

Handbook
swissdamed User Guide Actors

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1 Introduction

This user guide describes how actors can use the swissdamed actor registration module and is intended to provide 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 a **public site**:

- Company and actor-user registration and management
- Registration and management of devices
- Public search function

1.2 Actors and definitions

The actors involved in swissdamed are:

- **Manufacturers (MF)** – see Art. 4 para. 1 let. f MedDO and Art. 4 para. 1 let. e IvDO
- **Authorised representatives (AR)** – Art. 4 para. 1 let. g MedDO and Art. 4 para. 1 let. f IvDO
- **Importers (IM)** – see Art. 4 para. 1 let. h MedDO and Art. 4 para. 1 let. g IvDO
- **System and procedure pack producers (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

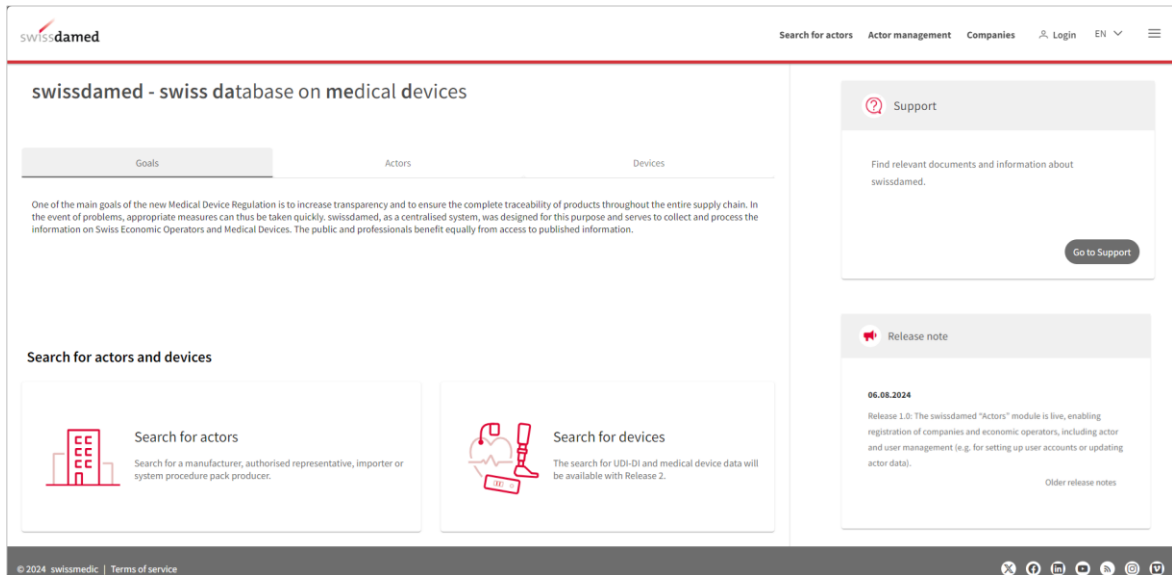
A CH-LOGIN (federal administration account) is required in order to access swissdamed. The CH-LOGIN is a standardised identification procedure provided by eIAM for users of certain federal internet portals, whether private individuals or actors. Each user must create a CH-LOGIN account to access swissdamed. 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](#)

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

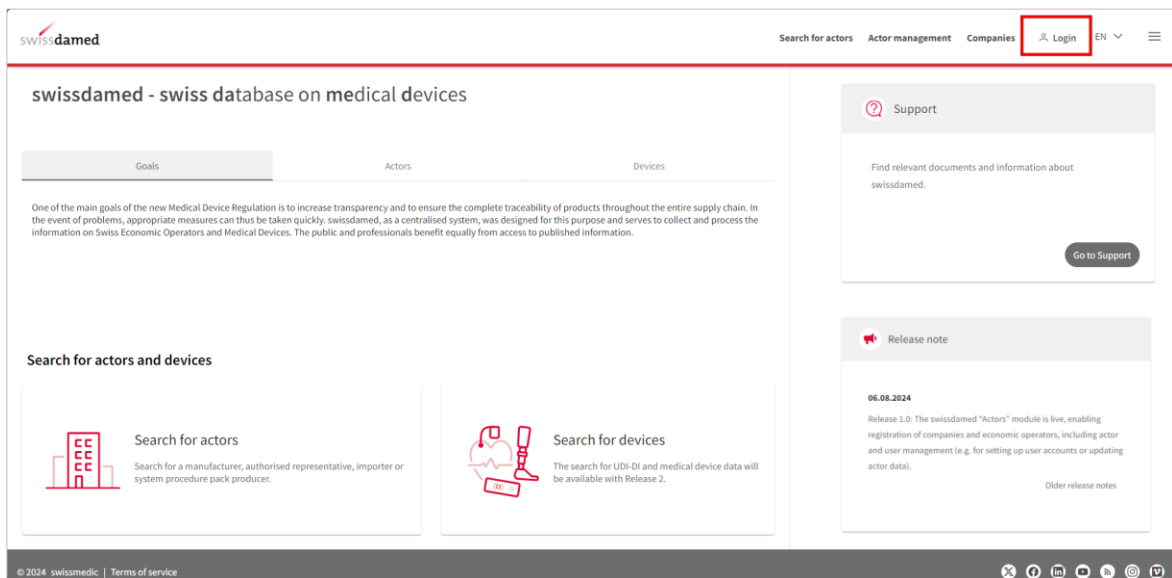
For more information about the CH-LOGIN account, visit: [CH-LOGIN FAQ — eIAM, Identity & Access Management of the Federal Administration](#)

1.3.1.1 To start swissdamed

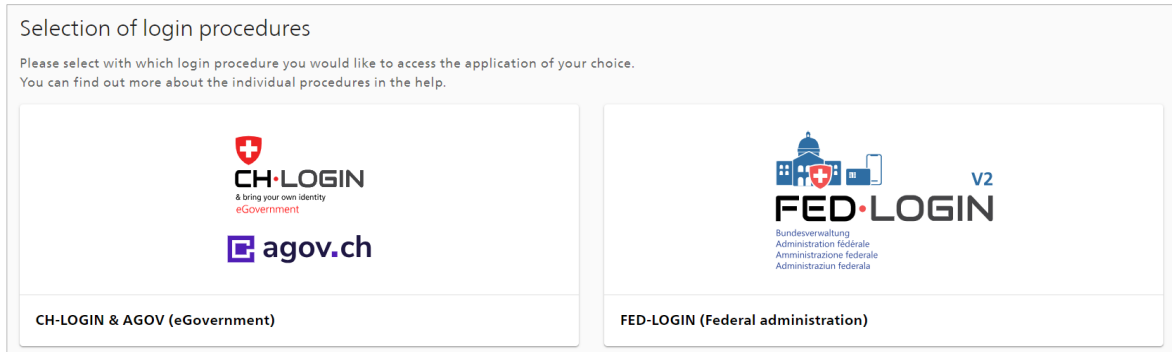
1. Go to the swissdamed site www.swissdamed.ch.



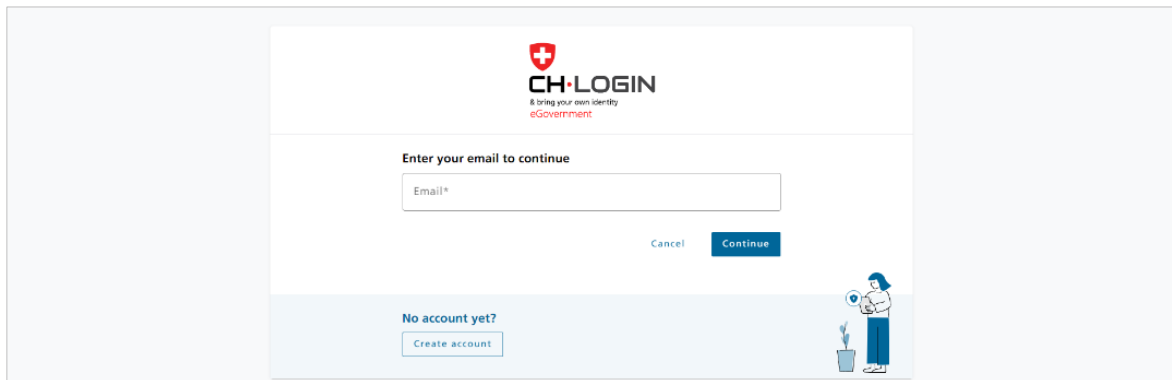
2. Click the “Login” button in the top right corner



