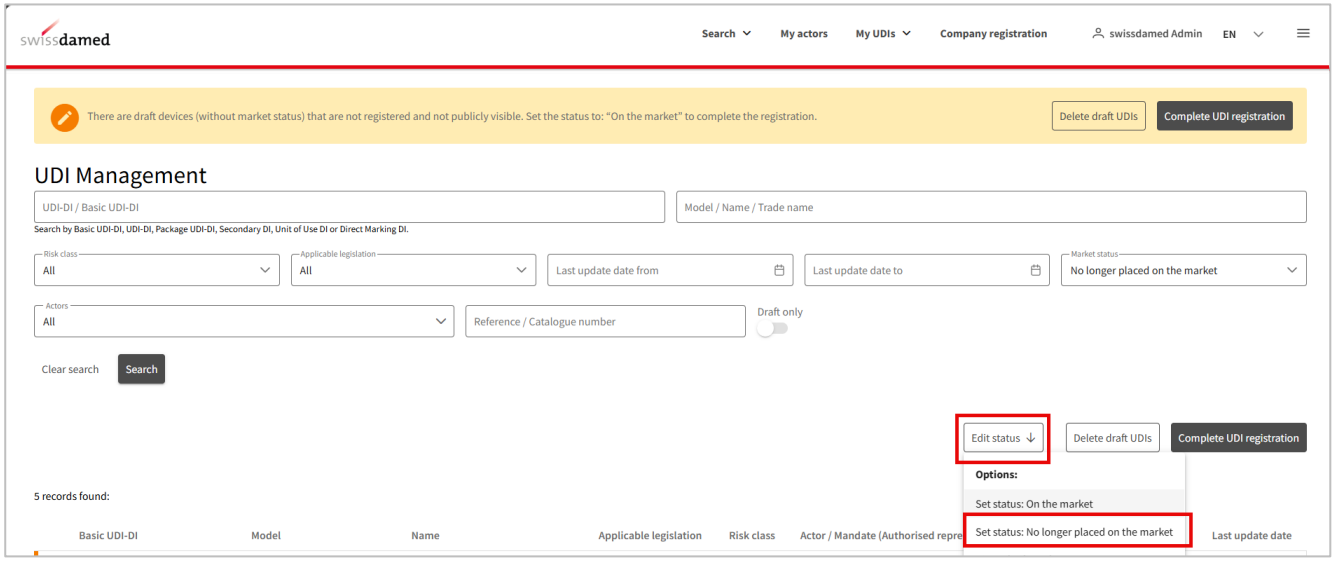


5. The selected UDIs now have the market status “On the market” and stay publicly visible. A **new version** of the corresponding UDI is created.

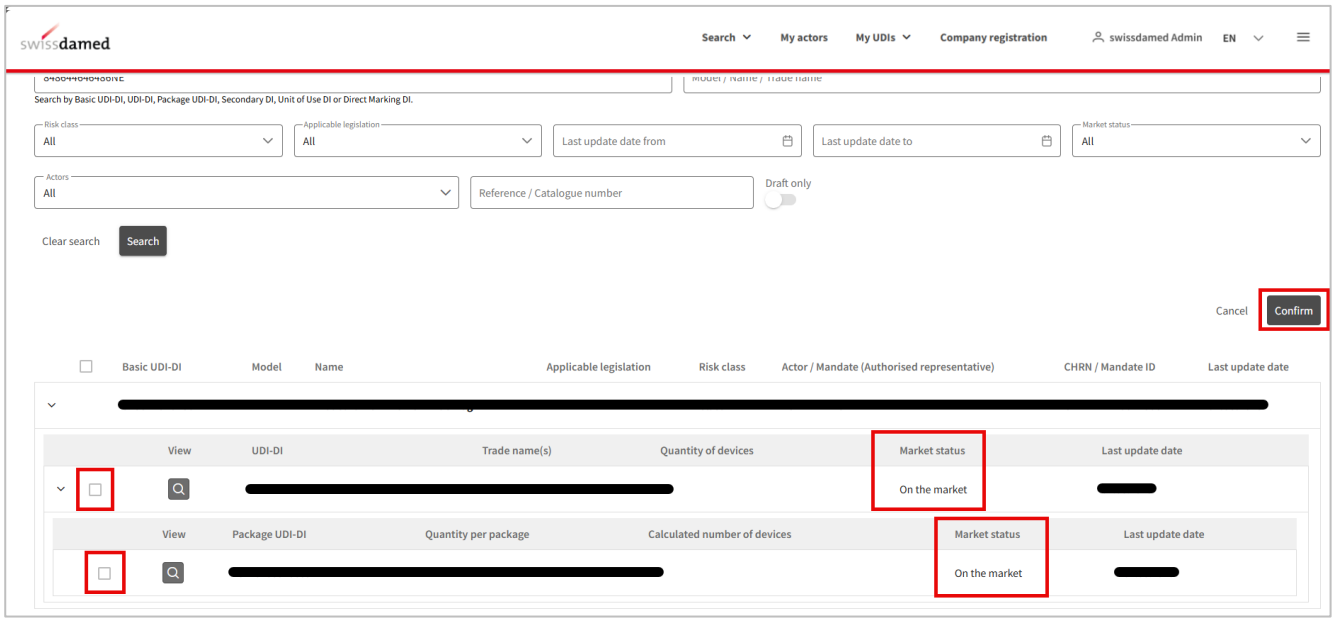
4.3 Edit status: Set status to “No longer placed on the market”

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”.



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”.

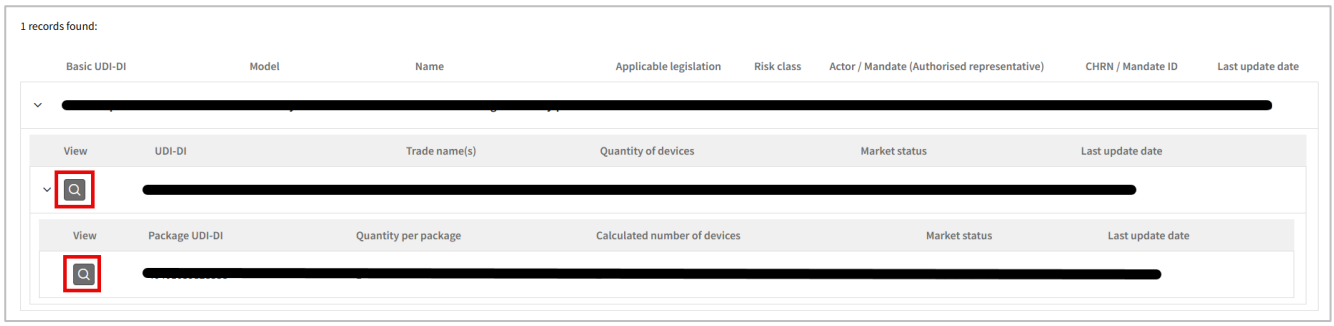


4. The selected UDIs now have the market status “No longer placed on the market” and stay publicly visible. A **new version** of the corresponding UDI is created.

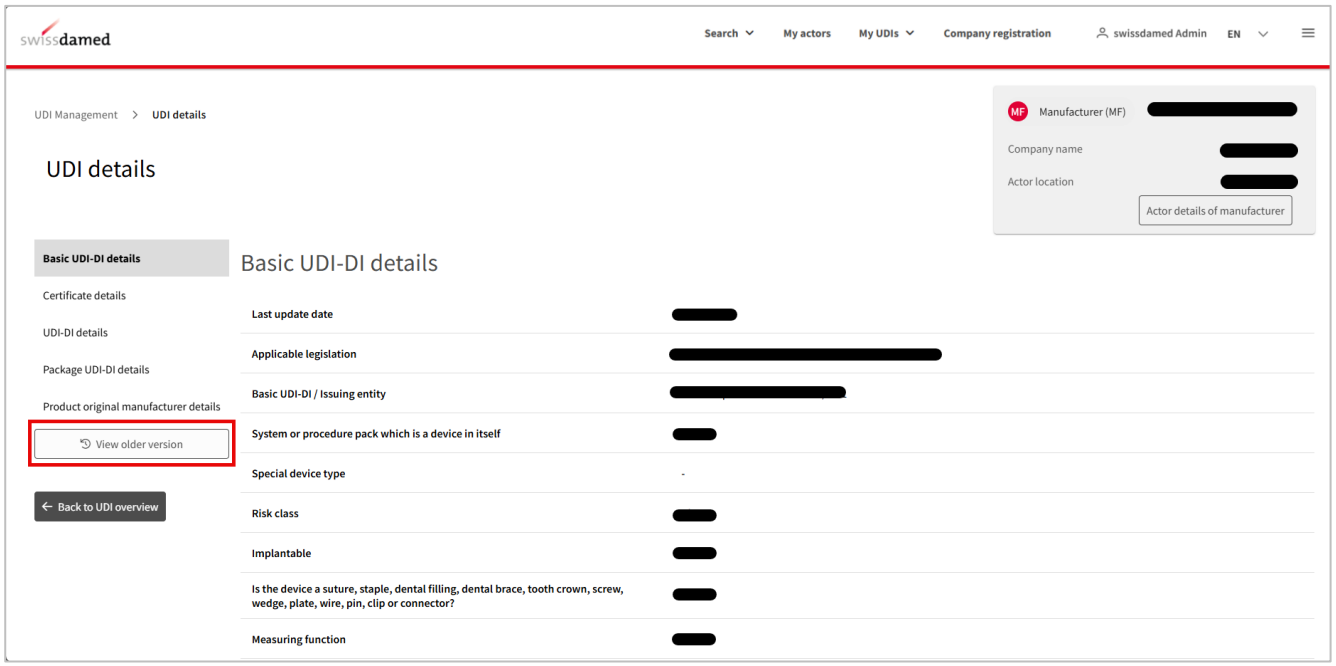
5 Versioning of UDI

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.



