

Handbook
swissdamed User Guide Actors

Identification number: BW630_40_001
Version: 1.1
Valid from: 08.05.2024

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1 Introduction

How actors can use the actor registration module – concept, registration, management, access and mandates.

This actor user guide is intended to provide companies with an overview 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** - see Art. 4 para. 1 let. f MedDO and Art. 4 para. 1 let. e IvDO
- **Authorised Representatives** - Art. 4 para. 1 let. g MedDO and Art. 4 para. 1 let. f IvDO
- **Importers** - see Art. 4 para. 1 let. h MedDO and Art. 4 para. 1 let. g IvDO
- **System and procedure pack producers** - 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. 1 MedDO / Art. 48 para. 1 IvDO

1.3 Application basics

This section describes a number of basic principles that you will acquire very quickly as you become familiar with swissdamed. These include:

- Starting and ending a swissdamed session
- Understanding the basic concepts
- Understanding user profiles and access grants/rights

1.3.1 Accessing 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

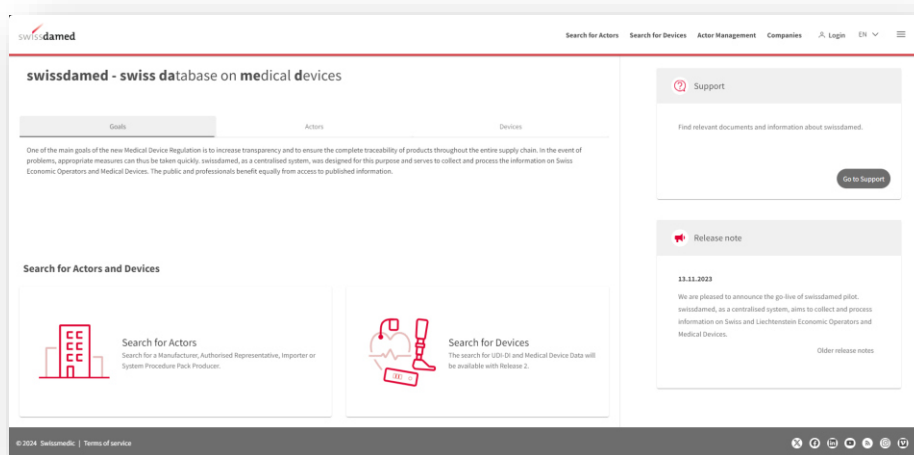
authentication process and to reset the personal password. If you do not have a CH-LOGIN yet, please follow the instructions here: [CH-LOGIN - Registration — eIAM Help Pages](#)

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

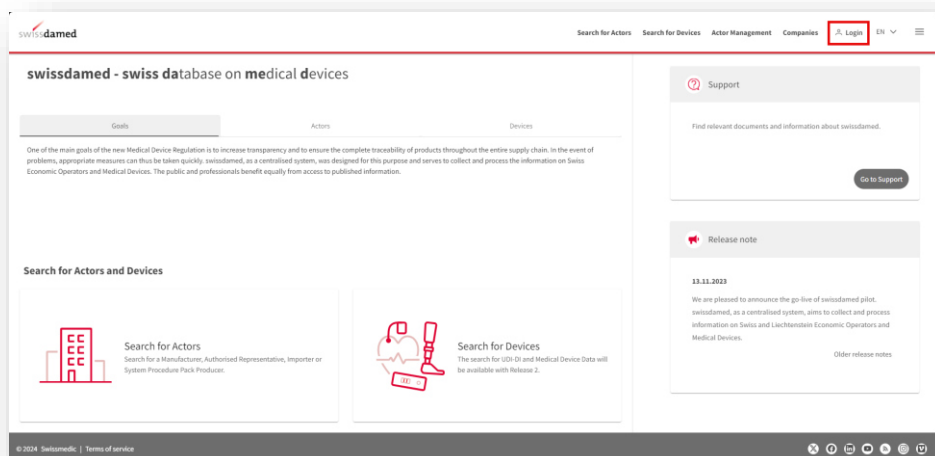
For more information about the CH-LOGIN account, visit: [CH-LOGIN FAQ — eIAM, Identity & Access Management of the Federal Administration](#)