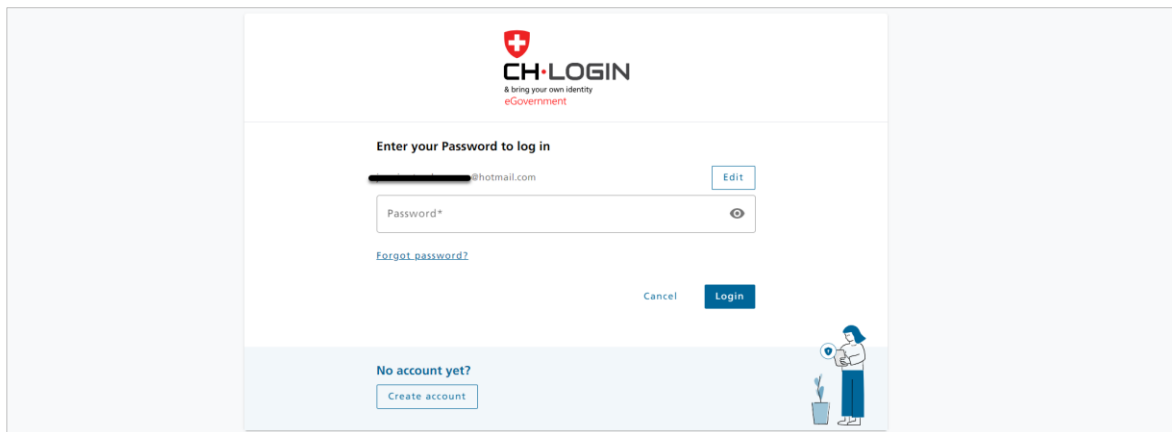
3. Select the “CH-LOGIN & AGOV (eGovernment)” procedure



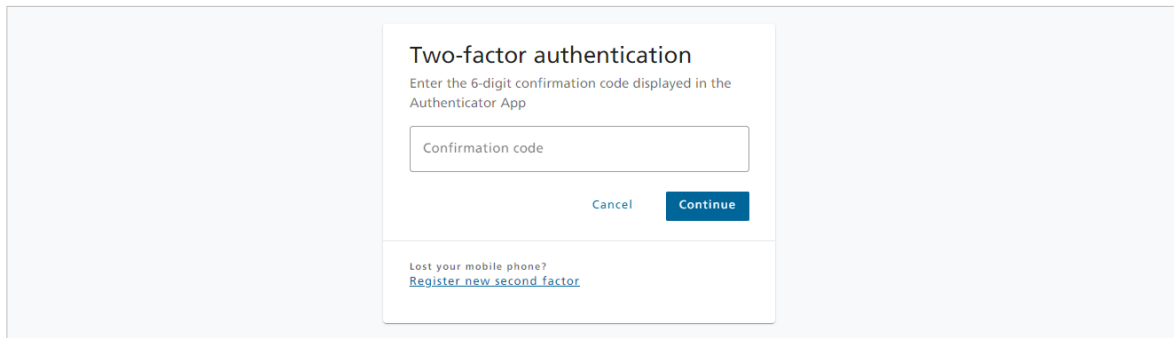
4. If you already have a CH-LOGIN account, enter your e-mail address and click “Continue” OR click “Create account” if you do not have one yet.



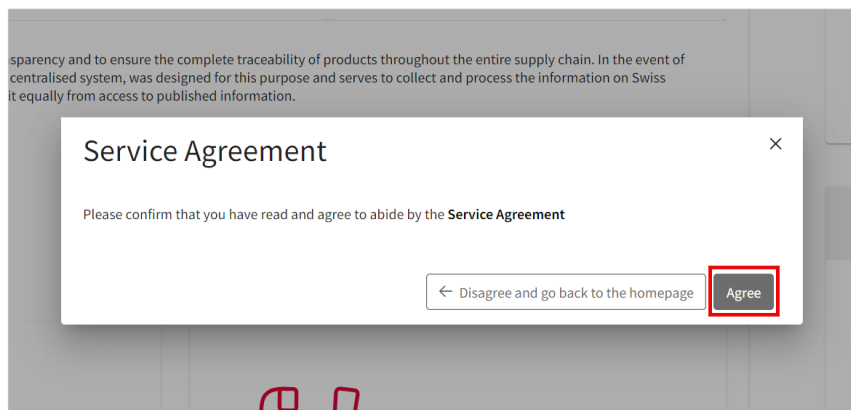
5. The second part of the CH-LOGIN - Sign-in page prompts you to enter your password. Enter your CH-LOGIN password and click “Login”.



- The third part of the CH-LOGIN - Sign-in page prompts you to enter the two-factor authentication code. Enter the two-factor authentication code and click “Continue”.

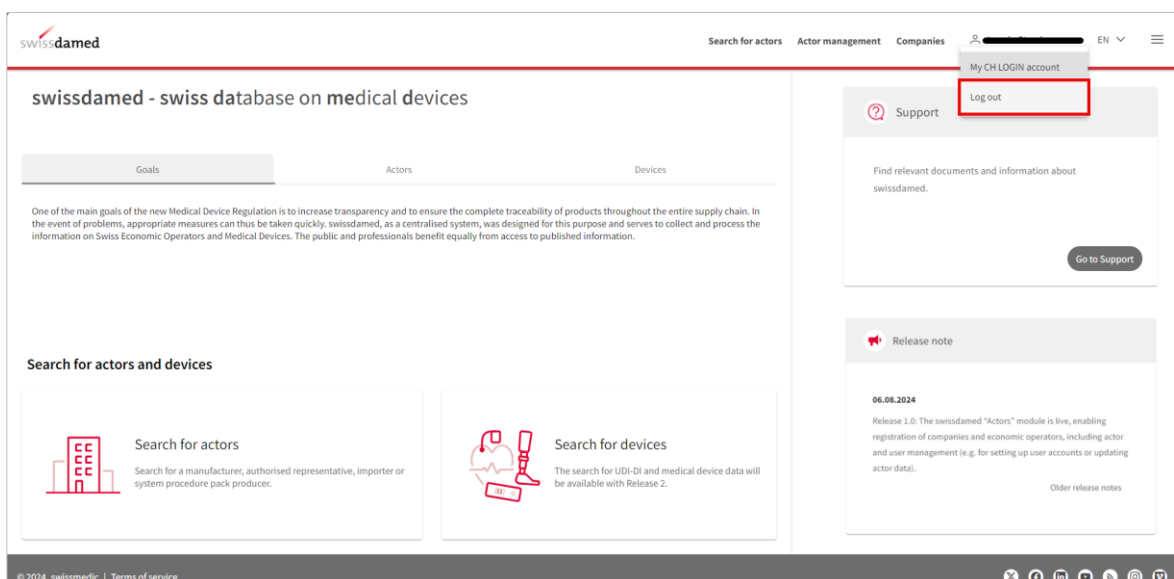


- When logging into swissdamed for the first time, you will be prompted to review and accept the service agreement. To continue using swissdamed, click “Agree”.



1.3.1.2 Logging out of swissdamed

- 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	<ul style="list-style-type: none"> ▪ After the initial login, whether through the creation of a CH-LOGIN 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	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ 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 Mandate admin	All	<ul style="list-style-type: none"> Can manage actor / mandate data respectively, as well as manage users associated with an actor or mandate. Have no rights to manage medical device data
UDI editor <i>Without impact until "Devices" module published</i>	All	<ul style="list-style-type: none"> Can manage medical device data, including tasks such as registering, updating and managing the market status of devices. This role will be assigned at the actor level for IM, MF and PR, but at the mandate level for AR. Users with this role cannot edit actor or mandate details, only medical devices. <p><i>Without impact until "Devices" module published</i></p>
Actor viewer Mandate viewer	All	<ul style="list-style-type: none"> Read-only permissions for actor / mandate and medical device 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

Register your actor in swissdamed with the appropriate actor role.

- The person who performs the actor registration automatically becomes actor admin for that actor once the registration is validated by Swissmedic.
- A Swiss Single Registration Number (CHRN) is generated by swissdamed and issued by the 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.