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



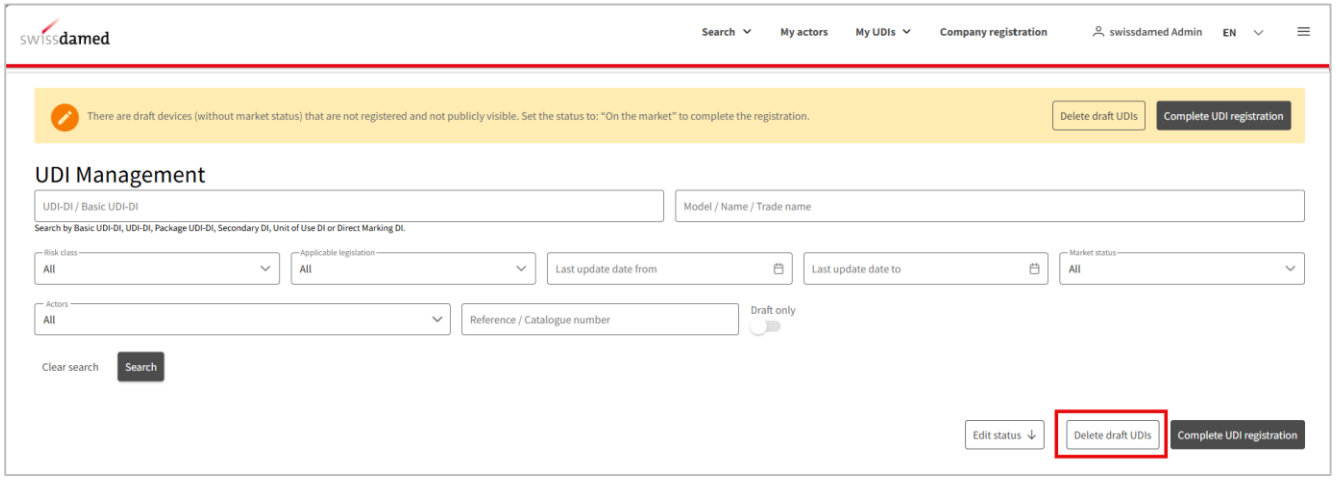
5. A new tab opens with the version / last update date selected.

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

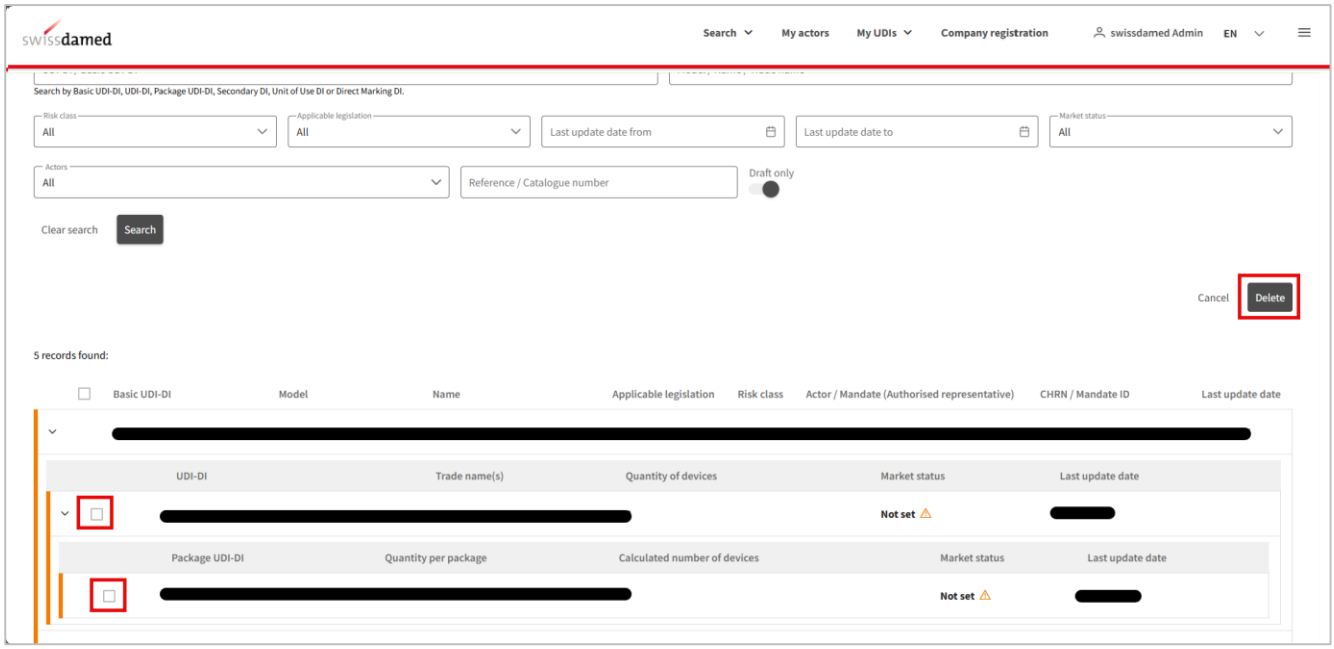
6 Delete draft UDIs

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.

Note: 30 days after the last update of an element in draft status, it will be deleted automatically. After 20 days, a reminder email will be sent to the UDI Editor(s) of the affected actor or mandate.

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.

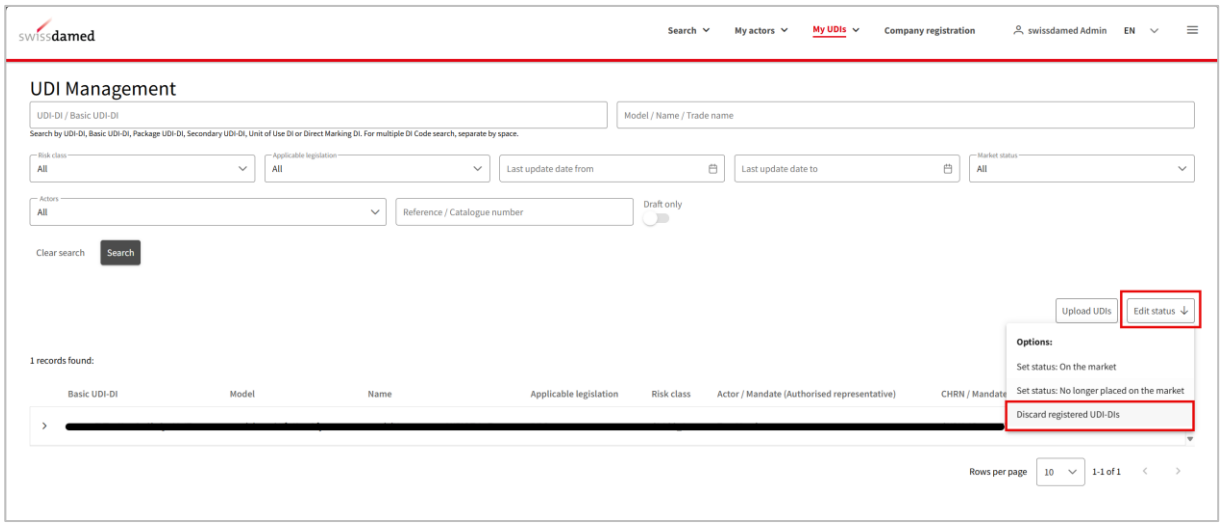
The procedure for transferring a mandate is described in the user manual BW630_40_001e_HB Handbook swissdamed User Guide Actors.

8 Discard UDIs

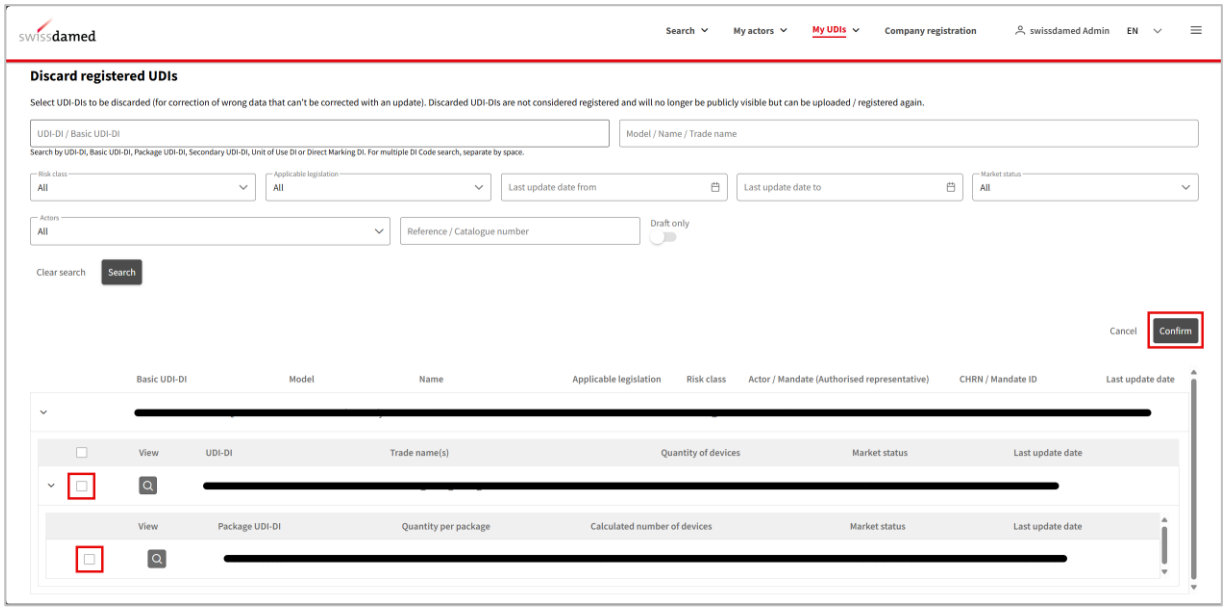
UDI-DIs are only allowed to be discarded in case of incorrect data that can't be corrected by updating because of business rules. Discarded items are deleted from the system, are no longer visible in the public search and can be newly registered.

Only registered UDI-DIs can be selected. Basic UDI-DIs will be discarded by discarding all their UDI-DIs. Package UDI-DIs are always included when discarding the UDI-DI. A UDI-DI can’t be discarded if it is in draft status or has Package UDI-DIs in draft status. Only UDI-DIs where the market status was set for both the UDI-DI and all its Package UDI-DIs can be discarded.