1.3.1.1 To start swissdamed

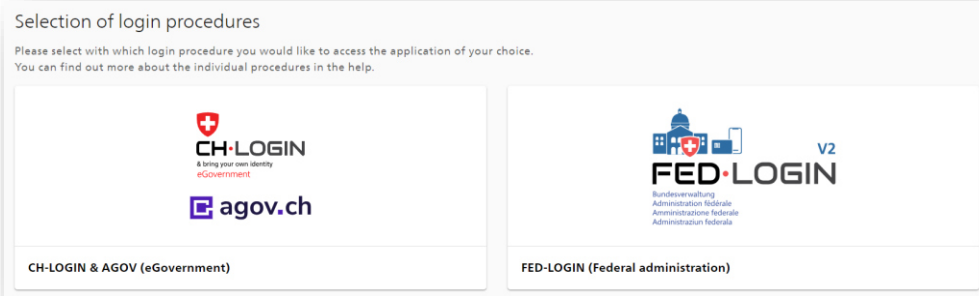
1. Go to the swissdamed public site (www.swissdamed.ch).



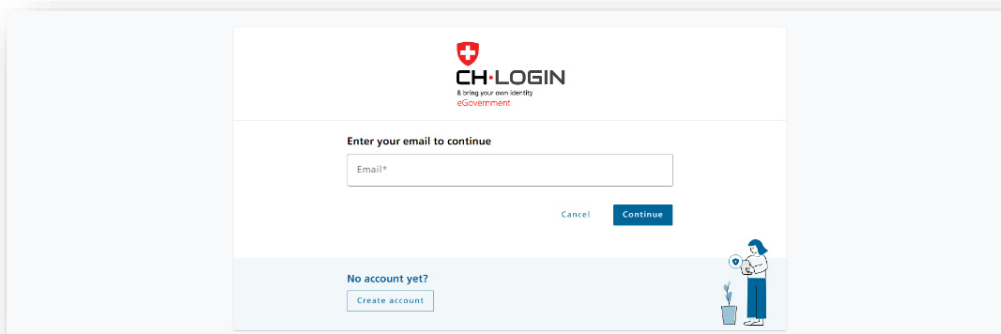
2. Click the “**Login**” button in the top right corner



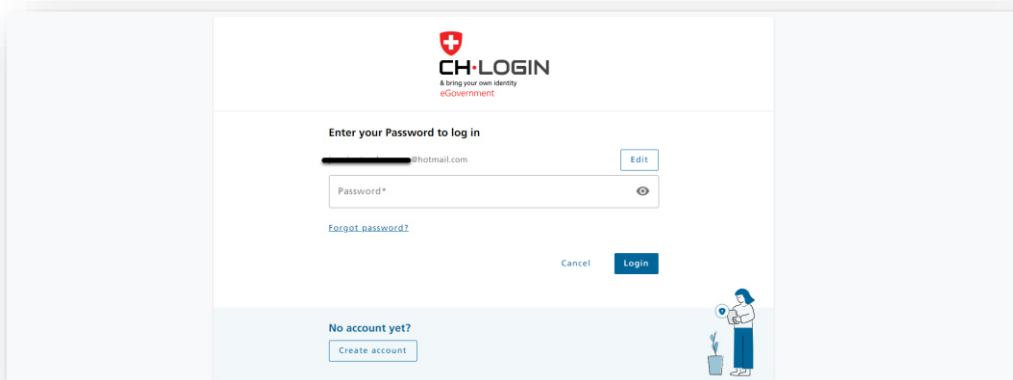
3. Select the “**CH-LOGIN & AGOV (eGovernment)**” procedure