3 How to operate in swissdamed - Instructions

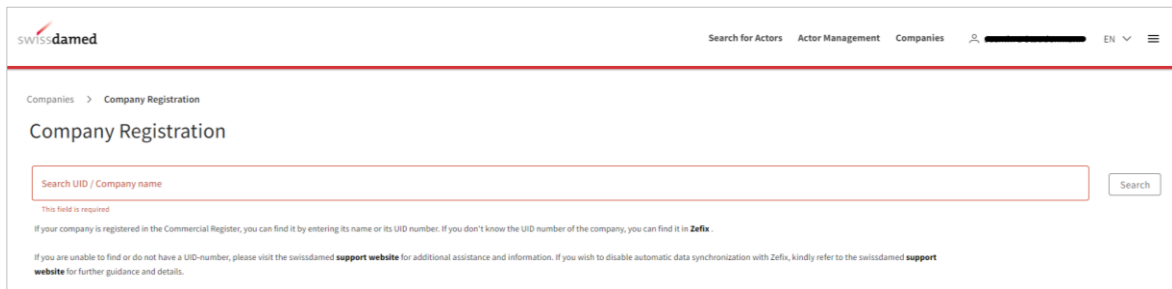
3.1 Register a company

The first step to take after successfully logging into swissdamed is to register your company. To do so, follow the instructions below:

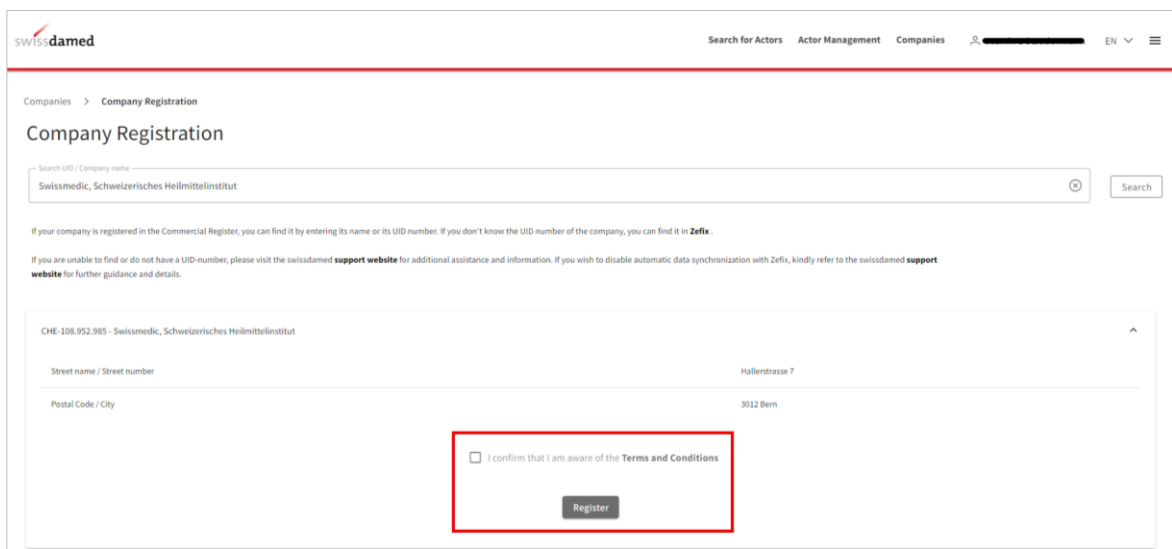
1. Go to the “Companies” tab and click the button “Register new company”.



2. Search for your company in the search field. The results from the search come from the [Central Business Name Index - Welcome \(zefix.ch\)](https://www.zefix.ch).



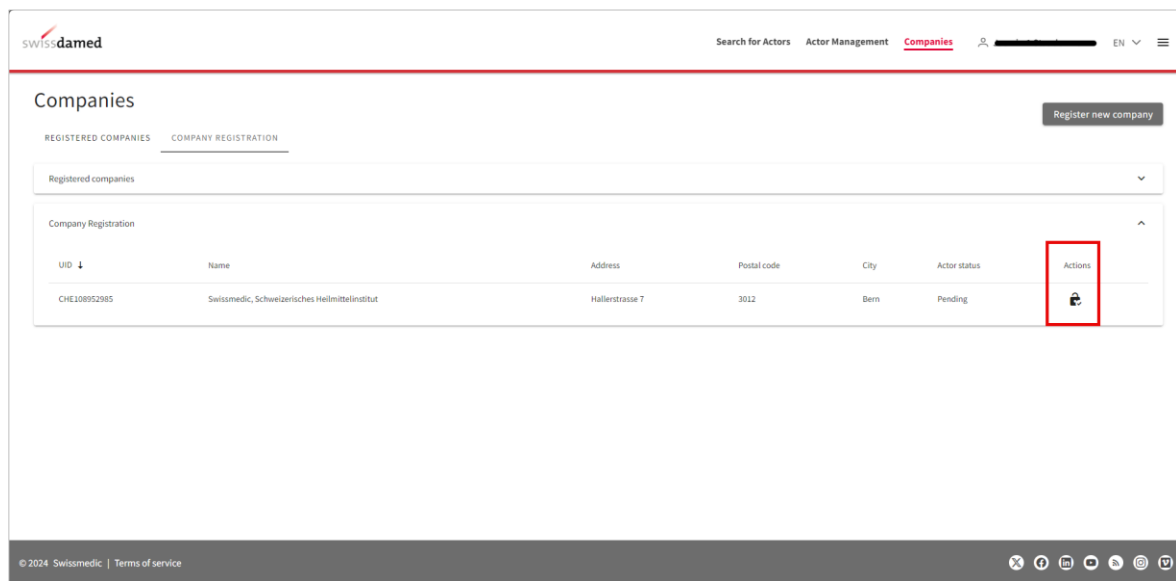
3. Select the desired company, tick the box “I confirm that I am aware of the Terms and Conditions” and click “Register”.



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 till you receive the verification letter by Swiss Post.
6. Once you have received the letter, log in to swissdamed, go to “Companies” 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:

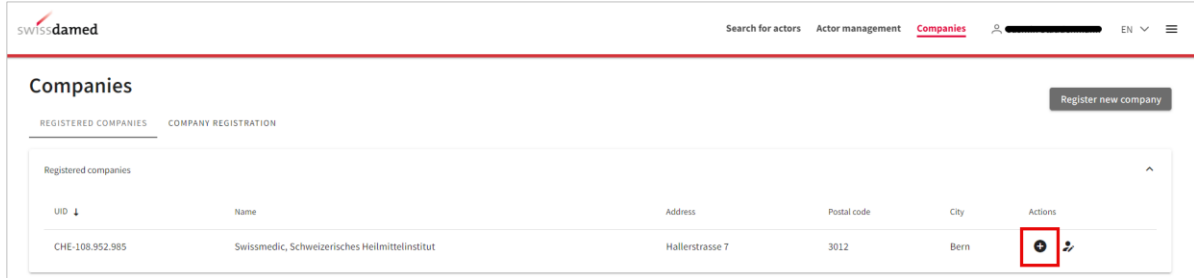
Swissmedic, Schweizerisches Heilmittelinstitut
 Hallerstrasse 7
 3012 Bern
 CHE108952985

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

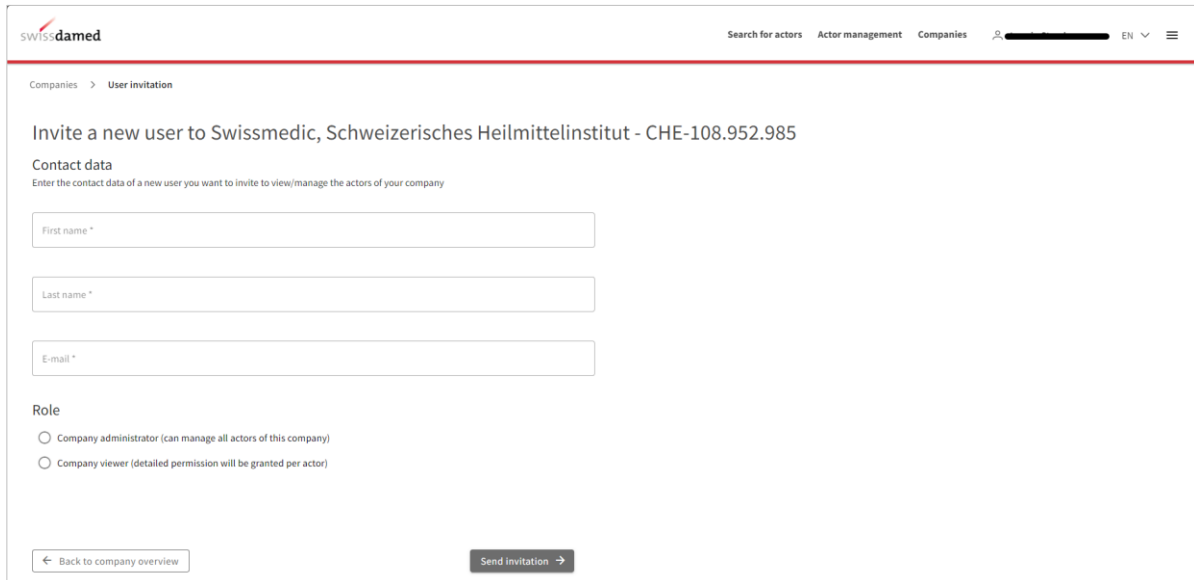
8. A confirmation appears telling you that the registration of your company has been successfully completed. The text above the icon explains what to do next: *“To begin using the company, please log out of the application. Once you log back in, the registered company CHE123456789 - XXX will be visible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