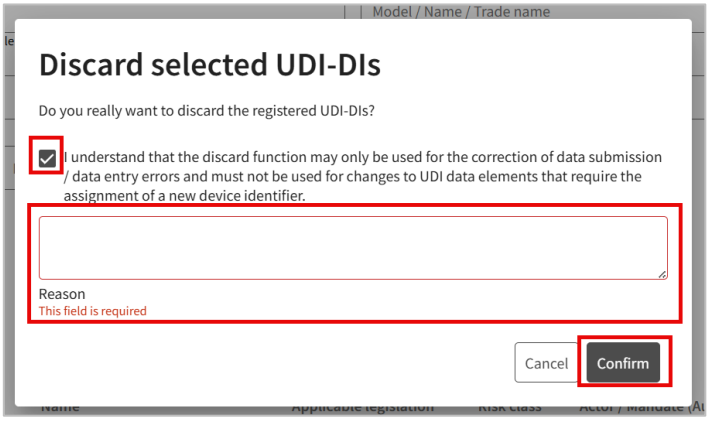
1. Open the “UDI Management” tab via the “My UDIs” dropdown.
2. Click on the button “Edit status”, then on “Discard registered UDI-DIs”



3. Select the UDIs that you want to discard. You can filter the list by entering data.



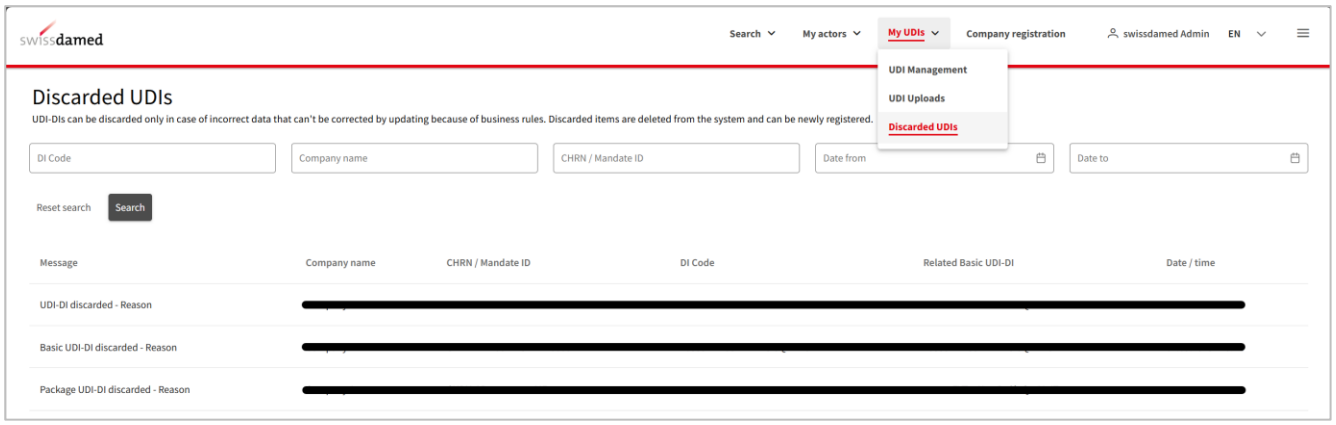
4. Confirm by clicking on the button “Confirm”.
5. A pop up opens, where you need to acknowledge and confirm and enter a reason.



6. The selected UDIs are discarded.

8.1 Discarded UDIs

Under “Discarded UDIs” in the “My UDIs” dropdown, you will find an overview of all discarded UDIs. You can filter the list by entering search criteria. The discarded UDIs in this list are visible only to the UDI Editor of the respective actor or mandate.



9 Machine-to-Machine (M2M) registration of devices

The technical documentation containing all information for implementing M2M registration of devices in swissdamed is available here: BW630_40_810e_PU swissdamed Machine-to-Machine REST API_DocumentationAPI_Documentation

Third-party Machine-to-Machine providers must be onboarded via the respective actors or mandates for whom they are submitting data to swissdamed.

10 Online editor – Create / manage UDIs manually

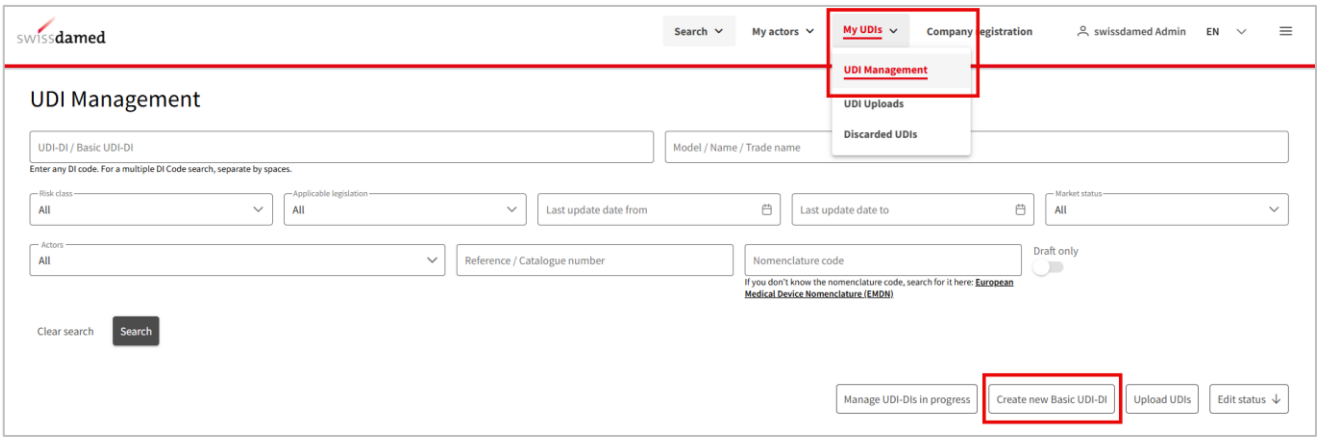
The online editor provides an interface for the manual entry of Basic UDI-DI and UDI-DI information, as well as for editing and updating existing UDI records already stored in swissdamed.

The online editor is accessible to all users who have been granted the UDI Editor permissions within a manufacturer (MF), a person who assembles systems or procedure packs (PR), or a MF/PR mandate.

The applied business rules can be found in the business rules document. The data dictionary specifies which data elements are mandatory for swissdamed, which elements can be updated and what type of data is required for each specific data element.

10.1 Open the online editor

1. Log in to go via the “My UDIs” dropdown to “UDI Management”. Click on the button “Create new Basic UDI-DI”.



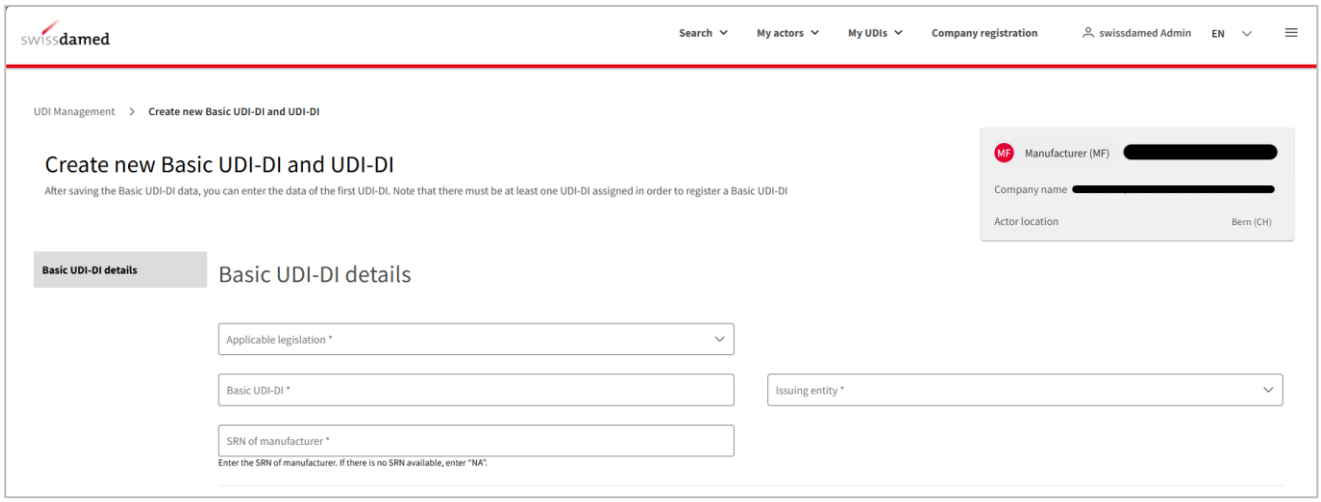
2. Select the actor or mandate from the dropdown for which you want to register UDIs. Only actors / mandates for which you have the “UDI Editor” user profile are shown. Click “Next” to move on with the registration.

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 online editor.

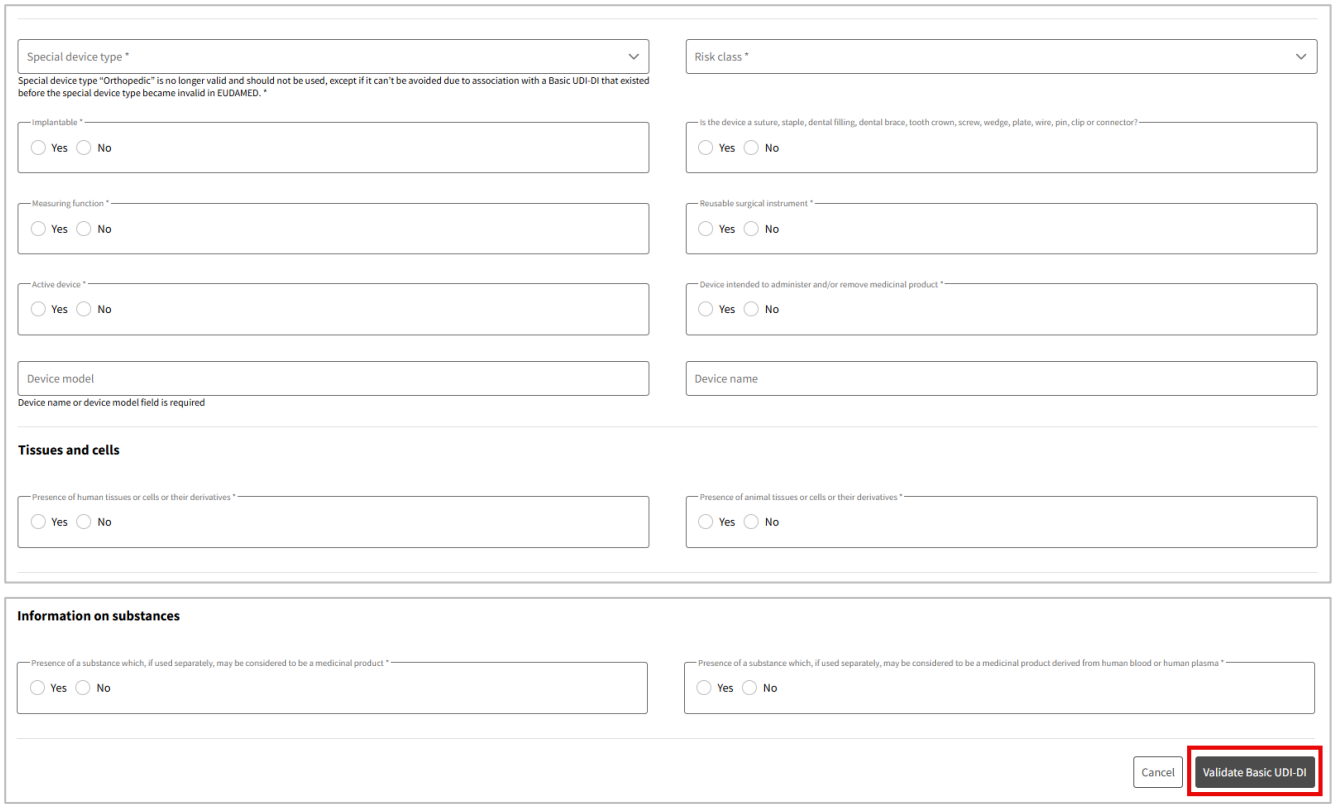
10.2 Enter Basic UDI-DI details

Note: The following steps show the process for an MDR, Class I device. This is only used as an example.