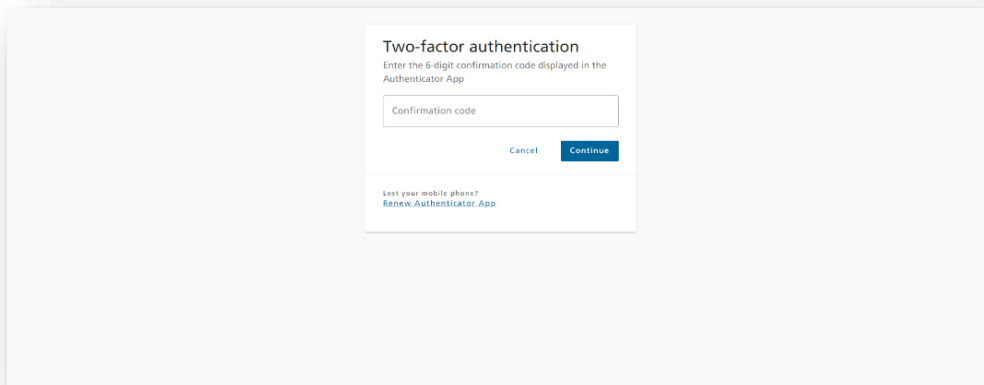
4. If you already have an CH-Login account, enter your e-mail address and click **Continue**. (OR click on “Create account” if you do not have one yet)



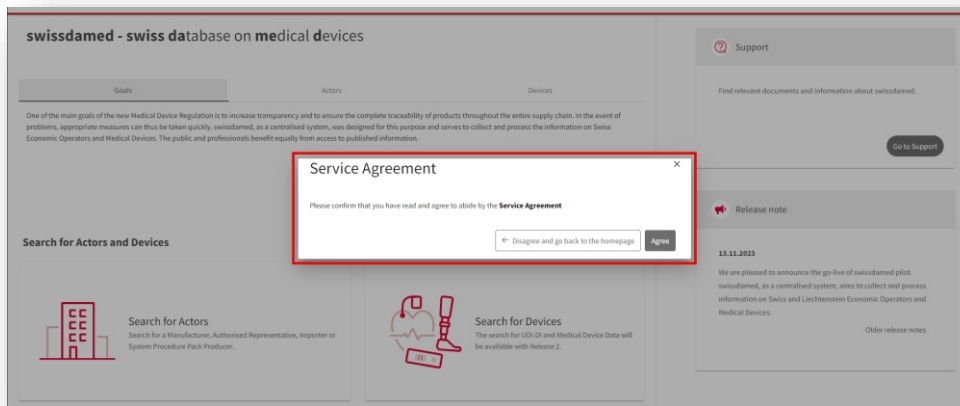
5. The second part of the CH-LOGIN - Sign-in page prompts you to enter your password. Enter your CH-LOGIN password and click **Login**.



6. 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**.