3.1.1 Add user(s) to the company

1. Go to “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.



Invite a new user to Swissmedic, Schweizerisches Heilmittelinstitut - CHE-108.952.985

Contact data
Enter the contact data of a new user you want to invite to view/manage the actors of your company

First name *

Last name *

E-mail *

Role

Company administrator (can manage all actors of this company)

Company viewer (detailed permission will be granted per actor)

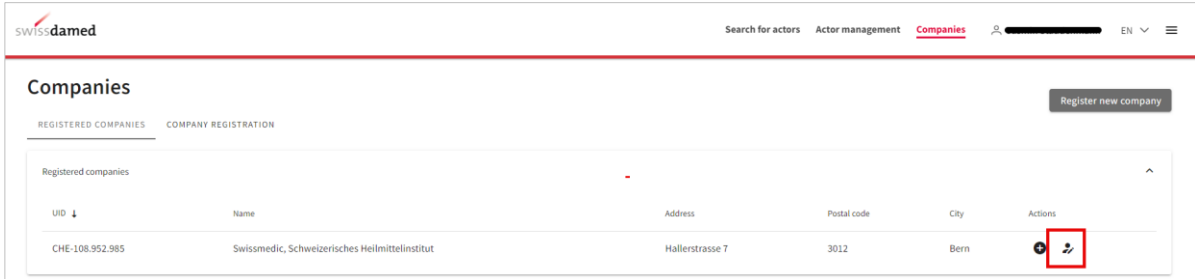
[← Back to company overview](#) [Send invitation →](#)

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 account). The person will have to follow the instructions, using the link and code provided.

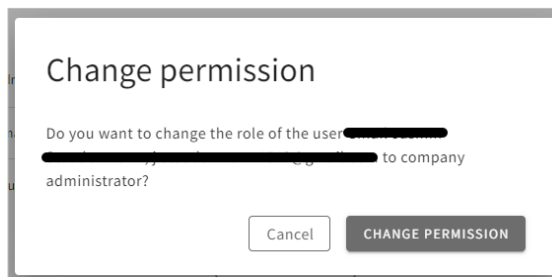
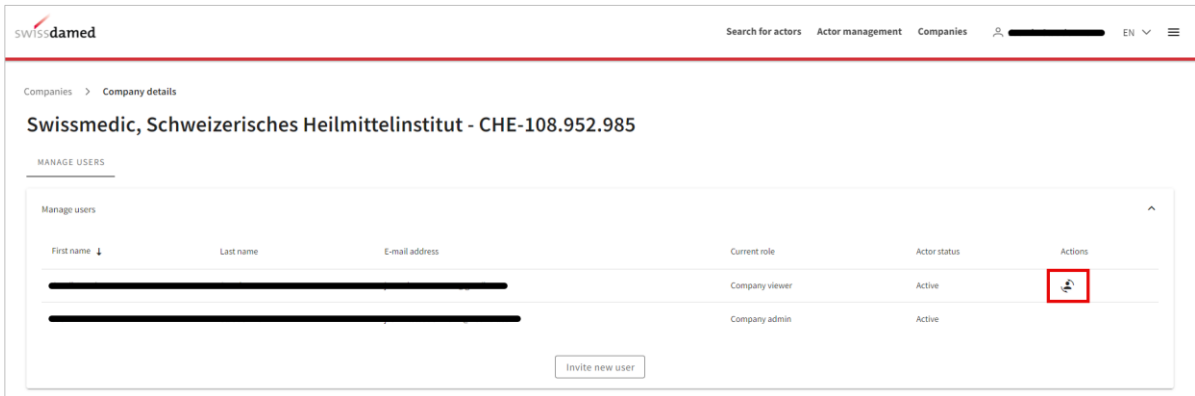
If the user already has a CH-LOGIN account, the e-mail will contain information about the invitation and the new role in the company.

3.1.2 Manage company users

1. Once the user is onboarded, their status can be checked in the “Registered companies” tab under “Companies”, 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 under the “Actions” column, you can edit the role of the users.

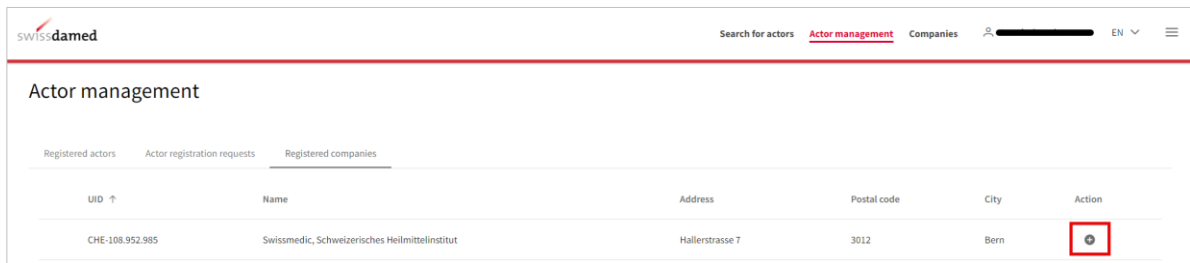



3.1.3 Change data of a company

1. The general information, such as 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.

3.2 Register an actor

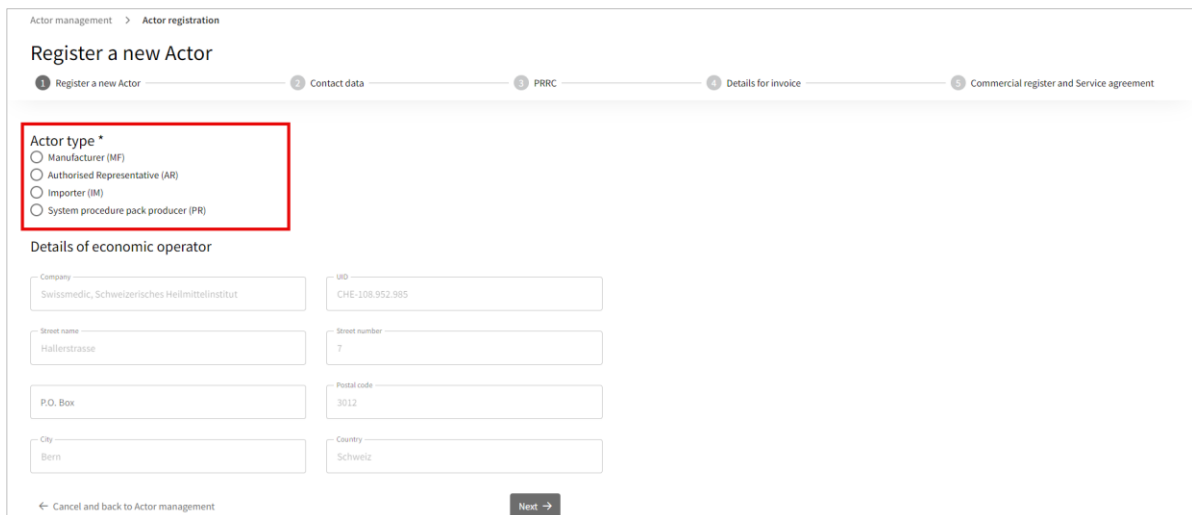
1. Log in to swissdamed with your CH-LOGIN account and go to your “Registered companies” in the “Actor management” tab. Click on the “Register a new actor” (“+” icon) action button on the right of the company to which you want to add an actor. A new page will open with a form to fill.