1. Select the applicable legislation. After selecting the applicable legislation, the input fields expand accordingly.
2. Enter the Basic UDI-DI. The format of the Basic UDI-DI structure will be checked against the format structure according to the selected issuing entity.
3. Select the issuing entity.
4. Enter the SRN of the manufacturer. For companies that are not registered in EUDAMED, and therefore don't have an SRN, “NA” can be entered. The SRN field is a non-updatable field and can therefore not be changed after submission.



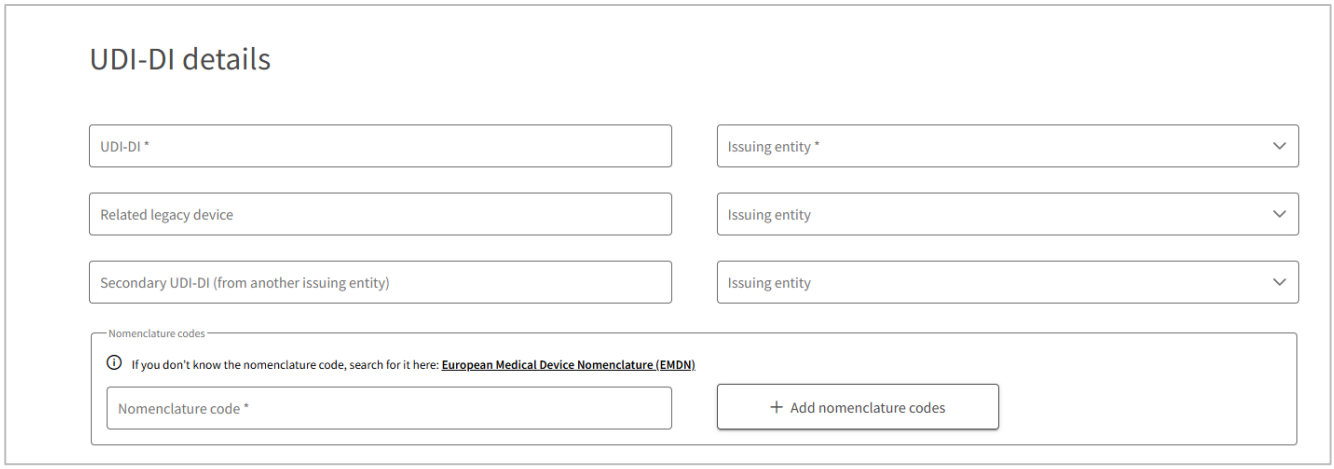
5. Complete the remaining information for the Basic UDI-DI (fields marked with a “*” are required). Click on “Validate Basic UDI-DI”.



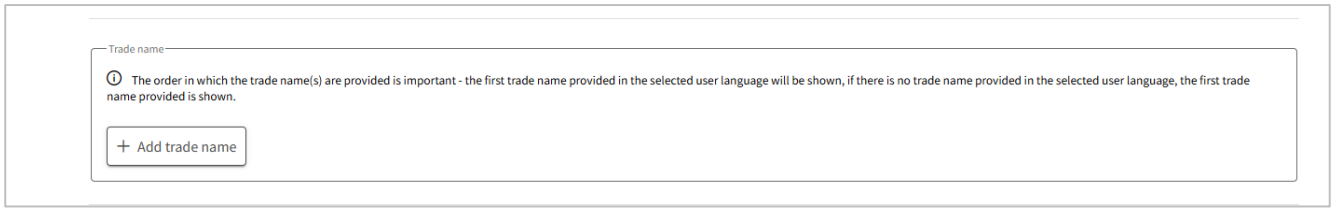
After clicking “Validate Basic UDI-DI,” the entered Basic UDI-DI data is validated. If required fields are missing or if any data is entered in the wrong format, an error message is displayed. If validation is successful, a success message is shown and the fields for the UDI-DI data appear.

10.3 Enter UDI-DI details

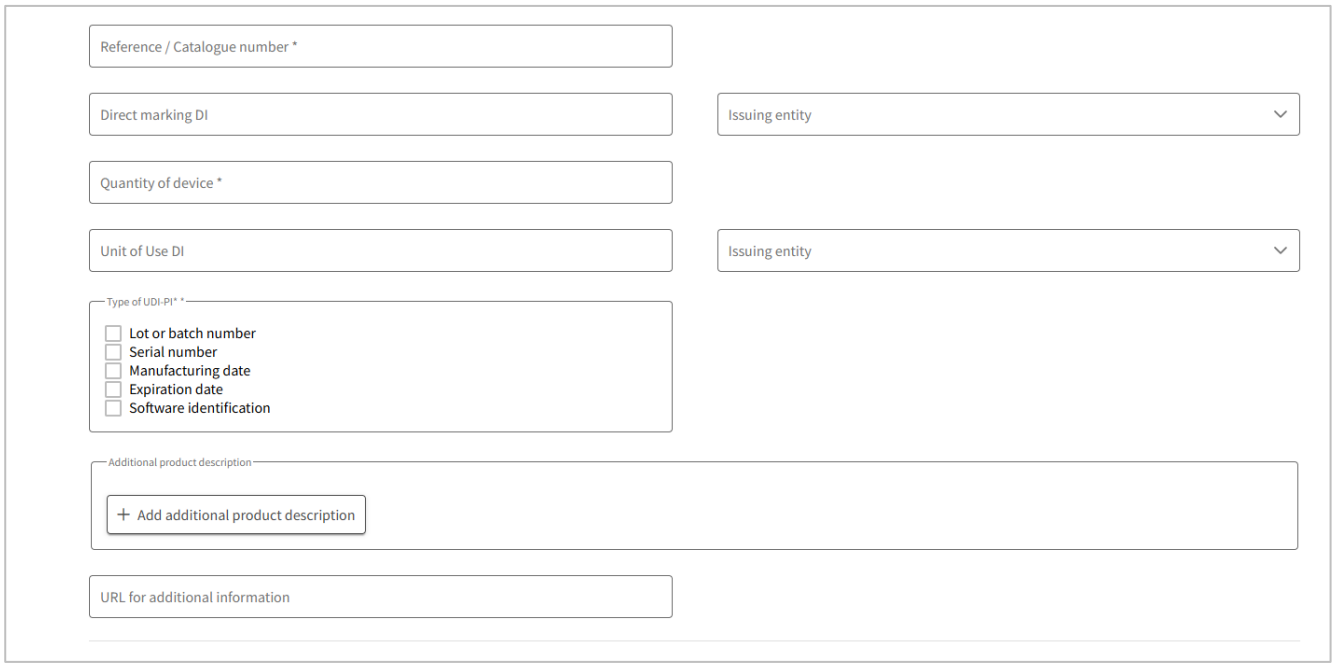
1. Enter the UDI-DI. The format of the UDI-DI structure will be checked against the format structure according to the selected issuing entity.
2. Enter the nomenclature code of the UDI-DI. If you don't know the nomenclature code, search for it here: European Medical Device Nomenclature (EMDN).
3. Complete the other fields if applicable.



4. Enter a trade name if applicable. The order in which the trade names are provided is important - the first trade name provided in the selected user language will be shown in the search results. If no trade name is provided in the selected user language, the first trade name provided is shown. Only trade names with the languages DE, EN, FR, IT and ALL can be saved in swissdamed. ALL can be used if the trade name is a name that is used identically in every language.

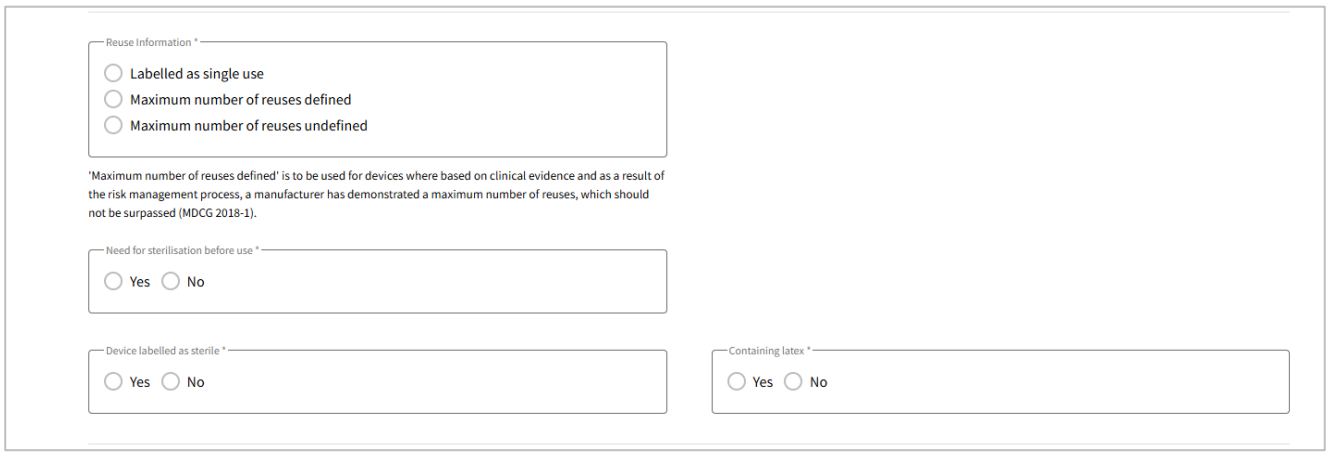


5. Enter the reference / catalogue number.
6. Enter the quantity of device.
7. Enter the type of UDI-PI by selecting the corresponding checkbox.
8. Complete the other fields if applicable.



9. Add clinical sizes if applicable.

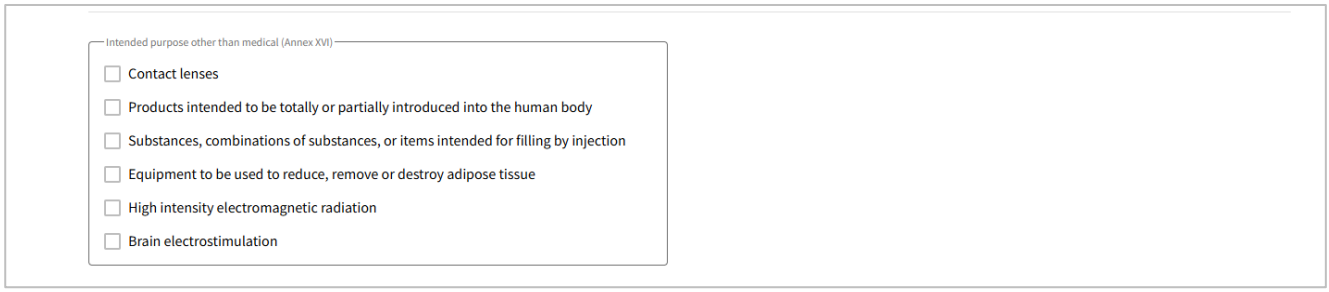
10. Select a reuse information
11. Click on the applicable radio buttons (fields marked with a “*” are required).



