Handbook

swissdamed User Guide Actors

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List of contents

1   Introduction

This user guide describes how actors can use the swissdamed actor registration module and provides companies with an overview of and guidance on the current productive functions of the system.

1.1   Overview

swissdamed is structured around **two modules** and one **public search site**:

- **Actors Module** - Company and actor-user registration and management
- **UDI Devices Module** - Registration and management of devices
- Freely accessible platform with search function

1.2   Actors and definitions

The actors involved in swissdamed are:

- **Manufacturer (MF)** – see Art. 4 para. 1 let. f MedDO and Art. 4 para. 1 let. e IvDO
- **Authorised representative (AR)** – Art. 4 para. 1 let. g MedDO and Art. 4 para. 1 let. f IvDO
- **Importer (IM)** – see Art. 4 para. 1 let. h MedDO and Art. 4 para. 1 let. g IvDO
- **Person who assembles systems or procedure packs (PR)** – any individual or organisation who places procedure packs and/or systems on the Swiss market

Definitions:

- **Medical device** – see Art. 3 MedDO
- **In vitro diagnostic medical device** – see Art. 3 IvDO
- **Swiss Single Registration Number (CHRN)** – see Art. 55 para. 4 MedDO / Art. 48 para. 4 IvDO

1.3   Application basics

This section describes a number of basic principles. These include:

- Starting and ending a swissdamed session
- Understanding the basic concepts
- Understanding user profiles, granting access and access rights

1.3.1 Accessing the swissdamed portal

A CH-LOGIN or an AGOV-Login (Federal Administration account) is required in order to access swissdamed. Please note that the CH-LOGIN is being replaced by the AGOV-Login. You can find information on this here: FED-LOGIN FAQ — eIAM, Identity & Access Management of the Federal Administration

CH-LOGIN:

The CH-LOGIN is a standardised identification procedure provided by eIAM for users of certain federal Internet portals, whether private individuals or actors. Each user must create a CH-LOGIN account to access swissdamed. A telephone number and some security questions must be entered for the two-factor authentication process and to reset the personal password. If you do not have a CH-LOGIN yet, please follow the instructions here: CH-LOGIN - Registration — eIAM Help Pages
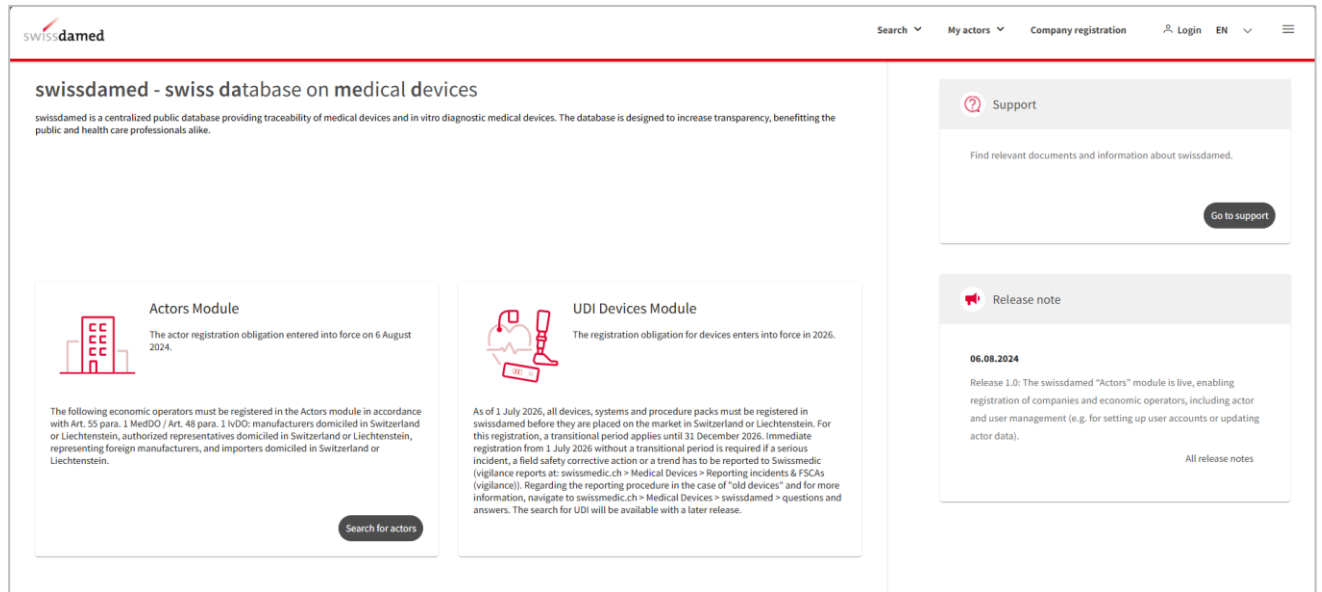
AGOV-Login:

AGOV is Switzerland's new public service login system. It can be used by individuals and business representatives in interactions with all levels of government in Switzerland (municipalities, cantons, Confederation). If you already have a CH-LOGIN account, you can upgrade this to an AGOV-Login account. When logging into an application, select AGOV instead of CH-LOGIN. Use your existing AGOV-Login or register for a new one. You will then be guided through the upgrade process. All your authorisations will be retained during the upgrade. If you do not have an AGOV-Login account yet, please follow the instructions here: AGOV help — agov.ch

**Note: Each user can change the login details (phone number, e-mail, password) of their own account.**

For more information about the CH-LOGIN account, visit: CH-LOGIN FAQ - eIAM, Identity & Access Management of the Federal Administration or for AGOV visit: AGOV - your public service login
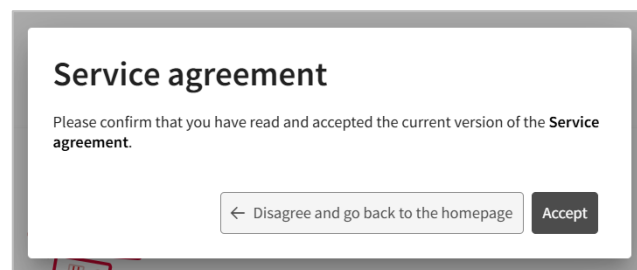
1.3.1.1 Login into swissdamed

1. Go to the swissdamed site www.swissdamed.ch.

2. Click the "Login" button in the top right corner. Log in with your CH-LOGIN or AGOV login.
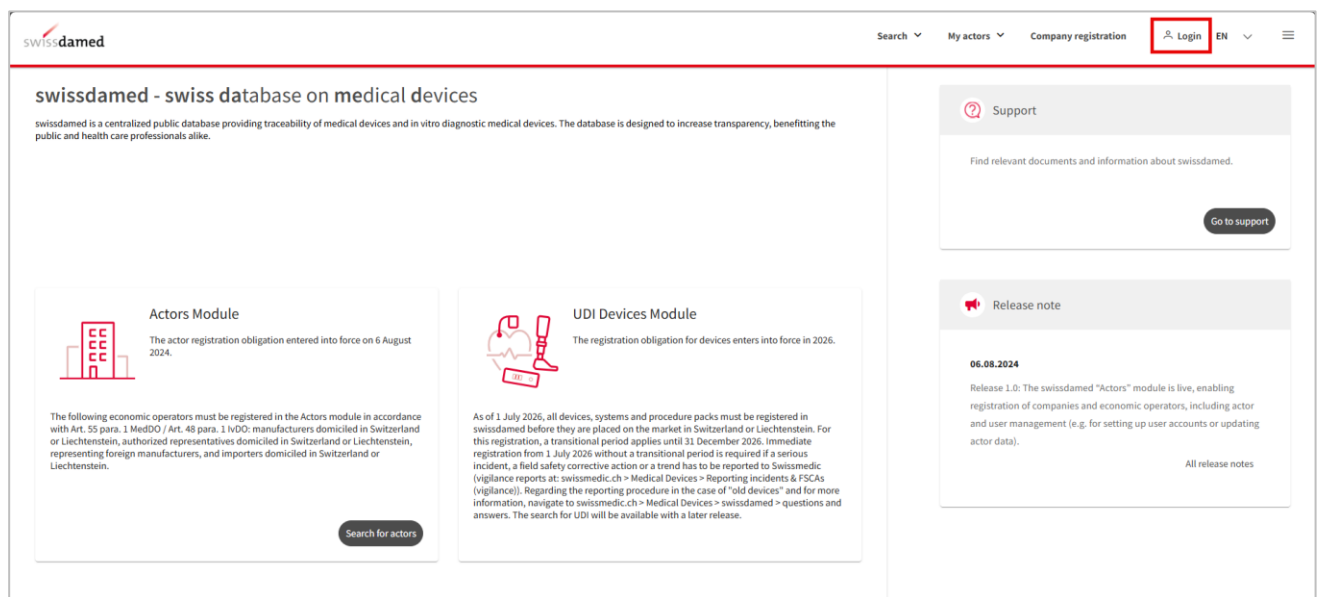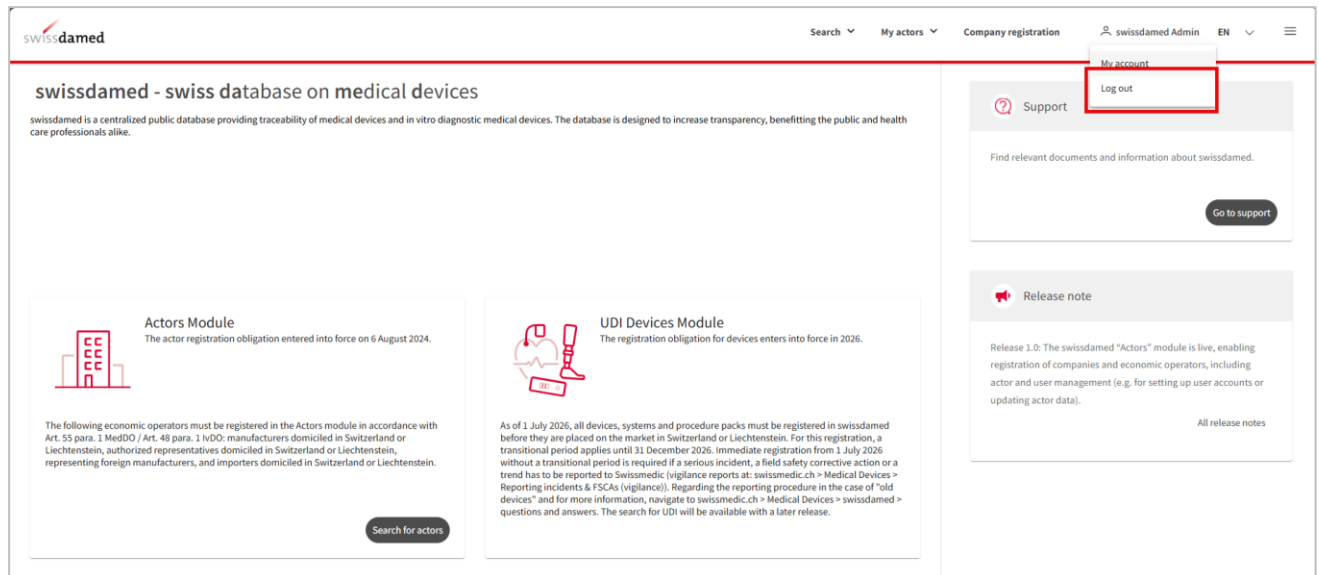