UID ↑	Name	Address	Postal code	City	Action
CHE-108.952.985	Swissmedic, Schweizerisches Heilmittelinstitut	Hallerstrasse 7	3012	Bern	

**If you go to the “Actor management” tab without having been granted company permission, you will see a notification stating, “No company permission found.” → Ask your company admin to assign you a role.*

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.



Actor management > Actor registration

Register a new Actor

1 Register a new Actor 2 Contact data 3 PRRC 4 Details for invoice 5 Commercial register and Service agreement

Actor type *

- Manufacturer (MF)
- Authorised Representative (AR)
- Importer (IM)
- System procedure pack producer (PR)

Details of economic operator

Company: Swissmedic, Schweizerisches Heilmittelinstitut UID: CHE-108.952.985

Street name: Hallerstrasse Street number: 7

P.O. Box: Postal code: 3012

City: Bern Country: Schweiz

← Cancel and back to Actor management **Next** →

- 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.

SWISSdamed Search for actors Actor management Companies EN

Actor management > Actor registration

Register a new Actor

Register a new Actor Contact data PRRC Details for invoice Commercial register and Service agreement

Commercial register and Service agreement *

Documentation to be supplied

Please upload the excerpt from the commercial register of your economic operator. If you are a natural person, please upload your residential address registration document. Note that the required documentation should not be older than 3 months. *

Drag and drop files to here to upload.

+ Choose file

The requesting company or natural person acknowledges to be aware of and abide by the [Service agreement](#)

I confirm that the indicated data are correct

← Back Submit → Preview actor request

- Submit the actor registration request to Swissmedic by clicking on the “Submit” button.
- If the request was successfully submitted, a confirmation appears. Swissmedic will check the request and assess it.
- In the meantime, the status of your request can be checked in the “Actor registration requests” overview in the “Actor management” tab.

SWISSdamed Search for actors Actor management Companies EN

Actor management

Registered actors Actor registration requests Registered companies

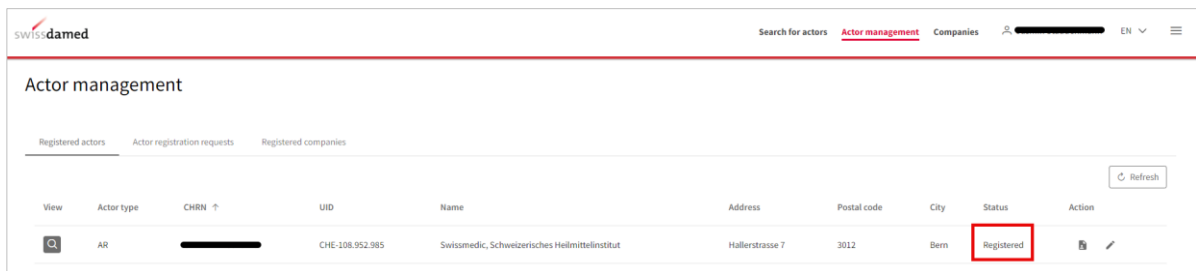
View	Application ID ↑	Actor type	Name	City	Creation date / time	Status	Action
	AT-REG-000003699	AR	Swissmedic, Schweizerisches Heilmittelinstitut	Bern	24.07.2024 - 10:38	Submitted	

- 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” overview in the “Actor management” tab, and your actor will be available in the “Registered actors” tab with the status “Registered”.

If your request needs correction, your request will remain in the “Actor registration requests” overview in the “Actor management” tab but with the status “Correction requested” and the option to edit the actor registration request (pencil icon in the action column).

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



3.2.1 Add user(s) to the actor

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 3.1.1 of this user guide.

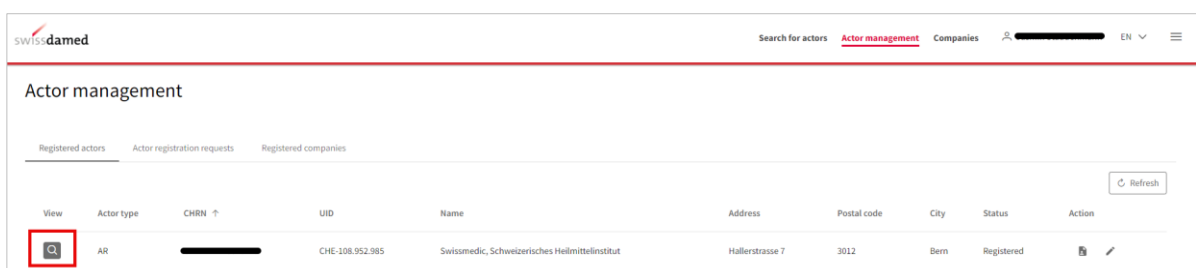
As soon as the desired user is registered in the company, they will automatically appear in the user list of the actors of that company. The following table shows which role will be automatically assigned at actor level to the company users.

Company role assigned	Actor role automatically assigned
Company admin	Actor admin & UDI editor
Company viewer	None

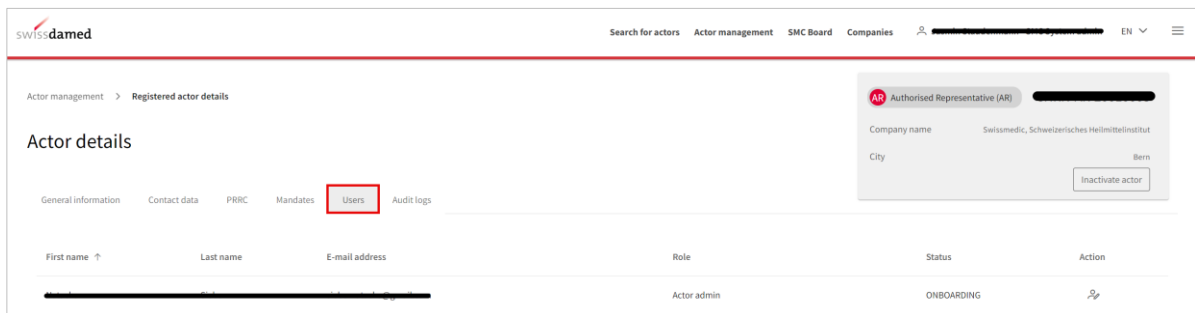
3.2.2 Manage actor users

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.

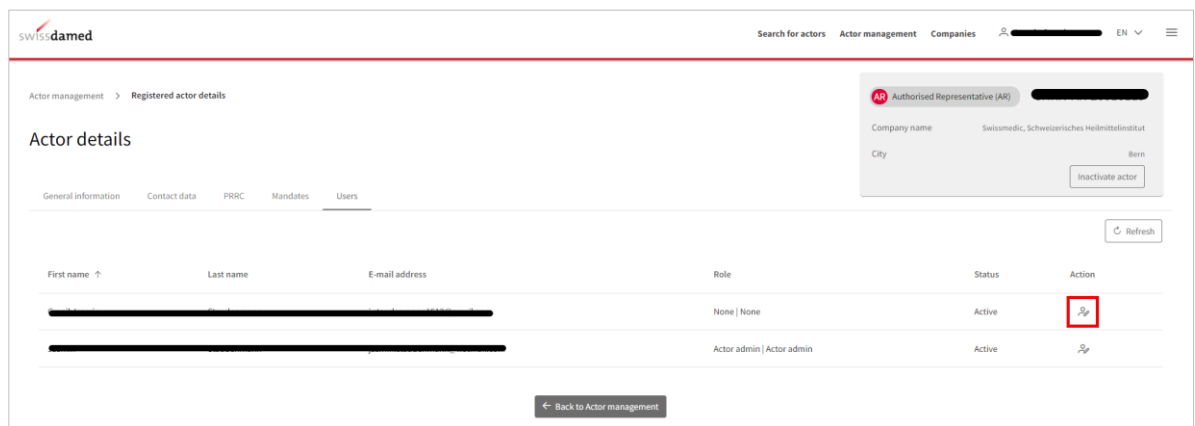
- Open the “Actor details” of the desired actor by clicking on the magnifier icon.



- Once in the “Actor details” view, open the “Users” tab. All users from the company are listed there with their role and status.



- If you want to change the role of one of the actors, click on the change permission button (character icon on the right)



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). For example, “Actor viewer”. Click on the “Change permission” button to validate your choice.