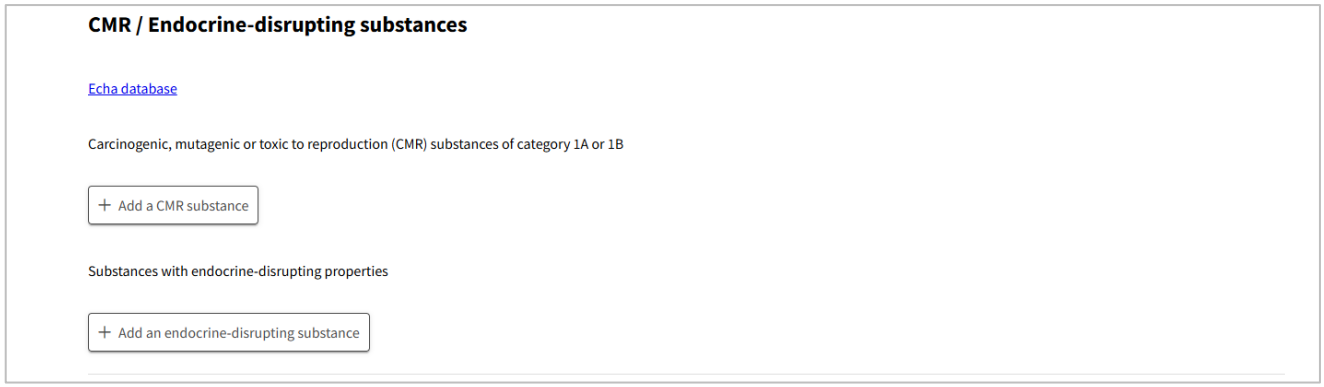
12. Add storage and handling conditions if applicable.

13. Add critical warnings or contra-indications if applicable.

14. Select the intended purpose other than medical (Annex XVI) if applicable.

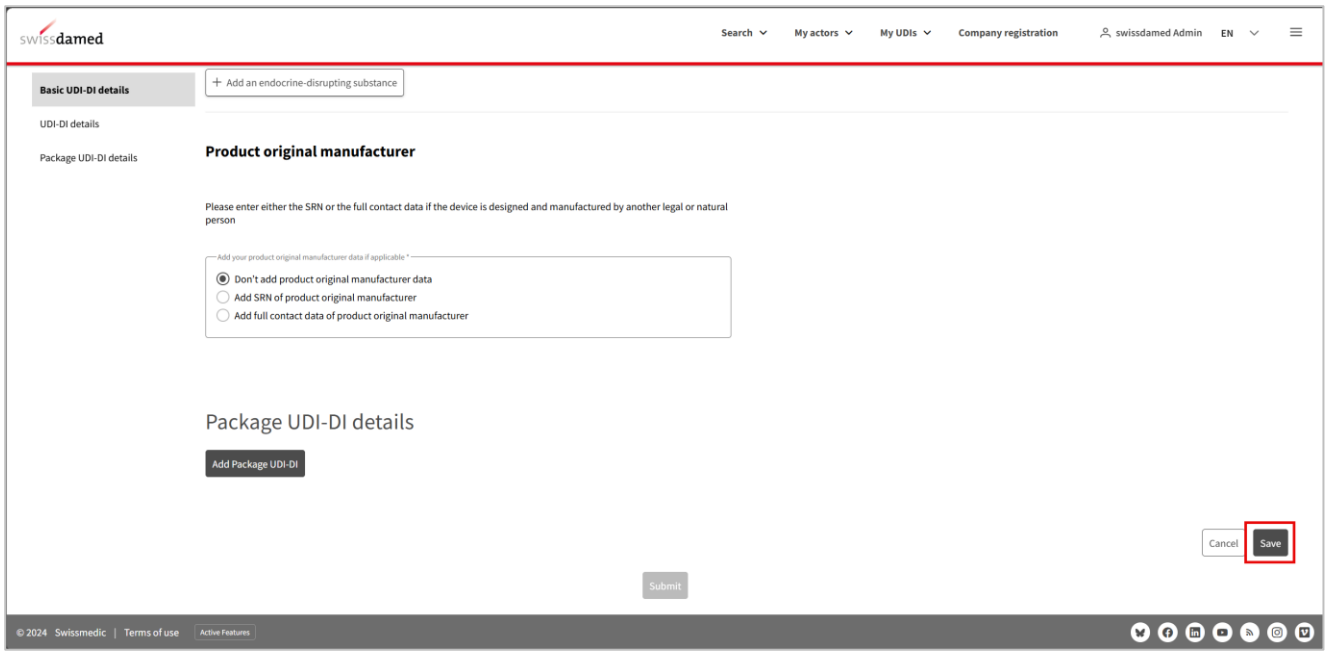


15. Add CMR / Endocrine-disrupting substances if applicable.

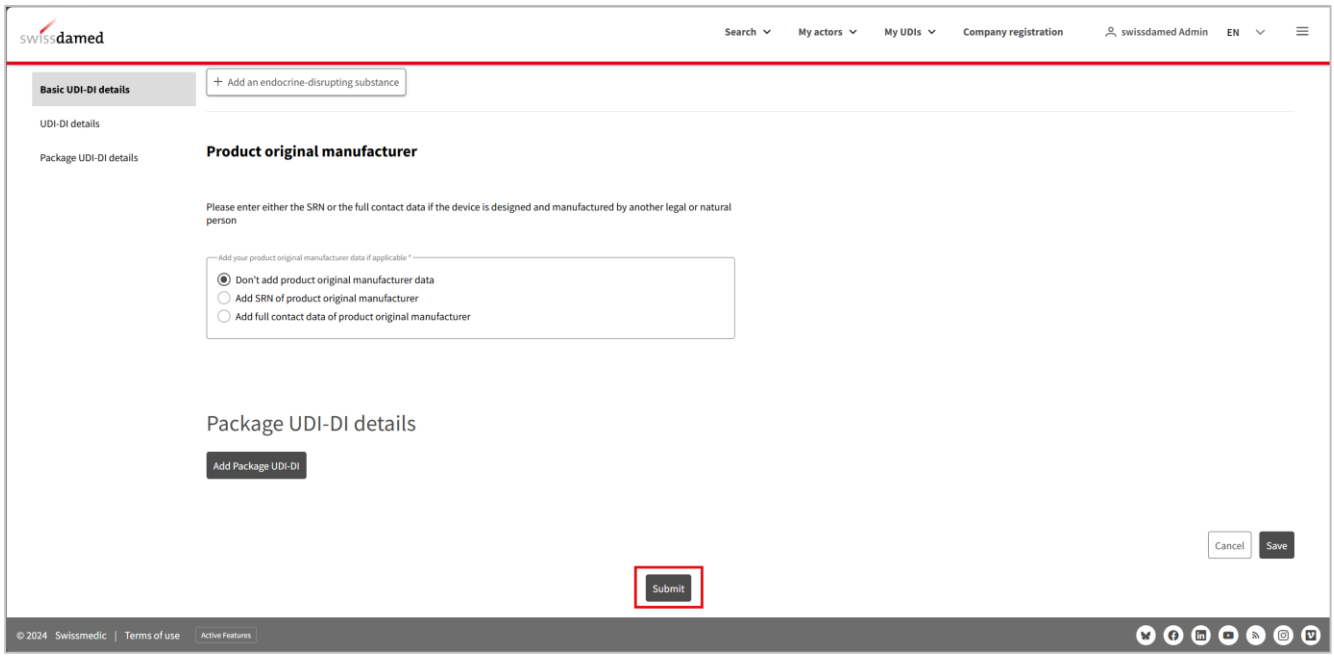


16. Click on the applicable radio button. Enter either the SRN or the full contact data if the device is designed and manufactured by another legal or natural person.

After clicking on the “Save” button, the devices are stored in the “Manage UDI-DIs in progress” overview. The entered UDI-DI data is validated. If any data is entered with the wrong format, an error message is displayed. If mandatory fields are missing, no error message is shown and the submit button is not clickable. The missing fields are outlined in red.
If validation is successful, a success message is shown and the submit button is clickable.



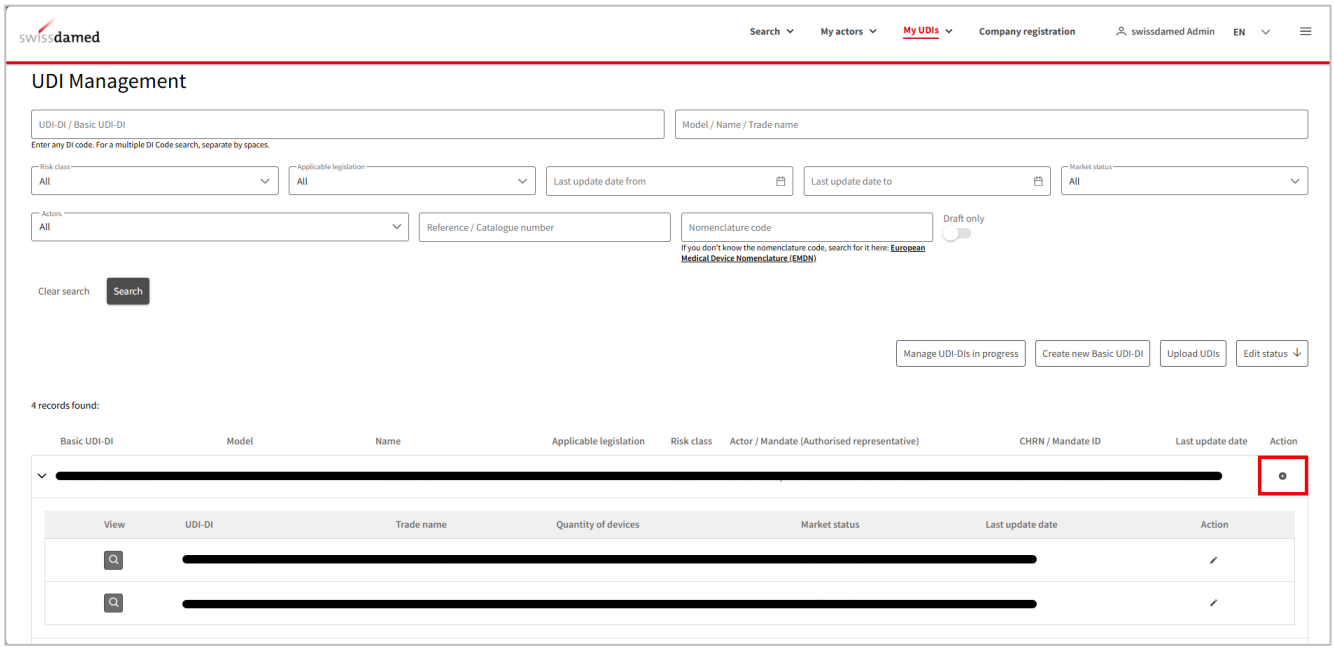
After clicking on the “Submit” button, the device is submitted in status “Draft”. A market status must be assigned. UDIs remain hidden from public view and are not considered registered until a market status has been assigned. See chapter 4 “**Fehler! Verweisquelle konnte nicht gefunden werden.**” for more information about setting a market status.