3. When logging into swissdamed for the first time, you will be prompted to review and accept the service agreement. To continue using swissdamed, click "Accept".

1.3.1.2   Logging out of swissdamed

1. Click on your username located in the top right corner of the screen. This will display a dropdown menu. From the dropdown, select "Log out".

1.3.2   User rights and profiles

Each user may have multiple accounts but can only access swissdamed with one account at a time.

Each actor is associated with one company. To register an actor in the system, a user must first register a company. Once the company is registered, the user must verify it. After the company is verified, the user's profile will be set as "Company admin" for that specific company. As a company admin, the user can invite other users to join the company and manage their roles within the company.

Users can also be invited to other companies, where they can either be assigned the company admin role or a viewer role. As a viewer, the user cannot take any actions for the company but is still considered part of it.

If a user is a company admin, they can manage the roles for all users that they invite to their company in the "Actors" module. This means that every user must have a role/permission for a company and then be assigned a specific role in the "Actors" module.

In summary, the user rights and profiles in the new application are designed to ensure that only authorised users can perform specific actions within their assigned company and the "Actors" module. Company admins have the ability to manage user roles and permissions within their company and the "Actors" module. Viewers can access company information but cannot take any actions.

User profiles for companies

User profile	Actors	Rights
ALLOW	All	▪ After the initial login, whether through the creation of a CH-LOGIN or AGOV account or utilising an existing one, a user will be assigned this role. ▪ Can register a new company and verify the company address. Upon successful completion of the verification, the user will be upgraded to company admin role. ▪ The ALLOW role will never be revoked, as otherwise the user will not be able to access the application.
Company admin	All	▪ The user that registers the company will be its admin. ▪ They have the ability to invite new users and manage existing users by changing their permissions.
Company viewer	All	▪ Will be invited to a company by a company admin. ▪ Has no permissions in this application, but is linked to company in eIAM

User profiles for actors / mandates

User profile	Actor	Rights
Actor admin	All	- Can manage actor data respectively, as well as manage users associated with an actor. - Has no rights to manage UDI data.
Mandate admin	MF Mandate, PR Mandate	- Can manage mandate data respectively, as well as manage users associated with a mandate. - Has no rights to manage UDI data.
UDI Editor	MF, PR, MF Mandate, PR Mandate	- Can upload and update UDI data. - Can register devices / UDIs by setting the market status. - Is assigned at the actor level for MF, PR, but at the mandate level for AR. - Cannot edit actor or mandate details.
Actor viewer	All	Has read-only permissions for actor / mandate and UDI data.
Mandate viewer	MF Mandate, PR Mandate	Has read-only permissions for mandate and UDI data.

2   Managing actors and user accounts

The actor module ensures that all actors using swissdamed have been authenticated.

There are two ways to gain access to swissdamed:

1. **Request registration as an actor (CHRN).** Register your actor in swissdamed with the appropriate actor role.
   1. The person who performs the actor registration automatically becomes actor admin for that actor once the registration is validated by Swissmedic.
   2. A Swiss Single Registration Number (CHRN) is generated by swissdamed and issued by Swissmedic after validating the actor registration request.

2. **Get onboarded as a user of a registered actor.** If your actor is already registered in swissdamed, the user with actor admin permission can invite you as a user of that actor. Once an actor admin from an actor has invited you, your account will be granted the appropriate user profile for that actor. It is good practice having at least two actor admins as a fail-safe mechanism in case one should be unavailable. Furthermore, an actor must have at least one active actor admin at all times, making it impossible for an actor to terminate the last actor admin.

A requirement for both options is a registered company.

3   How to operate in swissdamed – Instructions

3.1 Company

3.1.1   Register a company

The first step to take after successfully logging into swissdamed is to register your company. To do so, follow the instructions below:
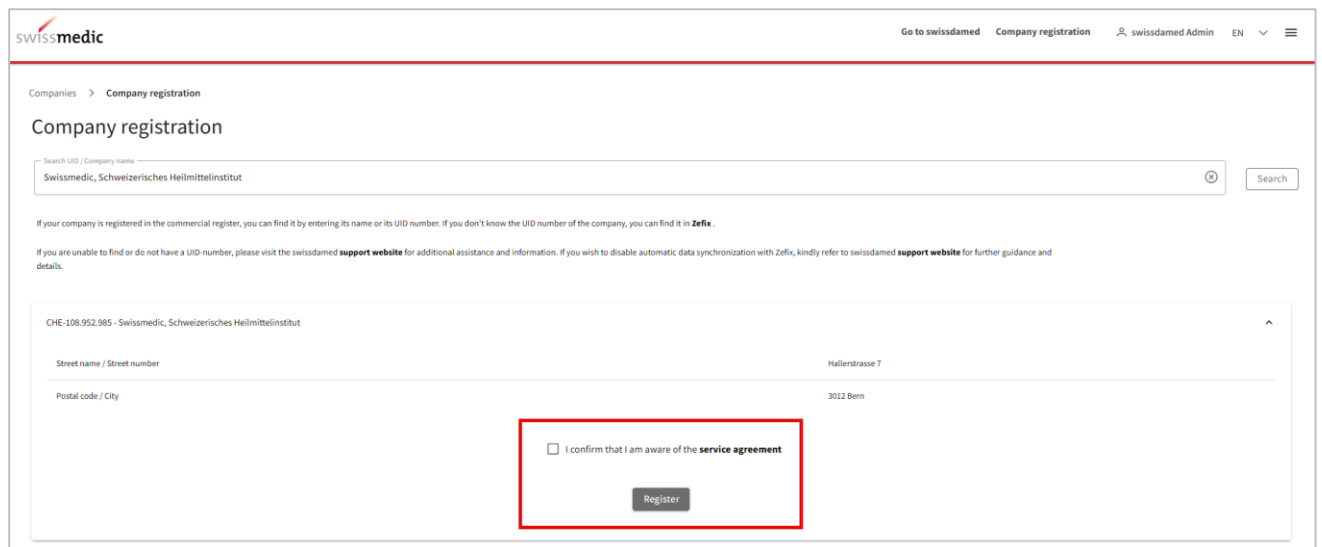
1. Go to the "Company registration" tab and click on the button "Register new company".

2. Search for your company in the search field. The results from the search come from the Central Business Name Index - Welcome (zefix.ch).
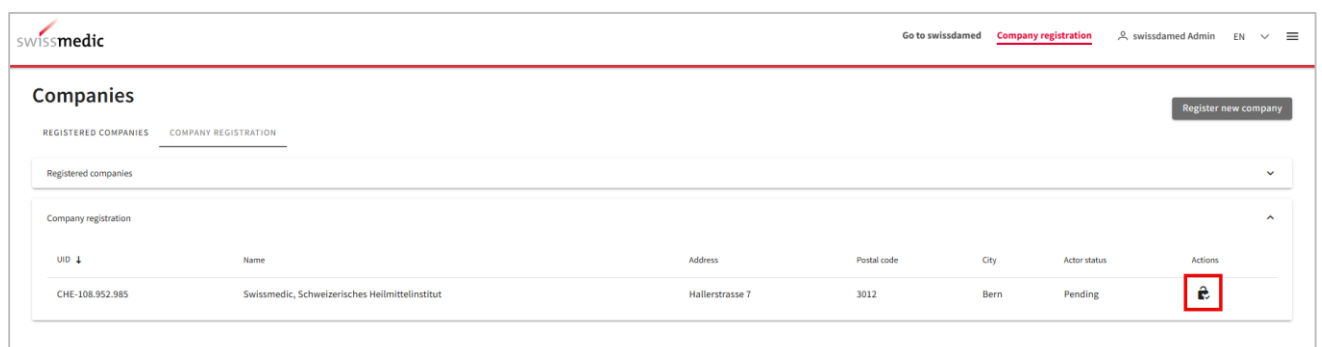
3. Select the desired company, tick the box "I confirm that I am aware of the service agreement" and click "Register".