Change permission

Change permission for Jasmin Staudenmann

Has actor roles

Yes
 No

Actor roles

Actor admin (can edit actor details, manage users but not the devices)
 Actor viewer (can see actor data)

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

3.2.3 Change data of an actor

If you need to change the registered data of an actor, you can do so by going to the “Registered actors” overview.

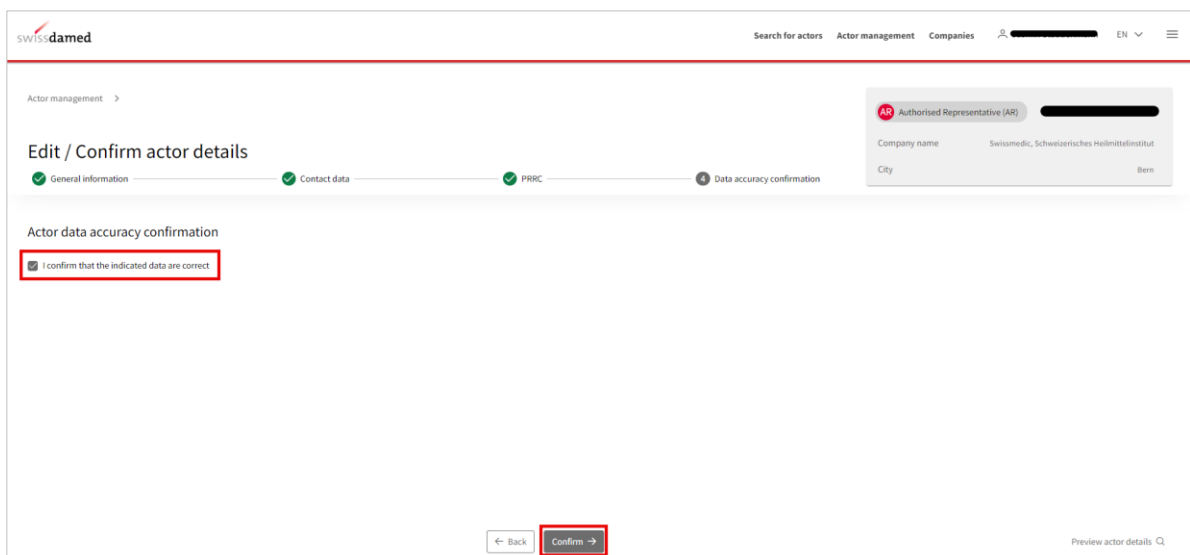
1. Click on the pencil icon on the right of the actor that you wish to update.



2. Change the data that needs to be updated. Confirm that the data are correct and submit 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.

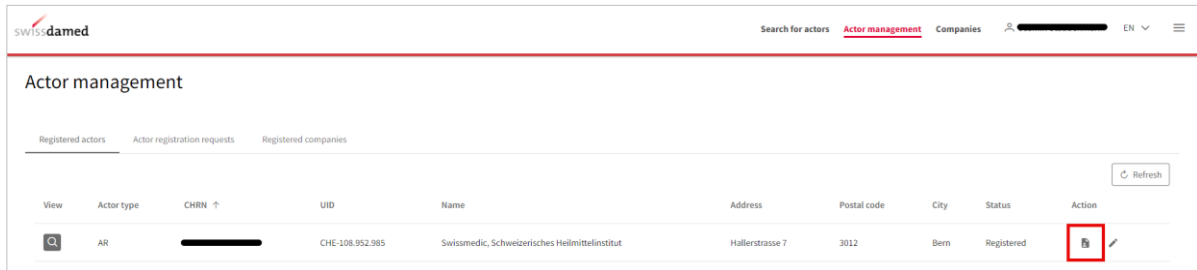


3. If the update was successful, a confirmation appears.

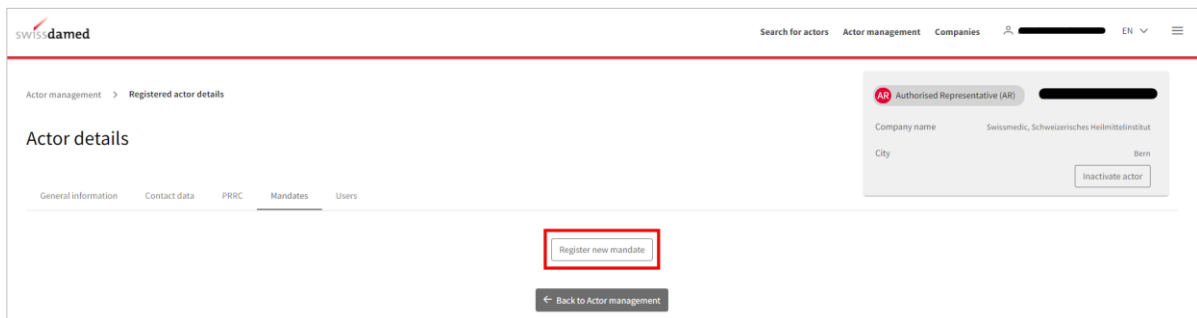
3.3 Register a mandate

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 already the case, follow the steps below to register a new mandate:

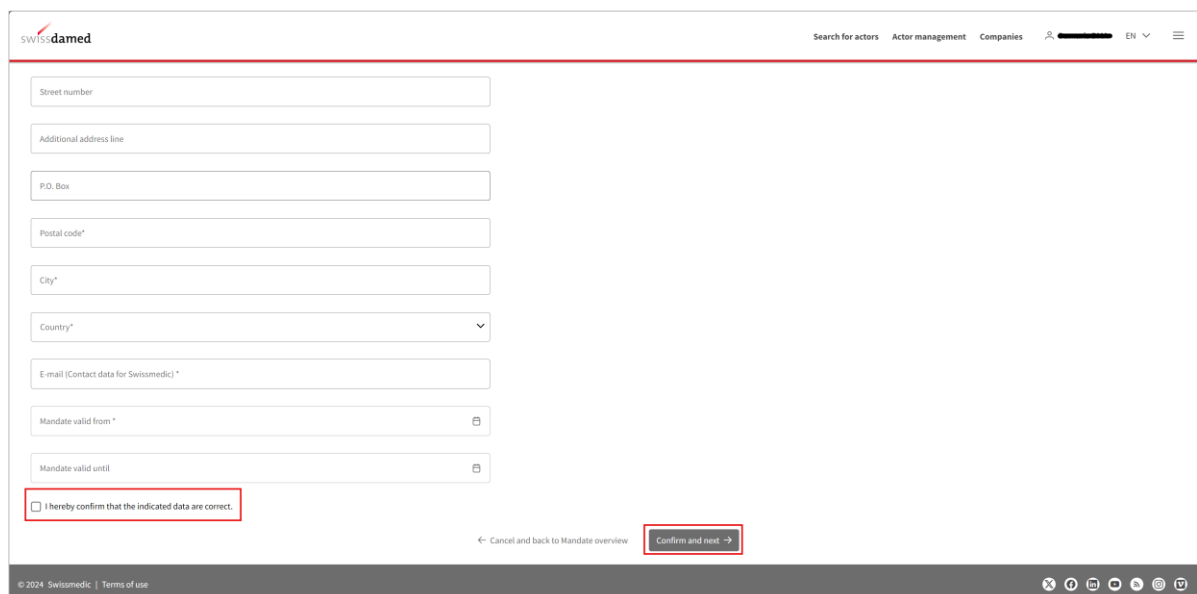
1. Go to the “Registered actors” overview in the “Actor management” tab. Click on the icon “Go to mandates” of the authorised representative actor to whom you want to add a mandate.



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.



Street number

Additional address line

P.O. Box

Postal code*

City*

Country*

E-mail (Contact data for Swissmedic) *

Mandate valid from *

Mandate valid until

I hereby confirm that the indicated data are correct.