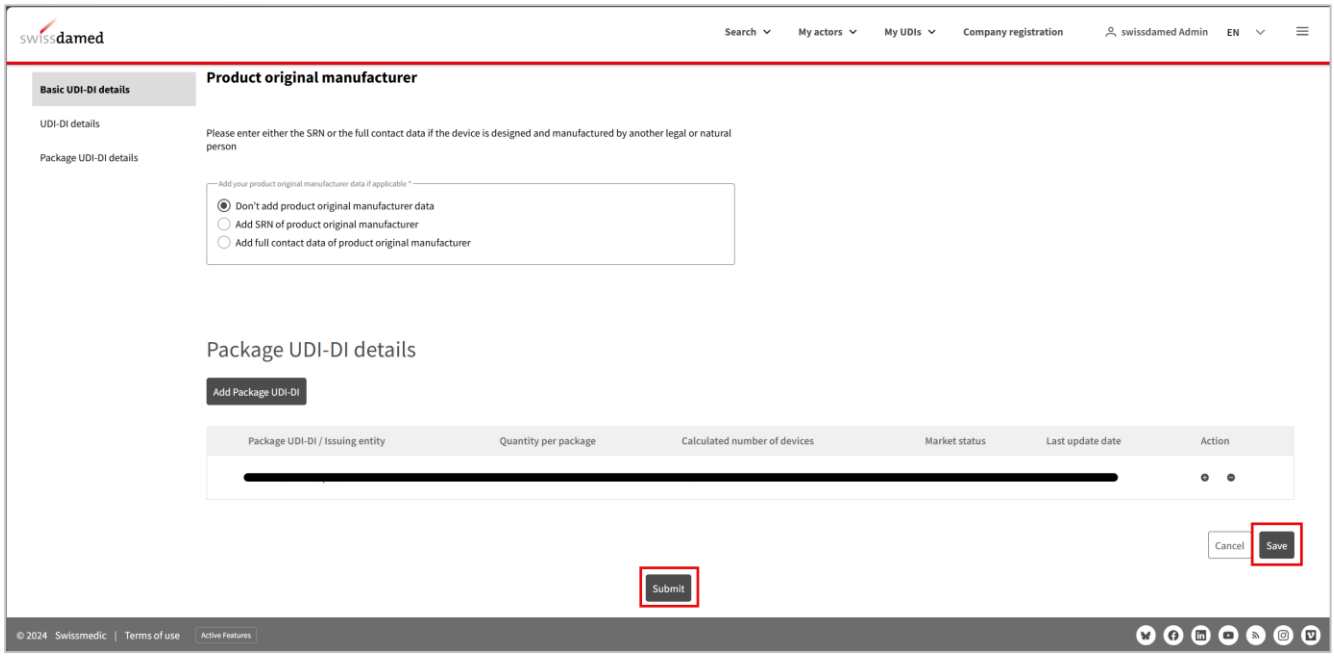
Note: Package UDI-DIs can be entered at the same time as the UDI-DI or added later; see chapter 10.5 “Add Package UDI-DI to existing UDI-DI” for more details.

10.4 Add UDI-DI to existing Basic UDI-DI

Click on “My UDIs”, then on “UDI Management”. Search for the Basic UDI-DI for which you want to add a UDI-DI. Click on the plus symbol.



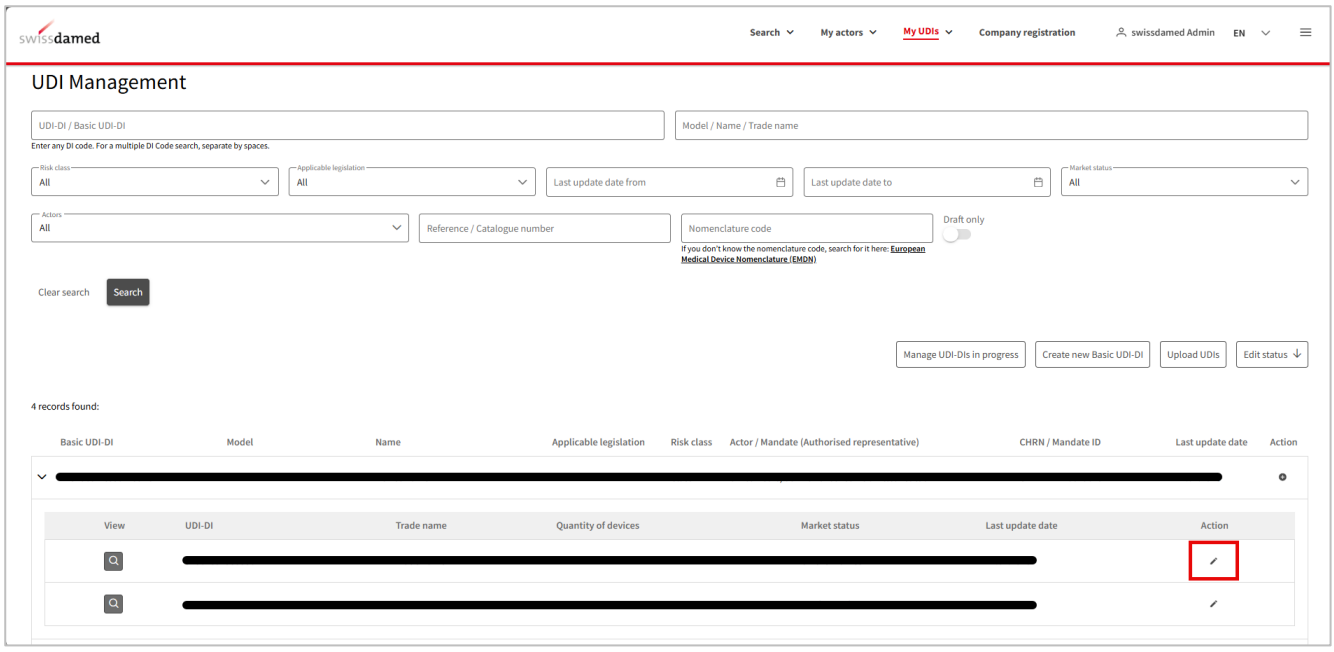
Enter the UDI-DI data accordingly. Click on “Save” and then on “submit”.



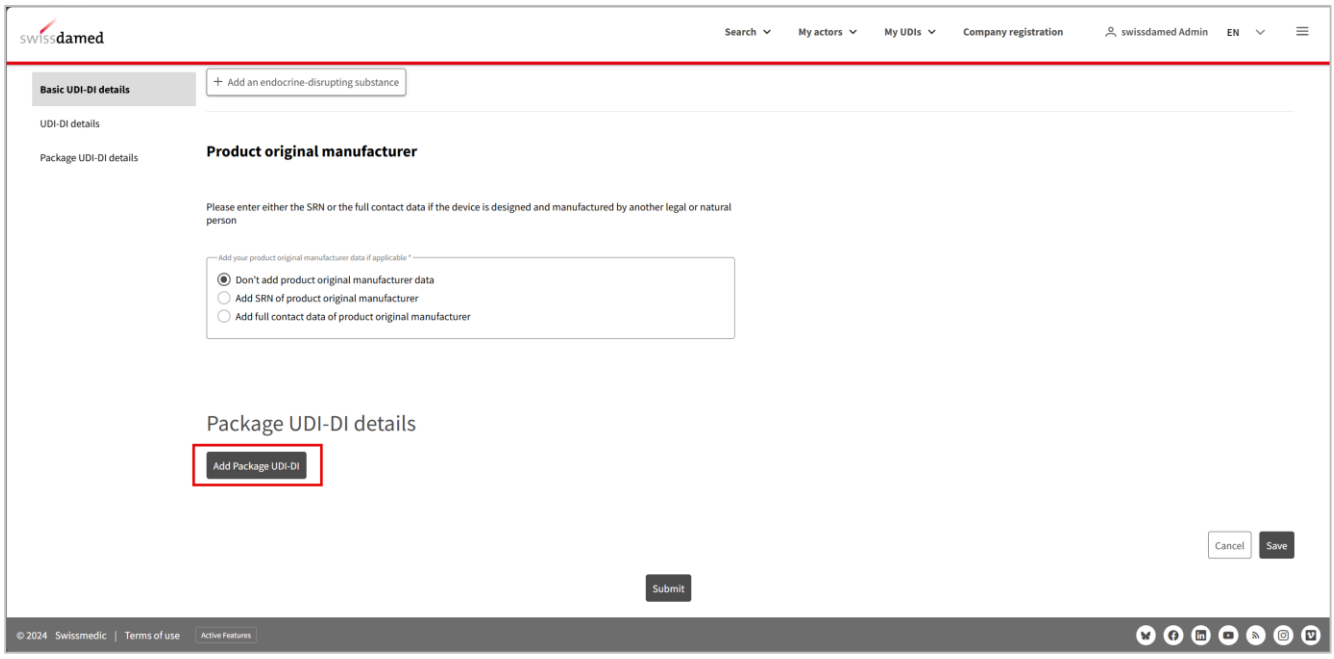
After a UDI-DI has been added, it appears with the status “Draft.” A market status must be assigned. UDIs remain hidden from public view and are not considered registered until a market status has been assigned. See chapter 4 “Market status” for more information about setting a market status.

10.5 Add Package UDI-DI to existing UDI-DI

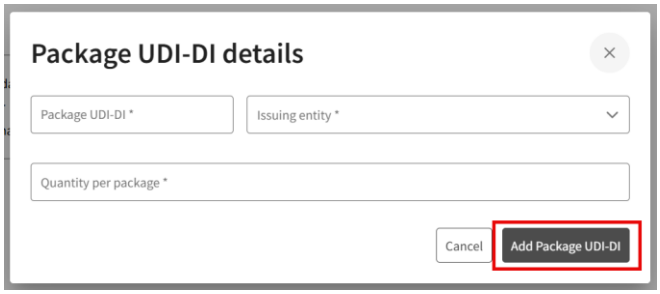
Click on “My UDIs”, then on “UDI Management”. Search for the UDI-DI for which you want to add a Package UDI-DI. Click on the pencil icon.