4. A confirmation appears telling you that the chosen company registration was successfully submitted. The text just below explains what to do next:

   "The company CHE-123.456.789 - XXX is provisionally registered. An address verification code will be sent by letter to STREET, NUMBER, CITY. Once you receive the letter, you can enter the address verification code and verify the company address in order to fully register the company."

5. Please wait until you receive the verification letter by Swiss Post.
6. Having received the letter, log in to swissdamed, go to "Company registration" and then the "Company registration" tab, and click on the padlock symbol of the corresponding company.

7. Enter the company verification code you received by letter and click on "Confirm".

Enter company verification code

You created a registration request for the following company:

Swissmedic, Schweizerisches Heilmittelinstitut
Hallerstrasse 7
3012 Bern
CHE-108.952.985

We have sent you an address verification code by letter to the company address. Please enter this code below and click "Confirm".

Verification code

Cancel Confirm

8. A confirmation appears telling you that the registration of your company has been successfully completed. The text above the icon explains what to do next: *"To begin using the company, please log out of the application. Once you log back in, the registered company CHE123456789 - XXX will be visible and ready for use."*

9. After logging back in to the application, the company should be in the list of "Registered companies" in the "Company registration" tab.

3.1.2 Add user(s) to the company

1. Go via "Company registration" to the "Registered companies" tab, where you will see your company. Click the "+" icon on the right of your company to "Invite new user".

2. Enter the first name, last name and e-mail address of the user you want to invite and choose the user role you want to assign to that person. When everything has been filled in, you can click on the "Send invitation" button below.
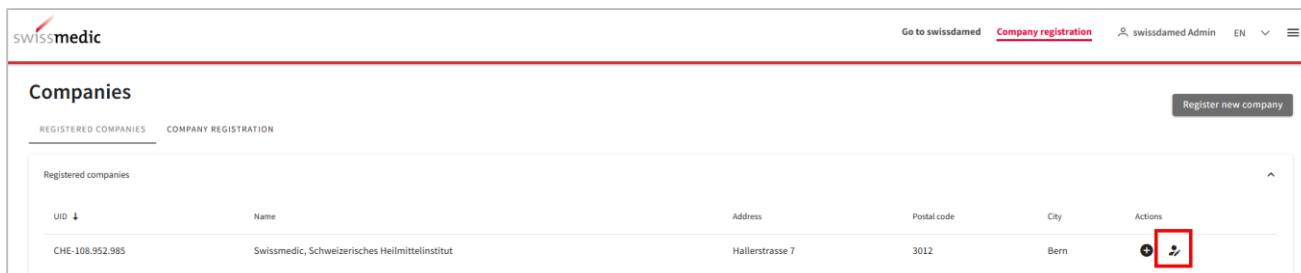
3. After sending the invitation, the invited user will get an e-mail in which the onboarding procedure will be explained (if the invited user does not yet have a CH-LOGIN or AGOV account). The person will have to follow the instructions, using the link and code provided in the email.

   If the user already has a CH-LOGIN or AGOV account, the e-mail will contain information about the invitation and the new role in the company.

3.1.3   Manage company users

1. Once the user is onboarded, their status can be checked in the "Registered companies" tab under "Company registration", which you can access by clicking on the character icon next to your company.

2. All the users of your company are listed in this overview with their role and status. By clicking the icon in the "Actions" column, you can edit the role of the users or delete the user.
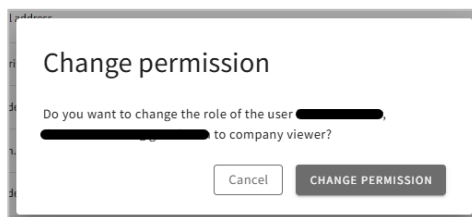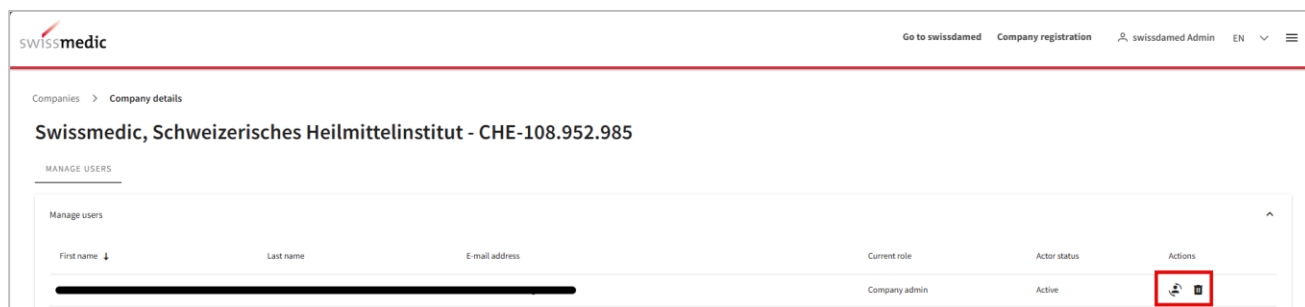
3.1.4 Change data of a company

1. The general information, such as name, the address and UID of the company cannot be changed, because this is an excerpt from the Swiss commercial register
2. If your company does not have a UID, please contact the swissdamed team for support by using the contact form: [Support swissdamed](#)

3.2 Actor (CHRN)

3.2.1 Register an actor (CHRN)

1. Log in to swissdamed with your account and go via the "My actors" dropdown to your "Registered companies". Click on the "+" icon (Register a new actor) action button on the right of the company to which you want to add an actor. A new page will open with a form to fill in.
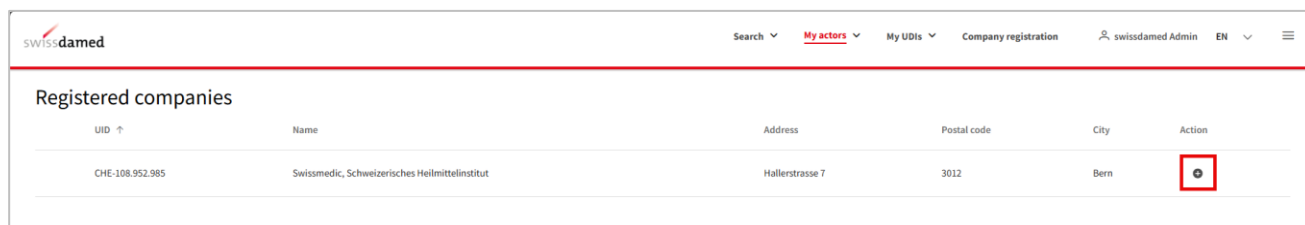
2. Choose an actor type and fill in the details for each stage of the form. To go through the form, press the "Next" button at the bottom of the page.

3. In the last step: Upload your excerpt from the commercial register, agree to the service agreement and confirm that the indicated data are correct.

   If you are a natural person, please upload your residential address registration document.

   Note that the required documentation should not be older than three months.

4. Submit the actor registration request to Swissmedic by clicking on the "Submit" button.
5. If the request was successfully submitted, a confirmation appears. Swissmedic will check the request and assess it.
6. In the meantime, the status of your request can be checked via the "My actors" dropdown in the "Actor registration requests" overview.

7. Once your request was assessed, you will receive an e-mail with the status of your request.

If your request is accepted, your request will get the status "Approved" in the "Actor registration requests" via the "My actors" dropdown. Additionally, your actor will be available under "Registered actors" with the status "Registered".

If corrections are required for your request, it will remain in the "Actor registration requests" overview via the "My actors" dropdown. The request will then receive the status "Correction requested", which makes it available for editing (pencil icon in the action column). In this status, the request can also be cancelled (cancel icon) under "Action". For further information see section 3.2.5.

If your request is refused, your actor will be displayed in the "Actor registration requests" overview with the status "Refused".

3.2.2 Add user(s) to the actor (CHRN)

Once Swissmedic has accepted your registration request and your actor is visible in the "Registered actors" overview, other users can be added to the actor level. To be able to add a user to an actor, the user you want to add must first be registered at company level. To do so, please follow the steps described in section 3.1.2 of this user guide.

As soon as the desired user is registered in the company, they will automatically appear in the user list of the actors of that company. The following table shows which role will be automatically assigned at actor level to the company users.

Company role assigned	Actor role automatically assigned
Company admin	Actor admin & UDI Editor (MF and PR)
Company viewer	None

3.2.3 Manage actor users (CHRN)

If the user is registered at company level, they will automatically appear at actor level. As actor admin, you can change (add/remove) permissions of actor users. To do so, please follow the steps below.