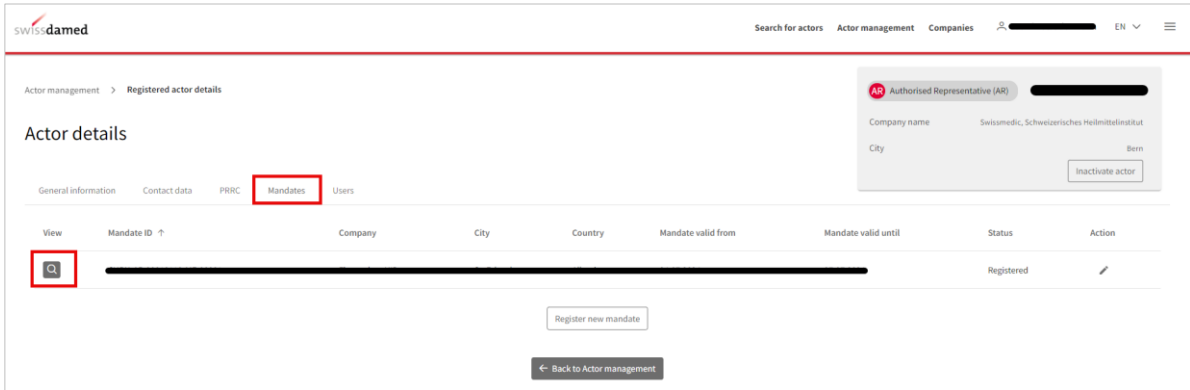
[Cancel and back to Mandate overview](#) [Confirm and next](#)

4. If the registration was successful, a confirmation appears.

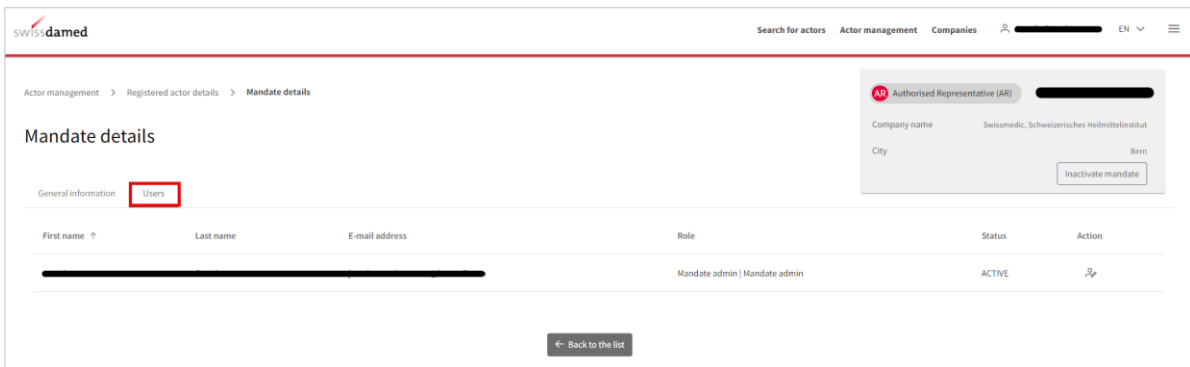
3.3.1 Manage mandate users

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:

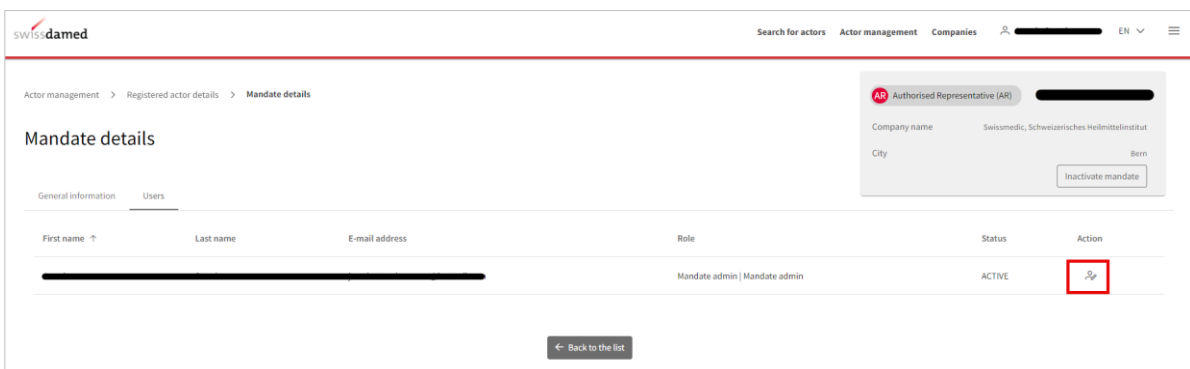
1. Open the “Mandate details” by clicking on the magnifier icon next to the chosen mandate.



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 to 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. For example, “UDI editor”. Click on the “Change permission” button to validate your choice.

Change permission

Change permission for Jasmin Staudenmann

Has mandate roles

Yes
 No

Mandate roles

Mandate admin (can edit mandate details, manage users but not the devices)
 UDI editor (can manage medical devices)
 Mandate viewer (can see mandate data)

5. If the change of role is 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 3.1.1 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.

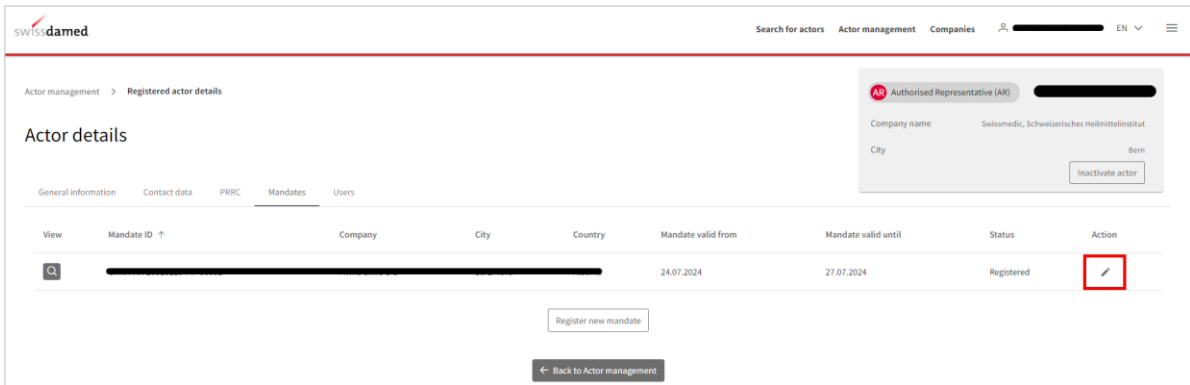
Company role assigned	Actor role automatically assigned	Mandate role automatically assigned
Company admin	Actor admin	Mandate admin & UDI editor
Company viewer	None	-

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.

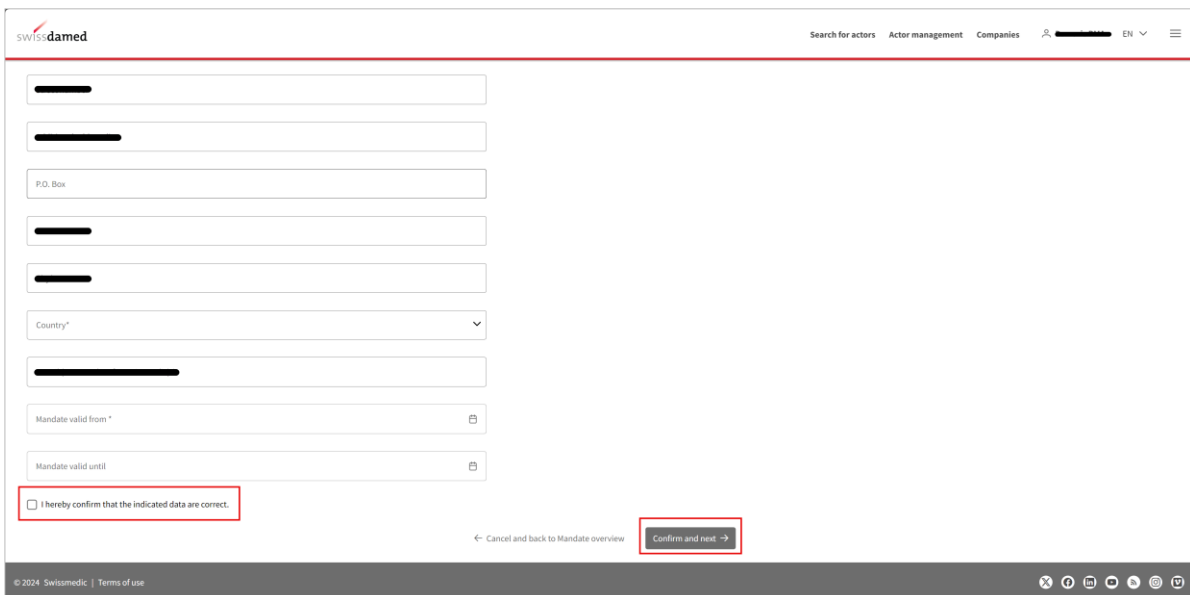
3.3.3 Change data of a mandate

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 register your changes by clicking on the “Publish mandate” button.