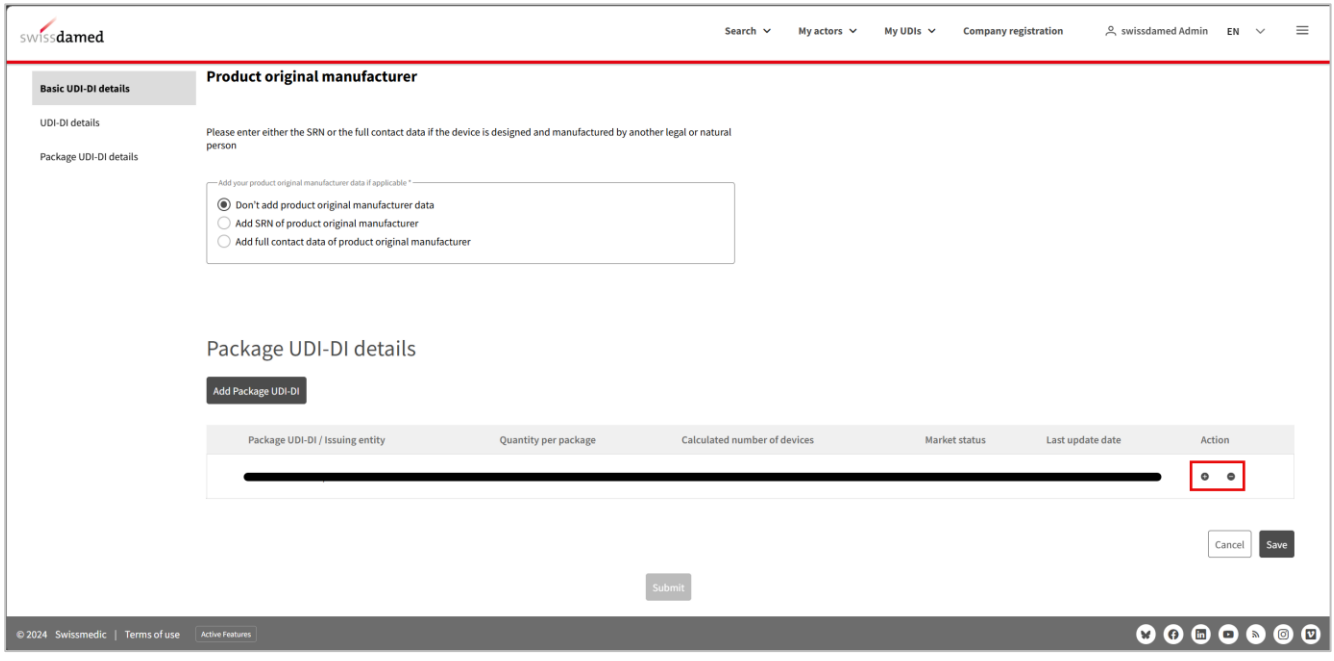
Click on the button “Add Package UDI-DI”.



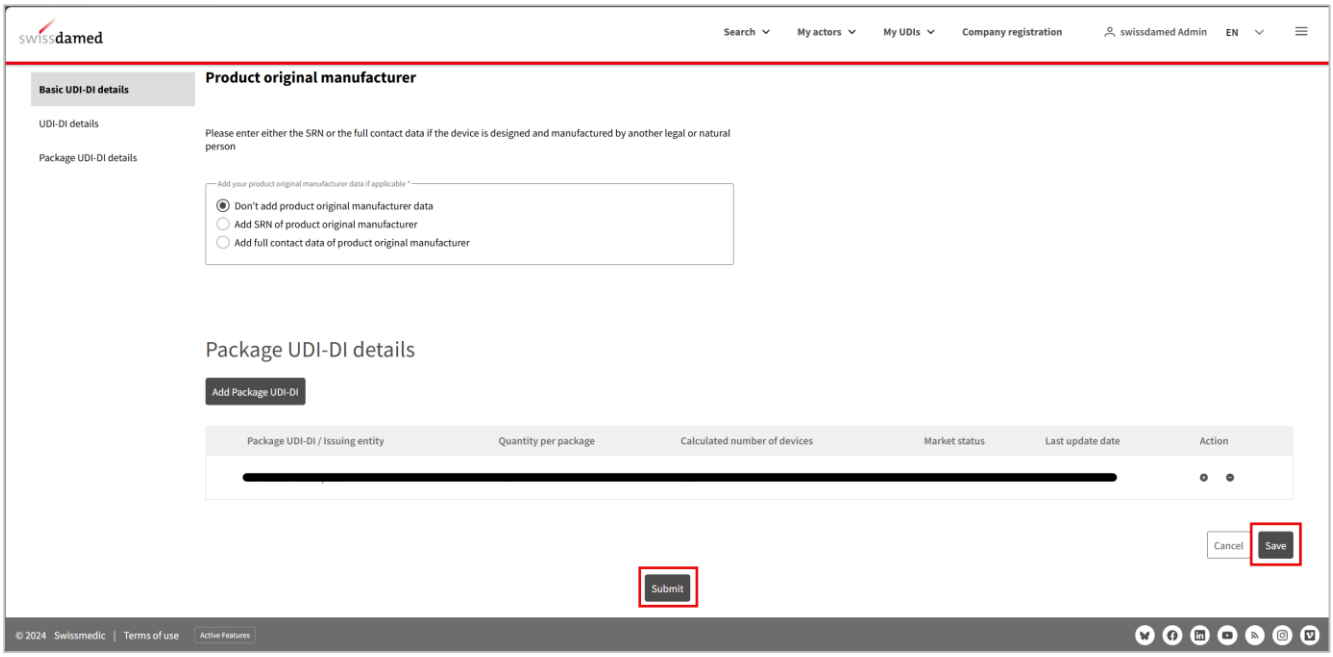
Enter the Package UDI-DI data and click on the “Add Package UDI-DI” button.



If you want to add a Package UDI-DI to an existing Package UDI-DI, click on the plus symbol. If you want to remove a Package UDI-DI, click on the minus symbol.



Click “Save” and click on the “Submit” button to submit the Package UDI-DI.

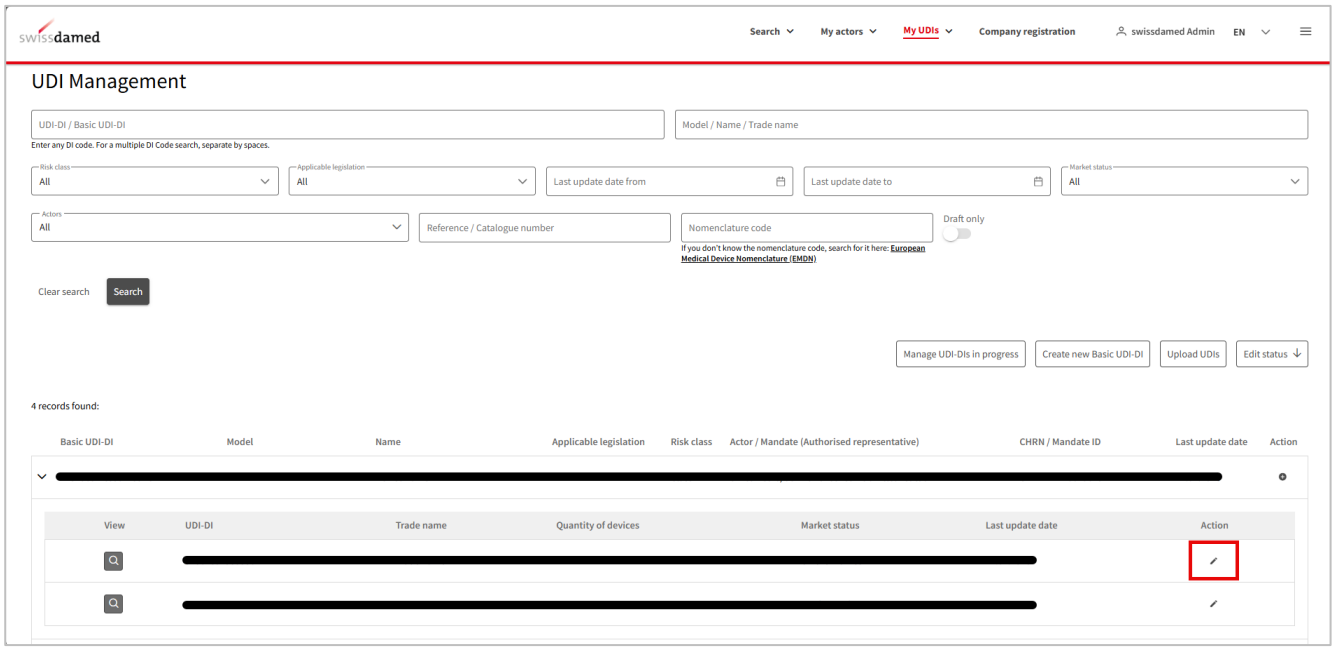


After a Package UDI-DI has been added, it appears with the status “Draft.” A market status must be assigned. UDIs remain hidden from public view and are not considered registered until a market status has been assigned. See chapter 4 “Market status” for more information about setting a market status.

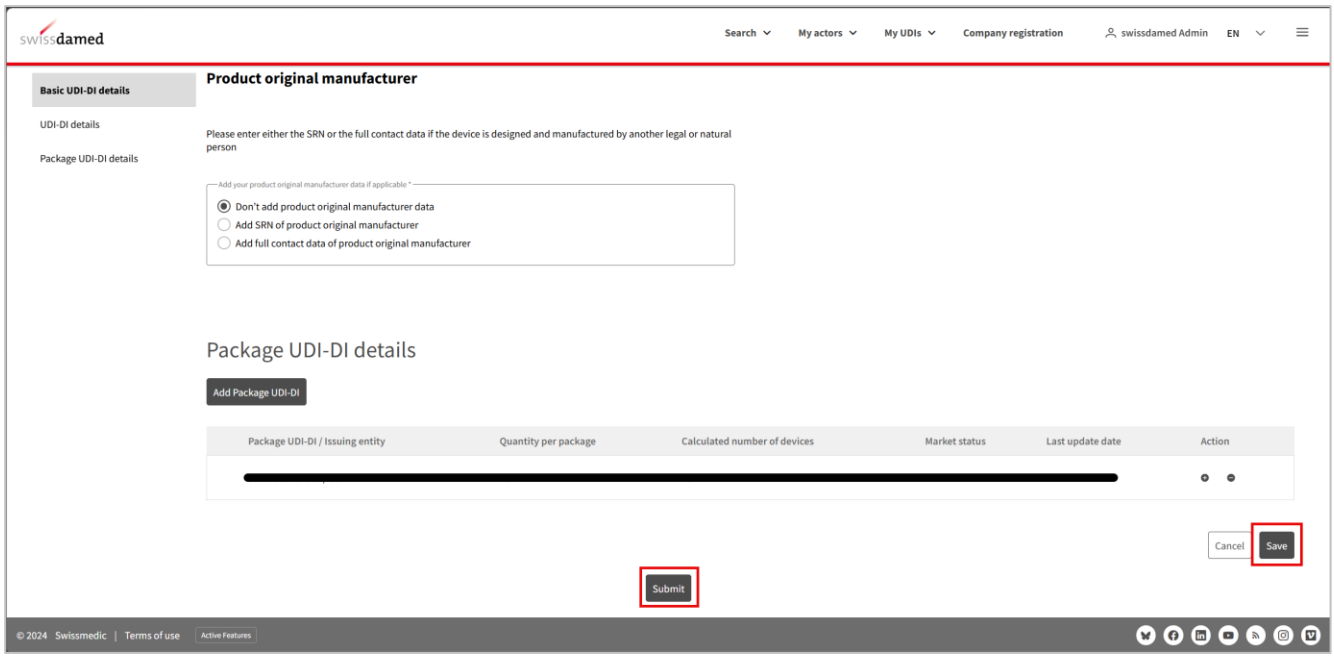
Note: A Package UDI-DI can only be added to UDI-DIs with the status «On the market” or “No longer placed on the market”.