1. Open the "Actor details" of the desired actor by clicking on the magnifying glass icon.

2. Once in the "Actor details" view, open the "Users" tab. All users from the company are listed there with their role and status.
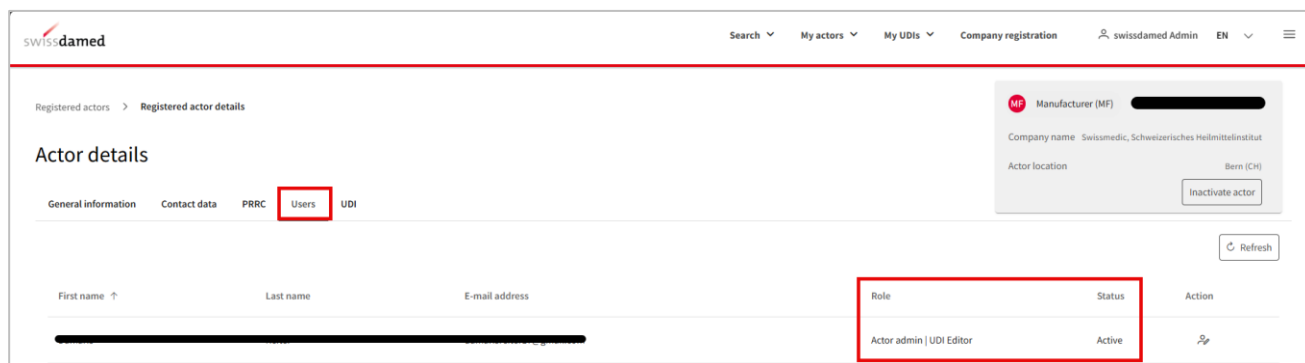
3. If you want to change the role of one of the actors, click on the change permission button (character icon on the right)
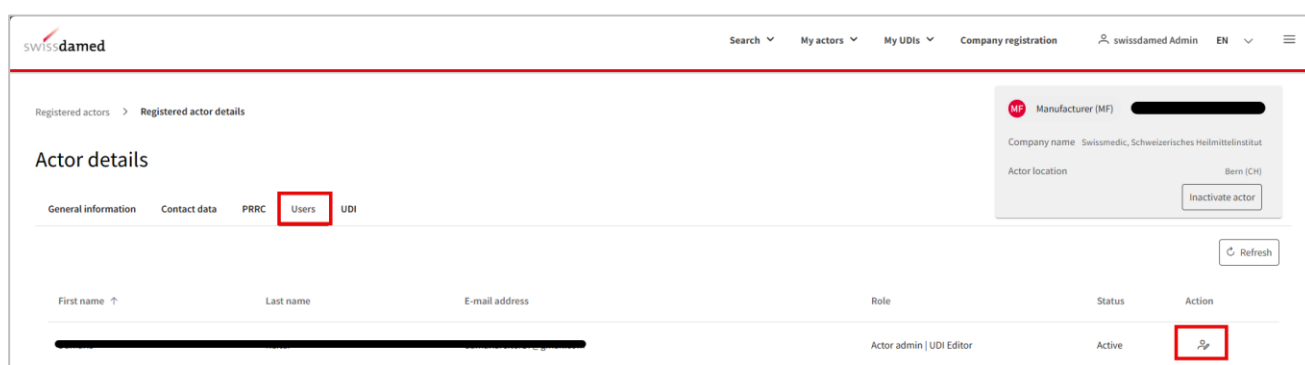
4. Add or remove a permission by choosing if the selected user should have an actor role or not, and if so, which one (multiple selection allowed). Click on the "Change permission" button to validate your choice.

5. If the change of role was successful, a confirmation appears.

3.2.4   Change data of an actor (CHRN)

If you need to change the registered data of an actor, you can do so by going to the "Registered actors" overview via the "My actors" dropdown.

1. Click on the pencil icon on the right of the actor that you wish to update.

2. Change the data that needs to be updated. Confirm that the data are correct and save your changes by clicking on the "Confirm" button.

   Please note: You cannot modify your company address details directly in swissdamed. Make sure that the UID register (Zefix) contains the correct data. The company data in swissdamed will be updated automatically.

   If your company is not registered in Zefix or you opted out of the automatic synchronisation between Zefix and swissdamed, your company was manually registered by a Swissmedic user. To update your company data in that case, please contact the support team.

3. If the update was successful, a confirmation appears.

3.2.5 Abort an actor registration request (CHRN)

If you want to abort an actor registration request after it has been set to the status "Correction requested" you can do so by going to the "Actor registration requests" via the "My actors" dropdown.

1. Click on the icon on the right of the actor registration request that you wish to abort.

2. A confirmation window appears asking you to confirm that you really want to abort this actor registration request. Click on "Abort request".

3. In the overview of "Actor registration requests" the actor registration request now has the status "Aborted".

3.2.6 Delete an actor registration request (CHRN)

If you wish to delete an actor registration request, you can do so in the "Actor registration requests" overview via the "My actors" dropdown. Please note that the request can only be deleted if it has the status "Draft".

1. Click on the trash icon.

2. Confirm that you want to delete the request by clicking the "Delete" button.

Delete actor registration request

Do you really want to delete this actor registration request? This can not be undone!

Cancel   Delete

3.2.7 Validate your actor details (CHRN)

According to Art. 31 para. 5 MDR and Art. 28 para. 5 IVDR, economic operators shall periodically confirm the accuracy of the registered data.

Twelve months after the creation of a new actor and then every two years, an e-mail from swissdamed is sent to the contact e-mail address and the actor admin(s) asking them to confirm the actor data registered in swissdamed. The respective actor who needs to confirm the data is marked (in orange) in the actor list.

1. To confirm or update your actor data, click via the "My actors" dropdown, on "Registered actors", then on the pencil icon on the right of the relevant actor.

2. Verify and change the data that need to be updated. Confirm that your data are correct and submit your validation / changes by clicking on the "Confirm" button.
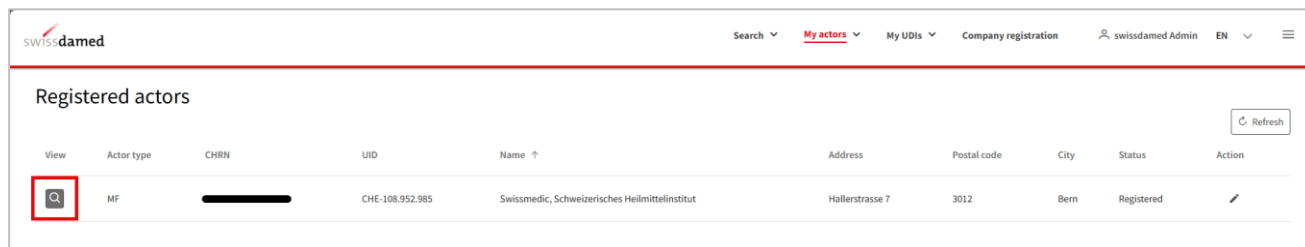

3. If the validation was successful, a confirmation appears.

3.2.8 Inactivate an actor (CHRN)

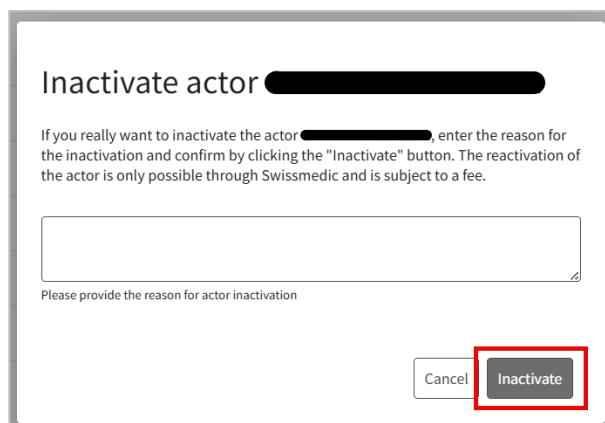If you need to inactivate an actor, you can do so by following these steps:

1. Go to the list of your "Registered actors" via the "My actors" dropdown and click on the magnifying glass icon on the left of the actor that you want to inactivate.

2. In the details of your actor, click on the "Inactivate actor" button in the grey box in the top right corner
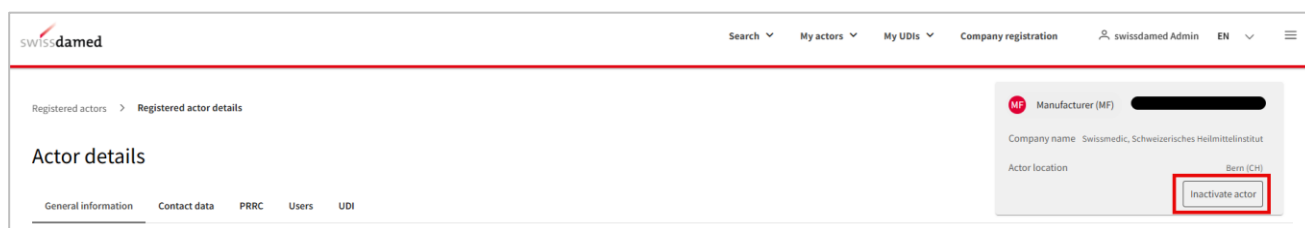
3. A confirmation window appears asking you to provide the reason for the actor inactivation and to confirm that you really want to inactivate this actor.

4. If the inactivation is successful, a confirmation appears.
5. Inactivated actors are shown in grey in the list of the registered actors, and an information box is also added in the actor details.