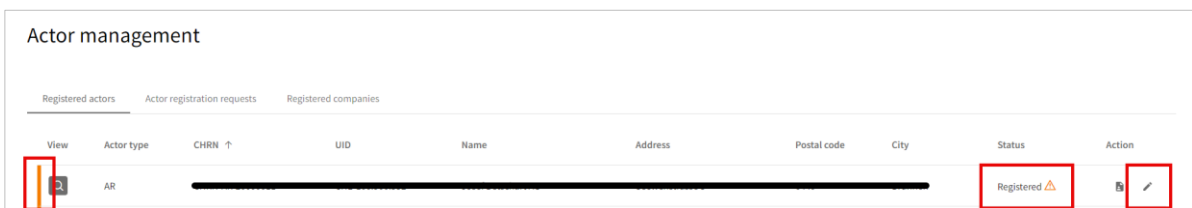
3. If the update was successful, a confirmation appears.




3.4 Validate your actor details

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

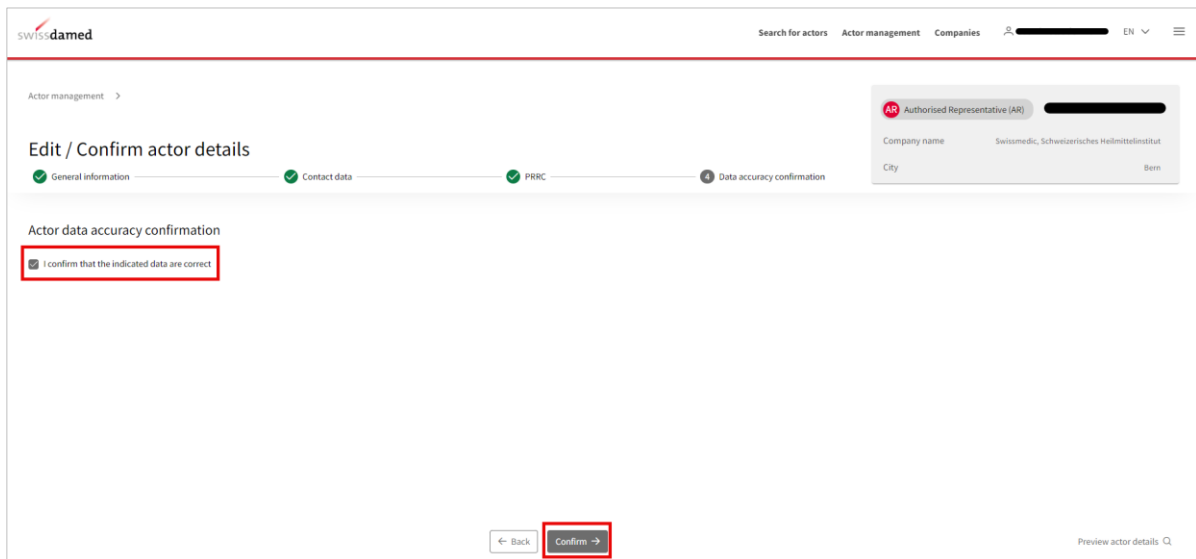
Twelve months after the creation of a new actor and then every two years, an e-mail from swissdamed is sent to the contact e-mail address and the actor admin(s) asking them to confirm the actor data registered in swissdamed. The respective actor who needs to confirm the data is marked (in orange) in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

1. To confirm or update your actor data, click on the pen icon on the right of the relevant actor.



View	Actor type	CHRN ↑	UID	Name	Address	Postal code	City	Status	Action
	AR							Registered 	

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.



swissdamed Search for actors Actor management Companies EN

Actor management >

AR Authorised Representative (AR)

Company name Swissmedic, Schweizerisches Helmitel Institut
City Bern

Edit / Confirm actor details

General information Contact data PRRIC Data accuracy confirmation

Actor data accuracy confirmation

I confirm that the indicated data are correct

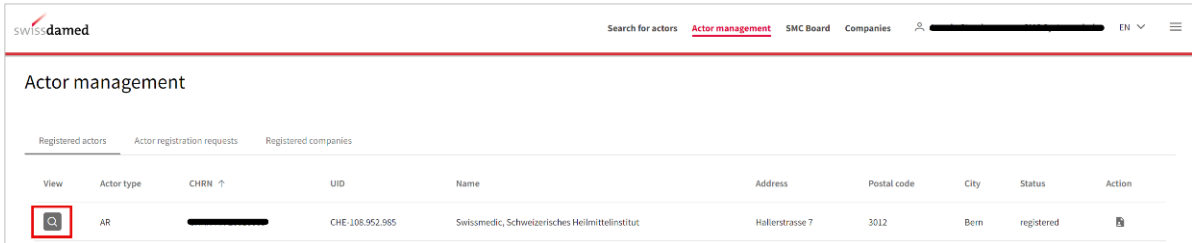
← Back Confirm → Preview actor details

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

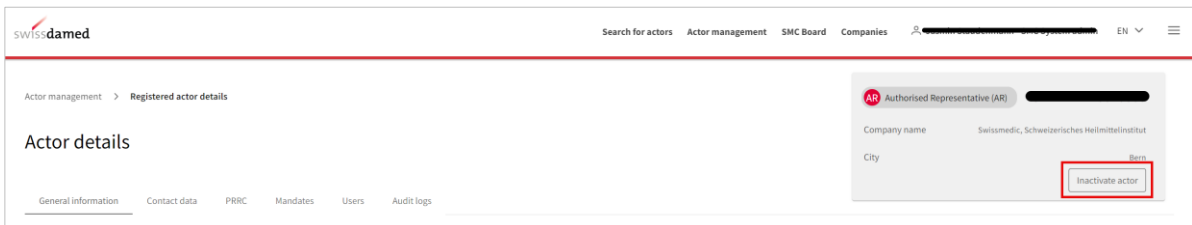
3.5 Inactivate an actor

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

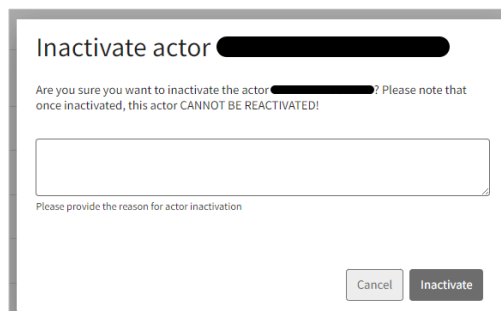
1. Go to the list of your “Registered actors” in the “Actor management” tab and click on the magnifier icon on the left of the actor that you want to inactivate.



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. Please note that once inactivated, this actor CANNOT be reactivated!



4. If the inactivation is successful, a confirmation appears.

- Inactivated actors are shown in grey in the list of the registered actors, and an information box is also added in the actor details.

View	Actor type	CHRN ↑	UID	Name	Address	Postal code	City	Status	Action
	AR	[redacted]	CHE-108.952.985	Swissmedic, Schweizerisches Heilmittelinstitut	Hallerstrasse 7	3012	Bern	Registered	
	IM	[redacted]	CHE-108.952.985	Swissmedic, Schweizerisches Heilmittelinstitut	Hallerstrasse 7	3012	Bern	inactive	

Actor management > Registered actor details

Actor details

This actor is inactive since 24.07.2024

IM Importer (IM) [redacted]

Company name: Swissmedic, Schweizerisches Heilmittelinstitut

City: Bern

3.6 Search for an actor

- In the “Search for actors” tab you have the possibility of searching for an actor by
 - Company name (minimum 2 characters)
 - CHRN (max. 16 characters) → Example: CHRN-MF-01234567
 - UID (max. 15 characters)
 - Actor type
 - City
 - Country
 - Actor status

Search for actors

The search for actors allows you to search and retrieve all records that contain the search terms you enter. At least one search criterion is mandatory.

Company name: CHRN: UID:

Actor type: City: Country: Actor status:

Clear search

- If you want to delete the filters, click on the “Clear search” button under the search fields on the left.

Change history

Version	Change	sig
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