10.6 Edit UDI-DI

Click on “My UDIs”, then on “UDI Management”. Search for the UDI-DI that you want to edit. Click on the pencil icon.



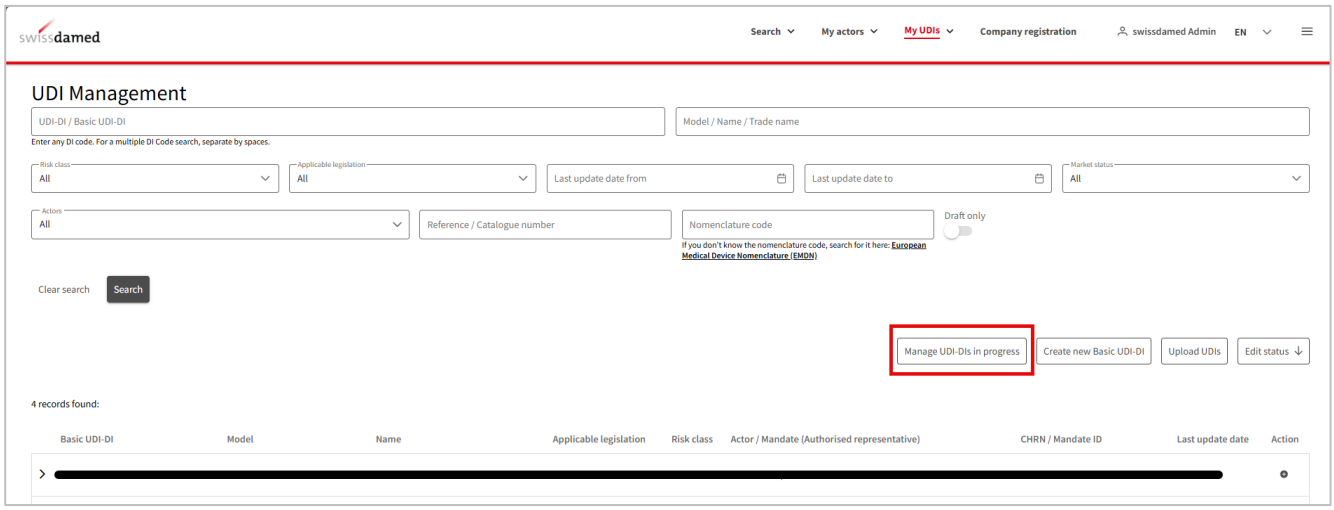
Edit the desired and updatable field(s), click “Save” and click on “Submit”.



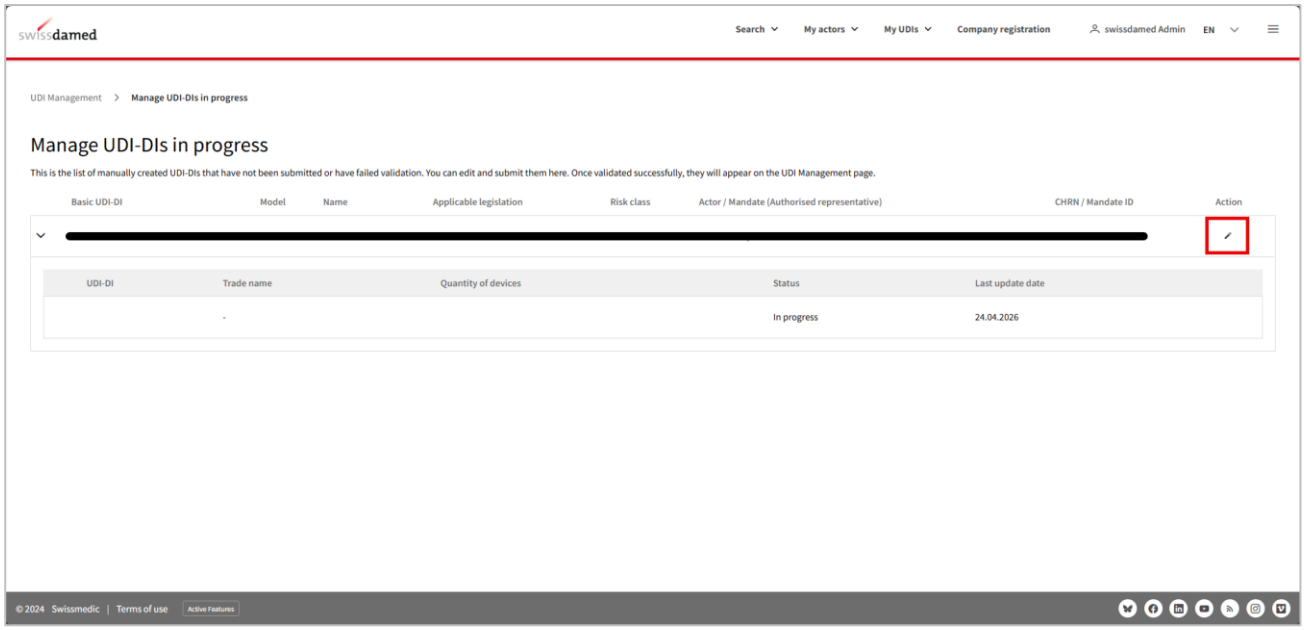
Note: Editing UDI-DIs is possible if the UDI-DI is in the status “Draft”, “On the market” or “No longer placed on the market”. Changes are always subject to the non-updatable fields. The non-updatable fields are described in the Data Dictionary.

10.7 Manage UDI-DIs in progress

Devices that were saved without being submitted are stored under “My UDIs”, “UDI Management” “Manage UDI-DIs in progress” and can be edited at any time.



From here, the device can be further edited by clicking on the pencil icon.



11 Master UDI-DI

According to Art. 17 MedDO and Annex VI Part C Section 6.6 MDR ((EU) 2017/745), the following highly individualised devices require a Master UDI-DI:

- Standard soft contact lenses
- Rigid gas permeable contact lenses
- Made-to-order soft contact lenses
- Made-to-order rigid gas permeable contact lenses
- Spectacle frames
- Spectacle lenses
- Ready-to-wear reading spectacles

Contact lenses must be registered in swissdamed with the Master UDI-DI starting 9 November 2026.

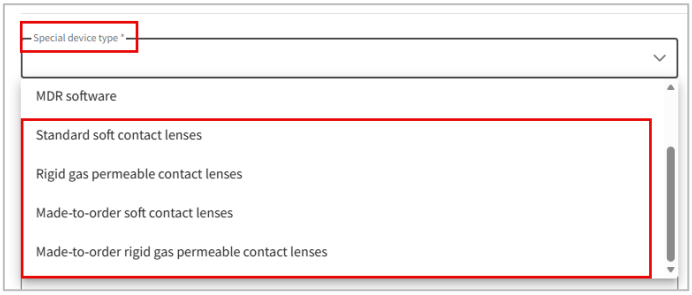
Spectacle frames, spectacle lenses and ready-to-wear reading spectacles must be registered in swissdamed with the Master UDI-DI starting 1 November 2028.

Devices that require a Master UDI-DI can be uploaded to swissdamed by Swiss manufacturers (MF), authorised representatives (AR) and foreign manufacturers with a mandate (MT). A UDI Editor role is required for uploading. Master UDI-DI can be uploaded via XML file upload, Machine-to-Machine (M2M) and by manual input in the online editor.

11.1 Manual entry of Master UDI-DI in the online editor

11.1.1 Special device type

If you select one of the following special device types a Master UDI-DI is required:



11.1.2 Issuing Entities - Structure of the Master UDI-DI

GS1:
• For Standard soft contact lenses and Standard Rigid Gas Permeable (RGP) contact lenses the system applies the GMN format validation algorithm.
• For Made-to-order soft contact lenses and Made-to-order Rigid Gas Permeable (RGP) contact lenses the system applies the GTIN UDI-DI format validation algorithm.

General specifications of GS1 can be found here: GS1 General Specifications - Standards | GS1

HIBCC:
The structure of the Master UDI-DI must comply with the specifications of HIBCC: HIBCC – Setting Safer Standards.

IFA:
The structure of the Master UDI-DI must comply with the specifications of IFA: ifaffm.de/en/ifa-codingsystem/udi/udi_issuing_entity.html

Note: GS1, HIBCC, and IFA are available as issuing entities. ICCBBA is not accepted, as they do not assign Master UDI-DI.

11.1.3 Reference / Catalogue number

For a Master UDI-DI, if there are multiple Reference/Catalogue numbers, you may enter "**many**" as the value.

11.1.4 Quantity of device

For a Master UDI-DI, indicate the maximum number of devices for the Quantity of device. When creating a new version of a Master UDI-DI, the Quantity of device field is editable, whereas for the UDI-DI, it is not.

11.1.5 Intended purpose other than medical (Annex XVI)

When registering a Master UDI-DI for contact lenses, if you select “Yes” for Annex XVI, the list of possible choices will not be displayed, as it is already predefined.

11.1.6 Package Master UDI-DI

When creating a new version of a Package Master UDI-DI, the maximum quantity per package field is editable, whereas for the Package UDI-DI, it is not.

12 Change history

Version	Change	sig
3.0	Added chapter 9: “Machine-to-Machine (M2M) registration of devices”, chapter 10: “Online editor – Create / manage UDIs manually” and chapter 11: “Master UDI-DI”	stj
2.0	Added chapter 8: Discard UDIs	stj
1.0	Initial version	stj