3.3 Mandate

3.3.1   Register a mandate

To register a mandate in swissdamed, you first need to have a registered authorised representative (AR) as an actor for your company. If that is the case, follow the steps below to register a new mandate:

1. Go to the "Registered actors" overview via the "My actors" dropdown. Click on the letter-icon (Go to mandates) of the authorised representative actor to whom you want to add a mandate.
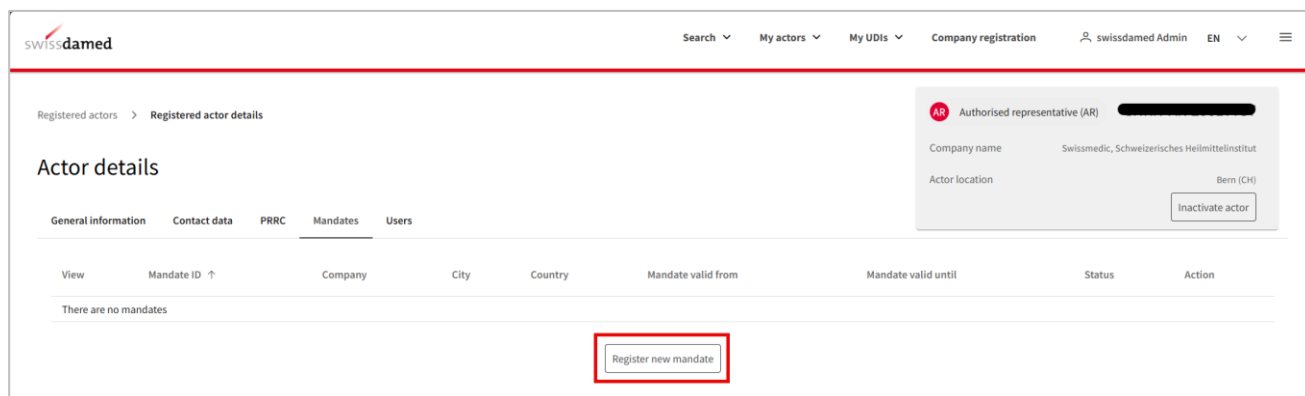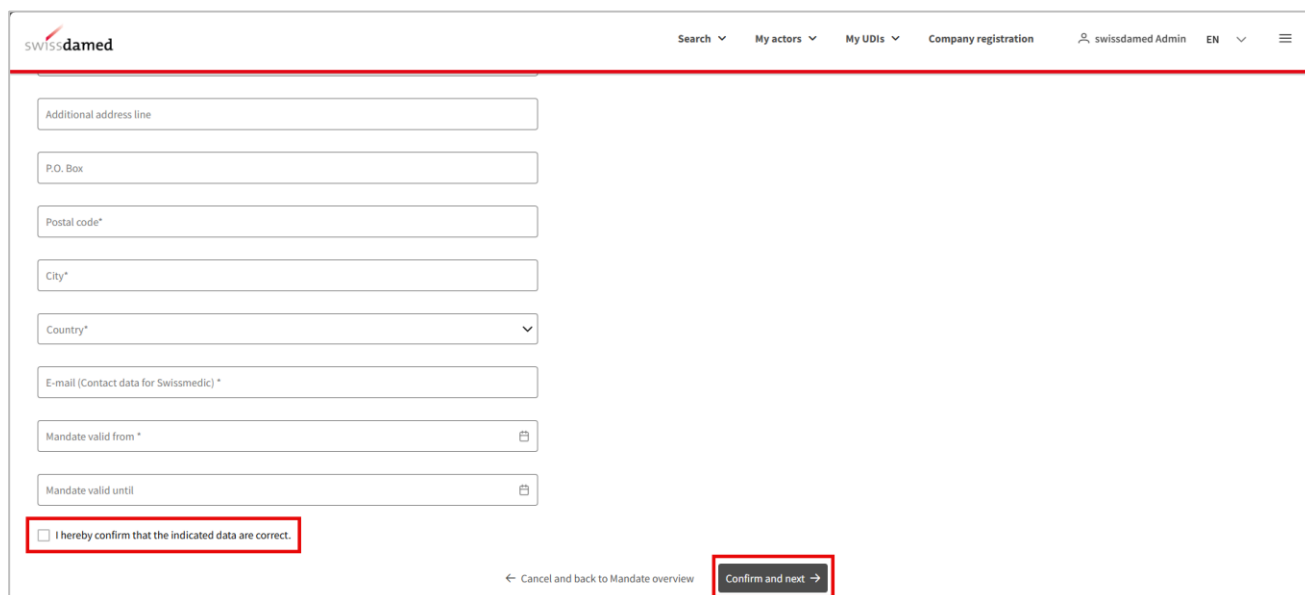
2. In the "Actor details", click on the "Register new mandate" button.

3. Fill in the form, confirm that the indicated data are correct and save the mandate by clicking on the "Confirm and next" button at the bottom of the form.

4. Click "Confirm". If the registration was successful, a confirmation appears.

3.3.2 Add user(s) to the mandate

If you wish to add a mandate user, you must first add them as an actor user at actor level.

Once your mandate is visible on the "Mandates" tab of your authorised representative actor, other users can be added to the mandate. To be able to add a user to a mandate, the user that you want to add must first be registered at company level. To do so, please follow the steps described in section 3.1.2 of this user guide.

As soon as the desired user is registered in the company, they will automatically appear in the user list of the actors of that company and in the corresponding mandates. The following table shows which role will be automatically given on mandate level to the company users.
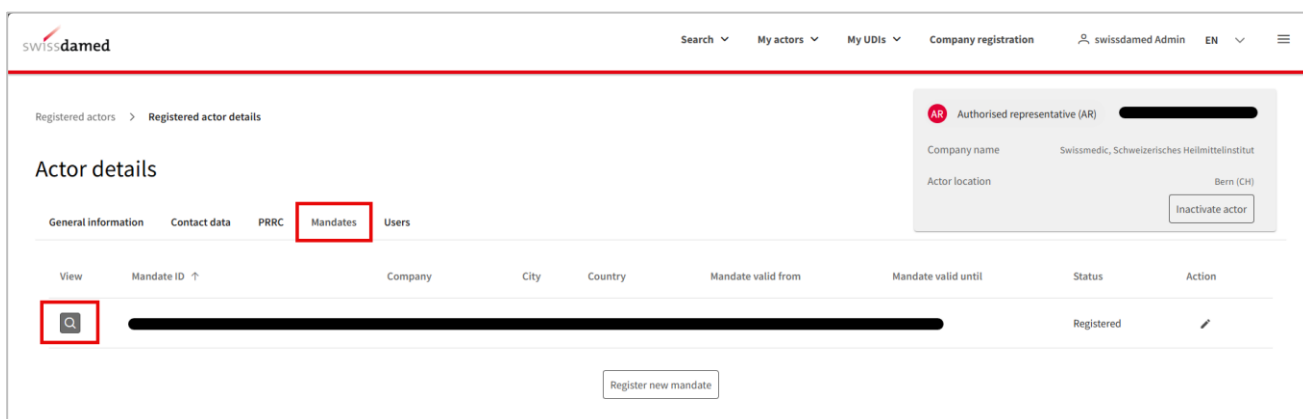
Company role assigned	Actor role automatically assigned	Mandate role automatically assigned
Company admin	Actor admin	Mandate admin & UDI Editor
Company viewer	None	-

If the user was given the role "Company viewer", the actor role needs to be manually changed from "None" to any other actor permission, so that the user also appears in the mandate users.
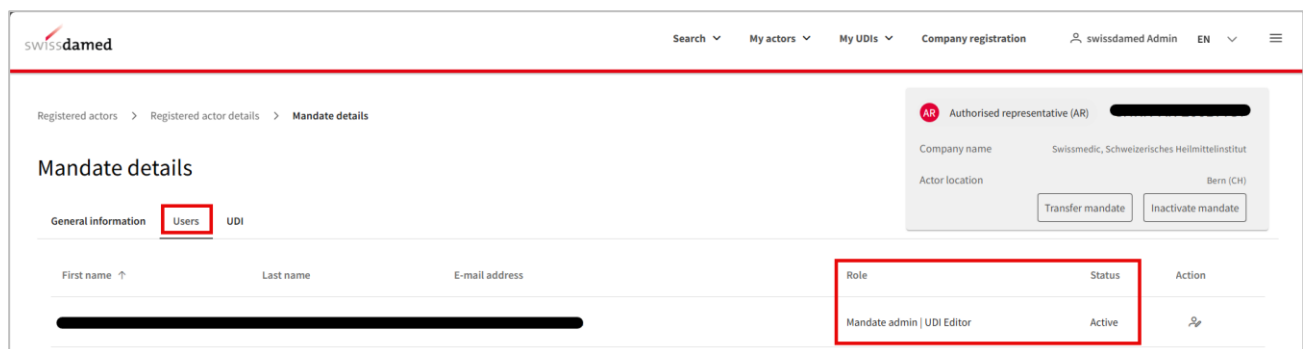
3.3.3 Manage mandate users

Once your mandate was saved and is visible in the mandate overview, you can manage the user at mandate level. To manage users at mandate level, follow these steps:
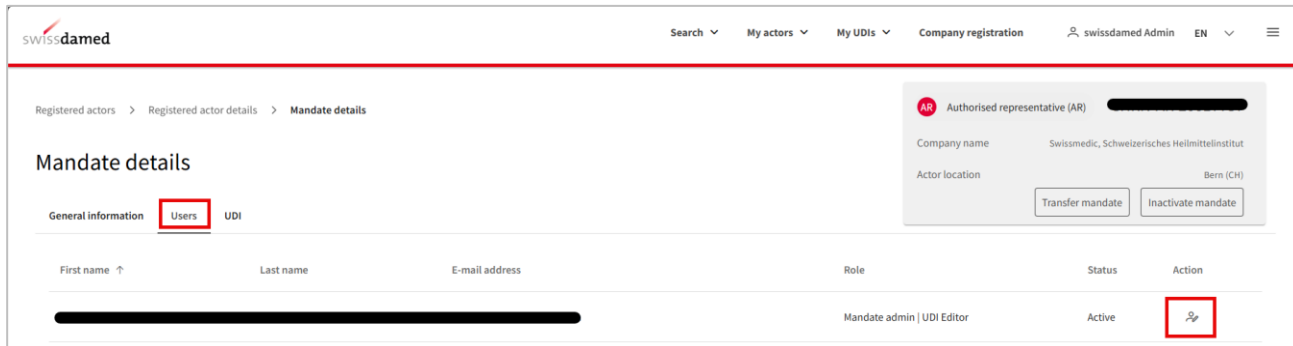
1. Open the actor details of the authorised representative via the "My actors" dropdown, then "Registered actors". Click on the "Mandates" tab and open the mandate details by clicking on the magnifying glass icon next to the chosen mandate.
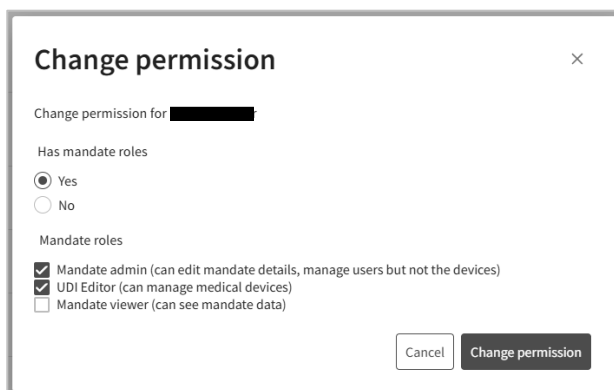
2. Go to the "Users" tab under "Mandate details". The users of your company that have a role at actor level (actor admin or actor viewer) will automatically be listed there.

3. As mandate admin you can manage the mandate users by clicking on the character icon on the right of the user whose role that you wish to change.

4. Add a permission by choosing whether or not the selected user should have a mandate role and, if so, what that role should be. Click on the "Change permission" button to validate your choice.
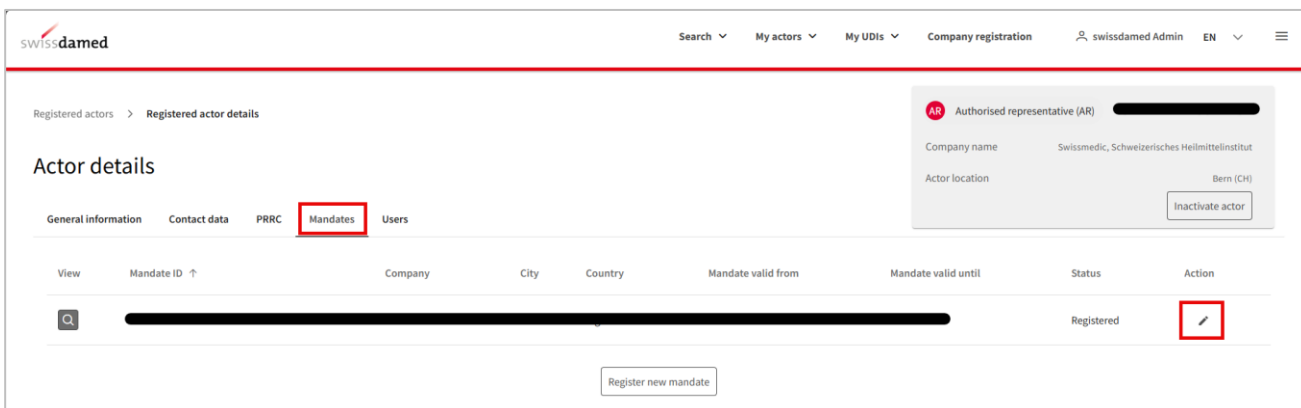

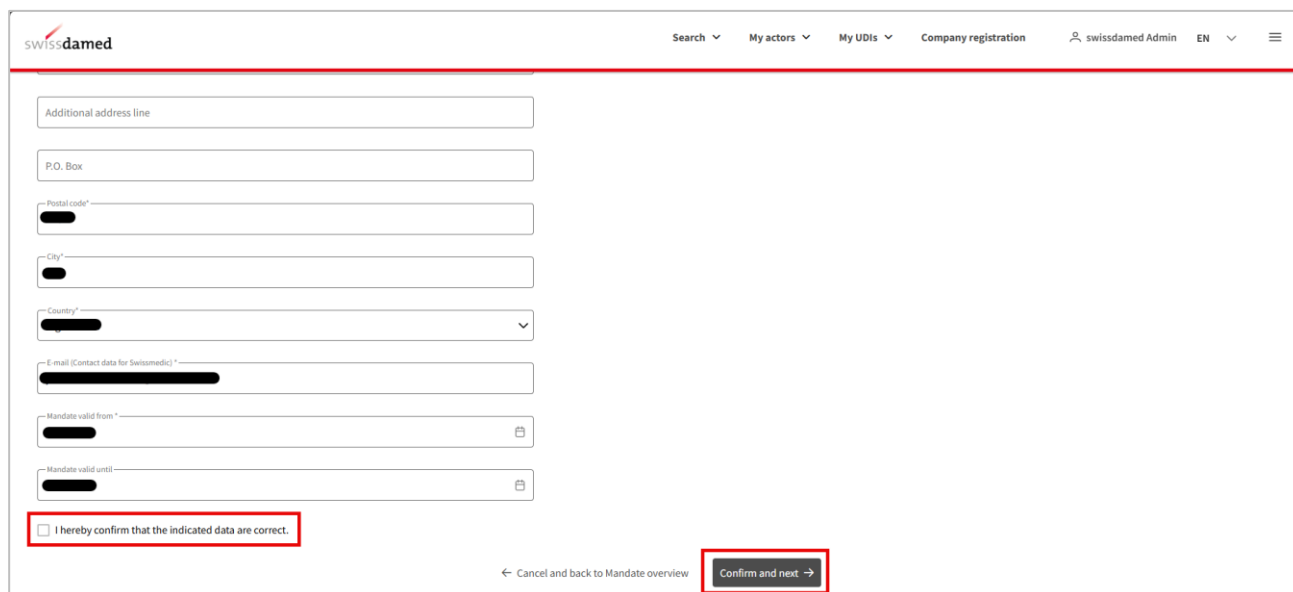5. If the change of role is successful, a confirmation appears.

3.3.4 Change data of a mandate

If you need to change the registered data of a mandate, you can do so by going to the "Mandates" tab in the "Actor details" of the corresponding authorised representative (AR).

1. Click on the pencil icon on the right of the mandate that you wish to update.

2. Change the data that needs to be updated. Confirm that the indicated data are correct and save your changes by clicking on the "Confirm and next" button.
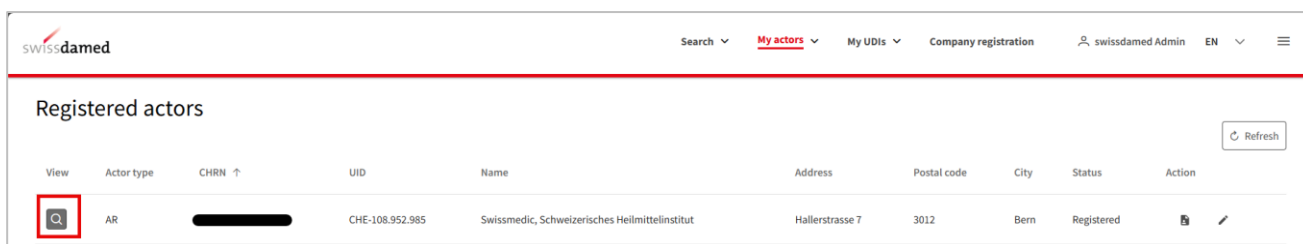
3. If the update was successful, a confirmation appears.
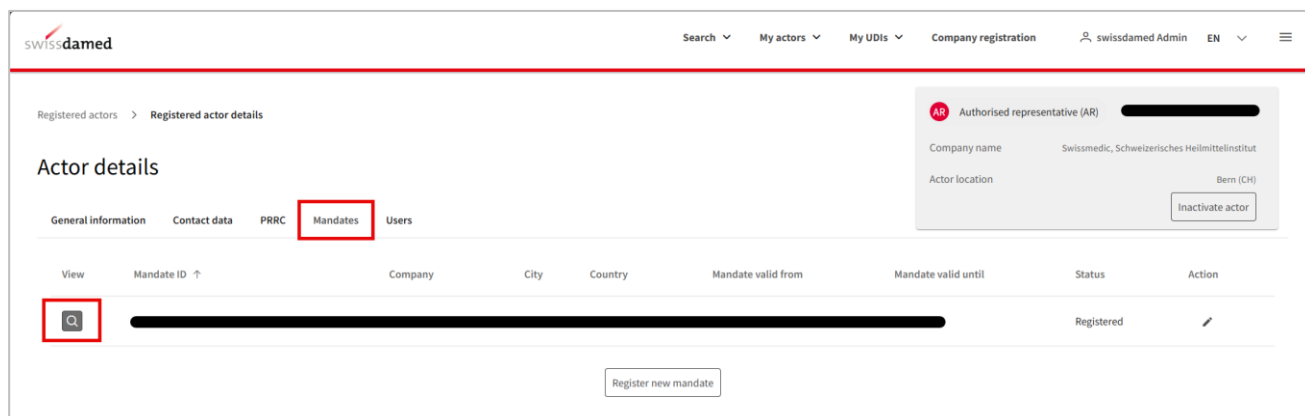
3.3.5   Inactivate a mandate

If you need to inactivate a mandate, you can do this by accessing the "Mandates" tab in the "Actor details" of the corresponding authorised representative (AR).

1. Click on "My actors", then choose from the dropdown "Registered actors". Open the actor details of the corresponding authorised representative (AR) by clicking on the magnifying glass icon.
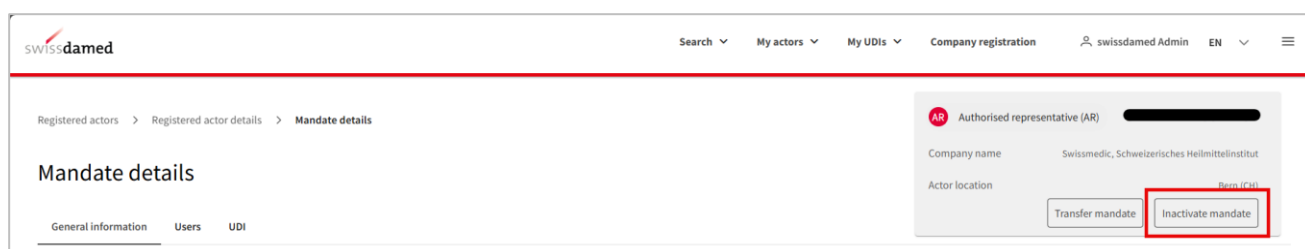

2. Click on the "Mandates" tab. Click on the magnifying glass icon of the desired mandate.

3. Click on the "Inactivate mandate" button.

4. Enter a reason for inactivating the mandate and confirm by clicking the "Inactivate" button.

3.3.6 Transfer of mandate to another authorised representative (AR)

If a mandate is transferred to another authorised representative, the mandate, including all registered medical devices, can be transferred to the new authorised representative in swissdamed by means of a mandate transfer.
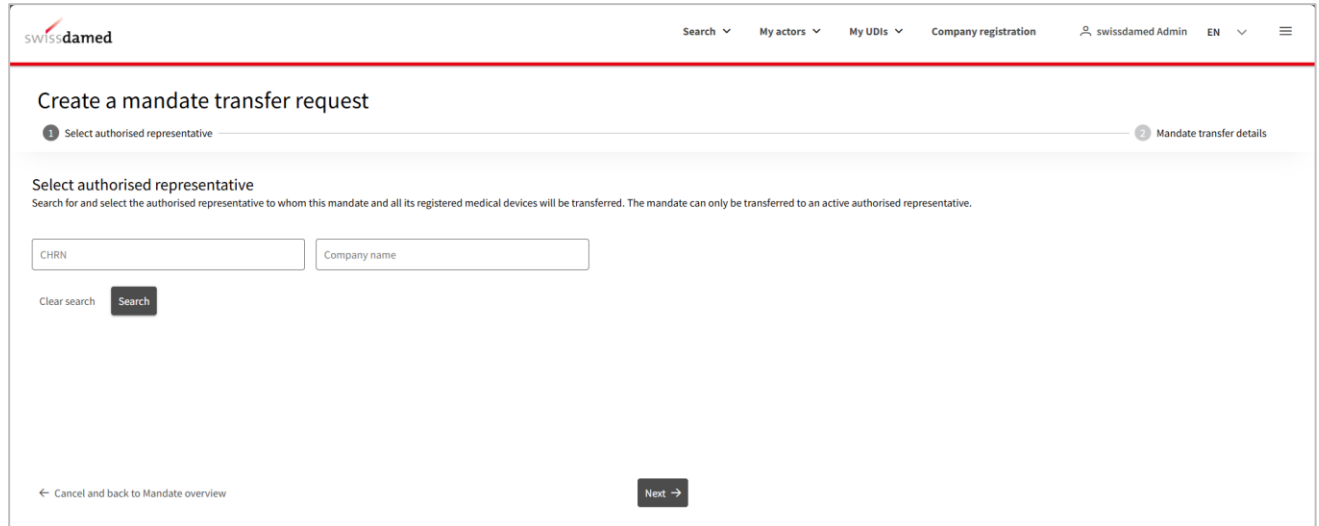
The existing authorised representative submits a request for a mandate transfer for their registered mandate to the new authorised representative. The prerequisite for this is that both the existing and the new authorised representative, as well as the mandate to be transferred, are registered in swissdamed and have the status "Registered". If the status of the new authorised representative is

changed to "Inactive" after the request has been submitted, the request for mandate transfer is automatically cancelled.

The request to transfer the mandate can be approved or rejected for the new authorised representative. If it is rejected, the mandate remains with the existing authorised representative. If it is approved, the mandate is transferred to the new authorised representative on the specified transfer date. If the new authorised representative has not processed the request by the transfer date, the request is automatically cancelled.

3.3.6.1 Existing authorised representative – Submit request to transfer mandate

If you wish to transfer a mandate to another authorised representative (AR), you can do so by following these steps:

1. Click on "My actors", then choose from the dropdown "Registered actors". Open the actor details of the corresponding authorised representative (AR) by clicking on the magnifying glass icon.
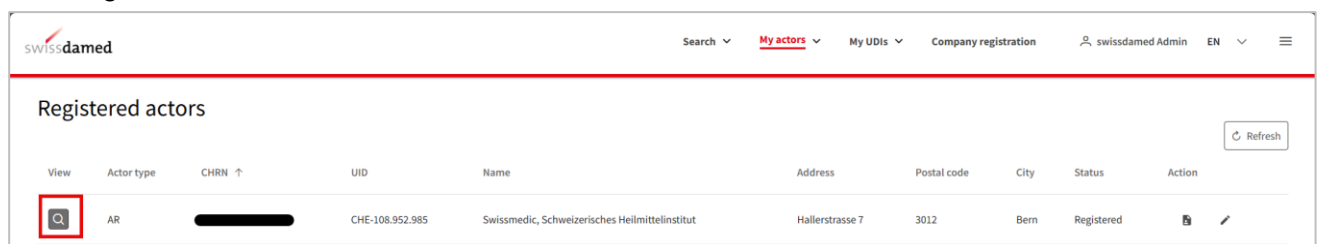
2. Click on the "Mandates" tab. Click on the magnifying glass icon of the desired mandate.
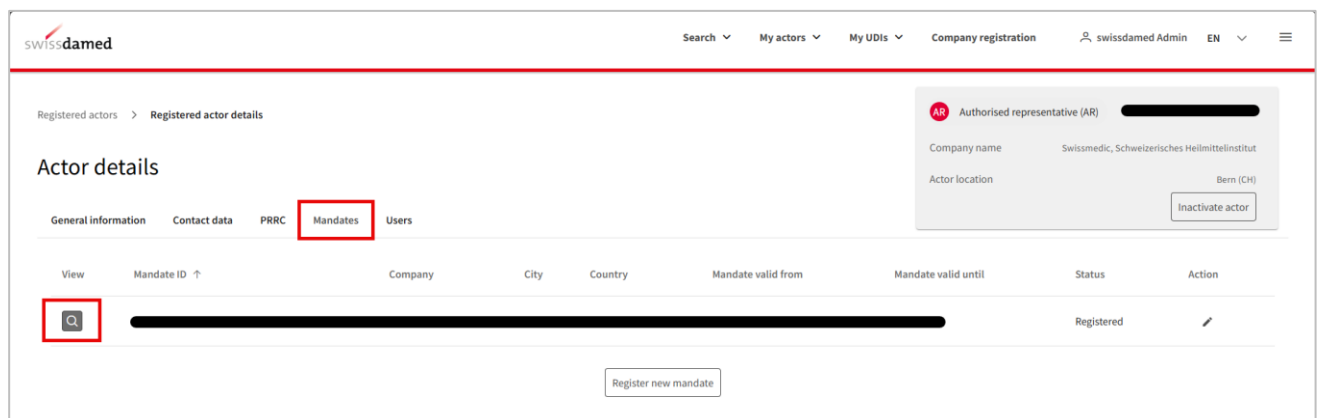
3. Click on the "Transfer mandate" button in the grey box at top right.
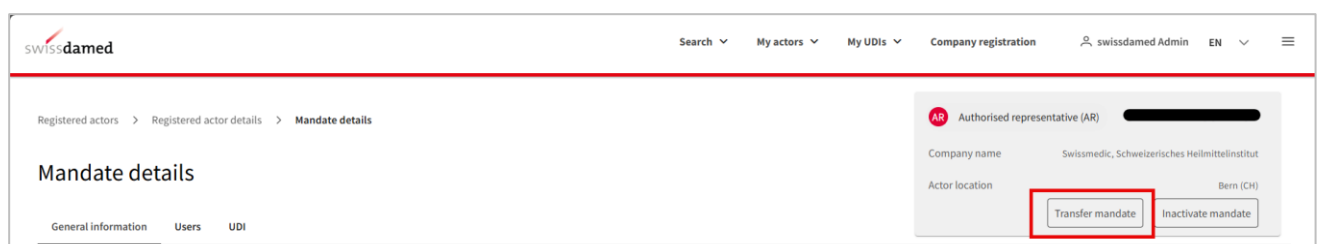
4. Search for the authorised representative to whom you wish to transfer the mandate. You can search for this person using the CHRN or the authorised representative's name.
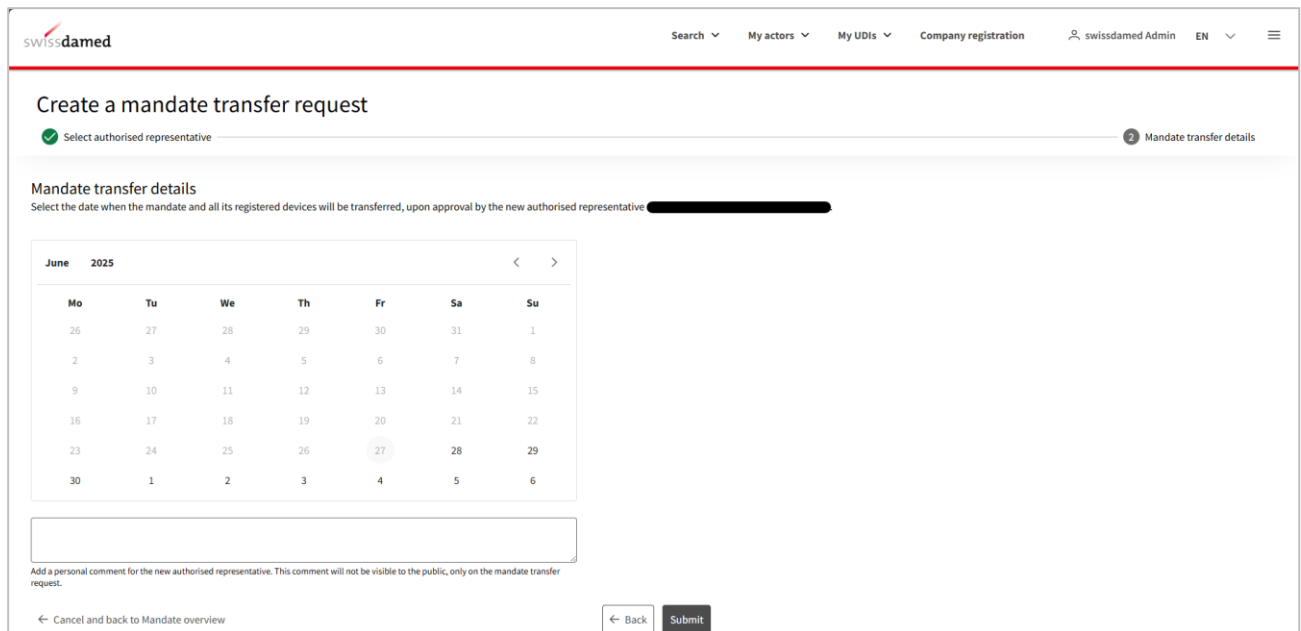
5. Select the authorised representative to whom you wish to transfer the mandate by clicking on the circle symbol. Click on "Next".
6. Select the date of the mandate transfer. You also have the option here to enter a comment for the new authorised representative.

7. Click on "Submit". A new window will open with instructions. Please read these through and submit the request for transfer by clicking on "Submit" again. If a transfer request already exists for the selected mandate, an error message will appear.
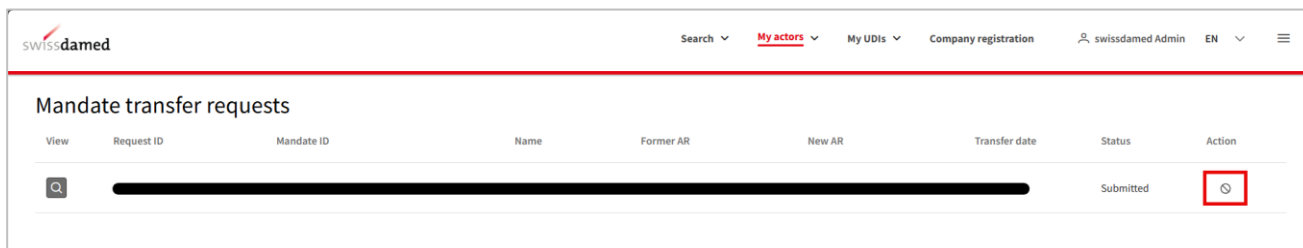
Once the request for a transfer of mandate has been submitted, the existing authorised representative will receive an e-mail summarising the request that has just been created.

The new authorised representative will receive an e-mail describing the next steps and the actions required to process the request.

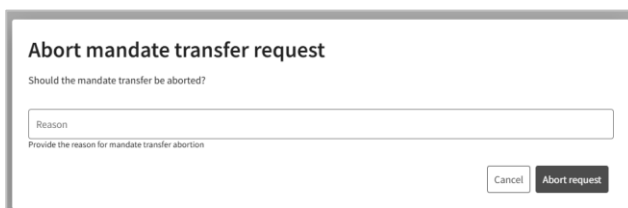### 3.3.6.2   Existing authorised representative – Cancel mandate transfer request

If the request for a transfer of mandate was submitted in error, the request can be cancelled by the existing authorised representative.

1. Click on "Mandate transfer request" via the "My actors" dropdown.
2. Click on the "Abort mandate transfer request" icon under "Action". A pop-up window will open.

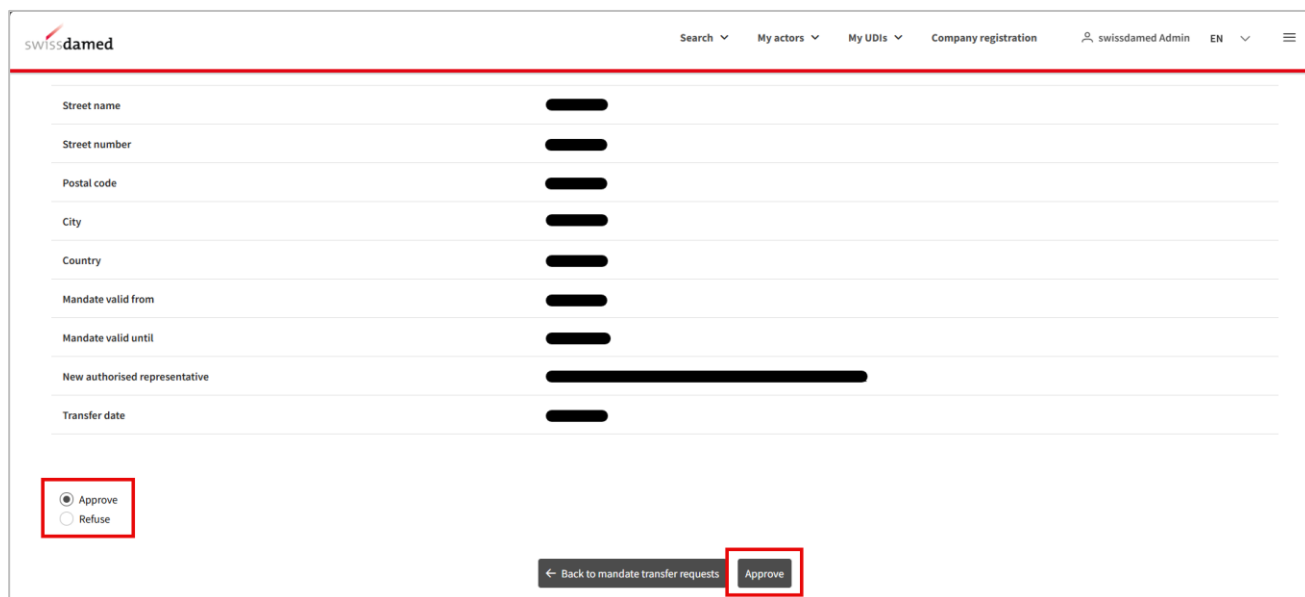3. Enter a reason for cancelling the request and click on "Abort request".
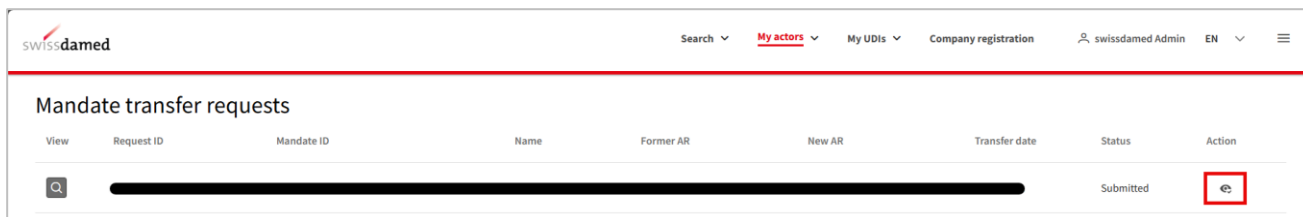
3.3.6.3   New authorised representative – Approve mandate transfer request

1. Click on "Mandate transfer request" via the "My actors" dropdown.
2. Click on the review symbol under "Action".

3. Review the mandate information.
4. If you agree to the transfer, select "Approve" and click the "Approve" button.
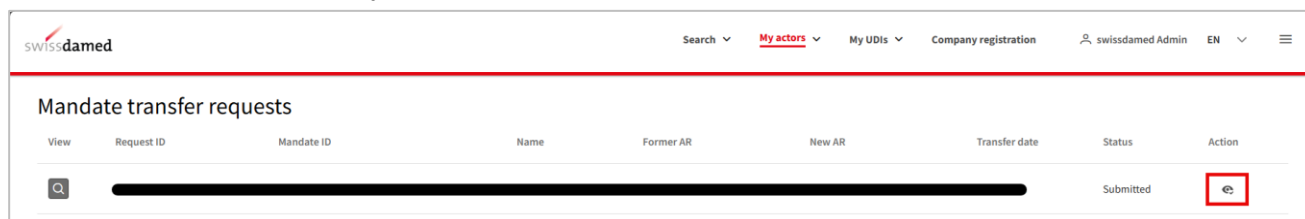
5. A pop-up window will open. Click "Approve" again.

The mandate and all its registered medical devices are transferred on the transfer date. If any data on the mandate is incorrect, you can correct it after the transfer (see section 3.3.4).

3.3.6.4 New authorised representative – Refuse mandate transfer request

1. Click on "Mandate transfer request" via the "My actors" dropdown.
2. Click on the review symbol under "Action".

3. Review the mandate information.
4. If you do not agree to the transfer, select "Refuse", enter a reason for the rejection and click the "Refuse" button.

5. A pop-up window will open. Click "Refuse" again.

The mandate and all of its registered medical devices will not be transferred and will remain with the existing authorised representative.

Change history

Version	Change	sig
1.3	Addition of cancellation / deletion of CHRN and creation of mandate transfer. General reorganisation of the content.	stj
1.2	Updates for go-live "Actors" module	sin / stj
1.1	Updates for go-live "Actors" module	sin / stj
1.0	First version for pilot swissdamed	lav / sin / red