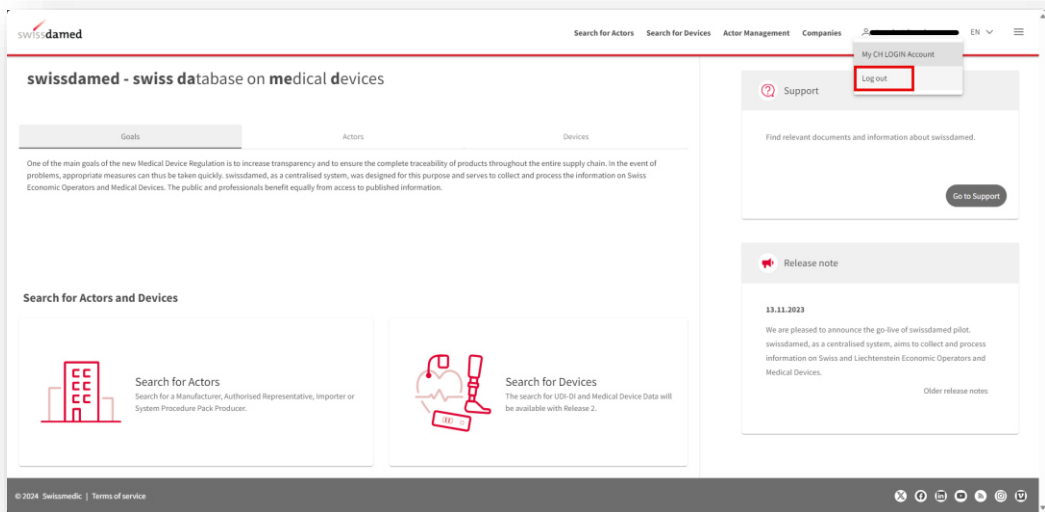


7. When logging into swissdamed for the first time, you will be prompted to review and accept the service agreement. To continue using swissdamed, click **Agree**.



1.3.1.2 Logging out of swissdamed:

1. Click on your **username** located at the top right corner of the screen. This will display a dropdown menu. From the dropdown, select **Log Out**.



- Once you have clicked on **Log Out** in swissdamed, you will be automatically redirected to the public site.

1.3.2 User rights and profiles

Each user may have multiple accounts but can access swissdamed with only 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 the actors module for all users that they invited to their company. 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 authorized 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 utilizing an existing one, a user will be assigned this role.

		<ul style="list-style-type: none"> 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 (which is needed for use in other applications)

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	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.
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 Administrator for that actor once the registration is validated by swissmedic.
- A Swiss Single Registration Number (CHRN) is generated by swissdamed and issued by the Competent Authority (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 invited you, your account will be granted the appropriate user profile for that actor.

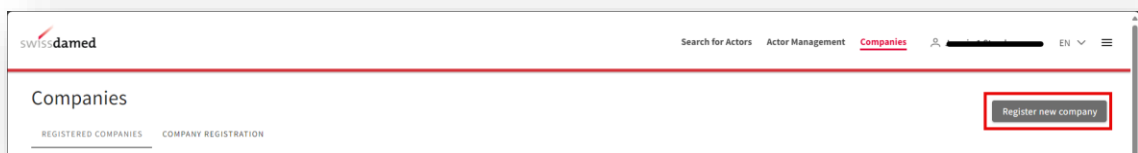
It is good practice having at least two Actor Admins, as a fail-safe mechanism if one should be unavailable. Furthermore, an actor must have at least one active Actor Admin at all times, making it impossible for an actor to terminate the last Actor Admin.

3 How to operate in swissdamed - Instructions

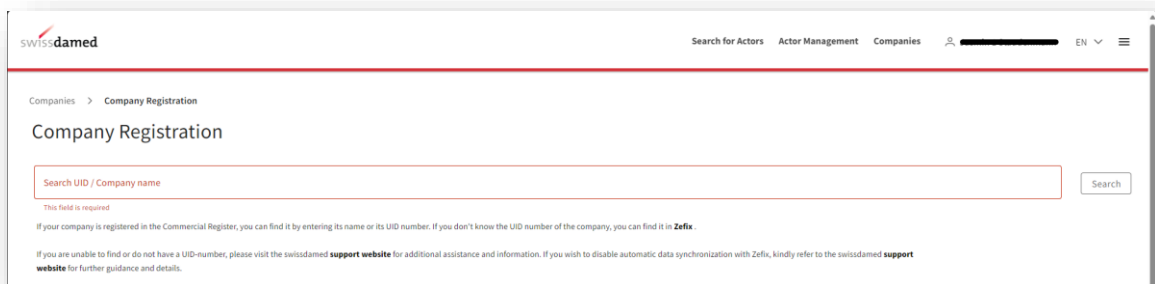
3.1 Register a company

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

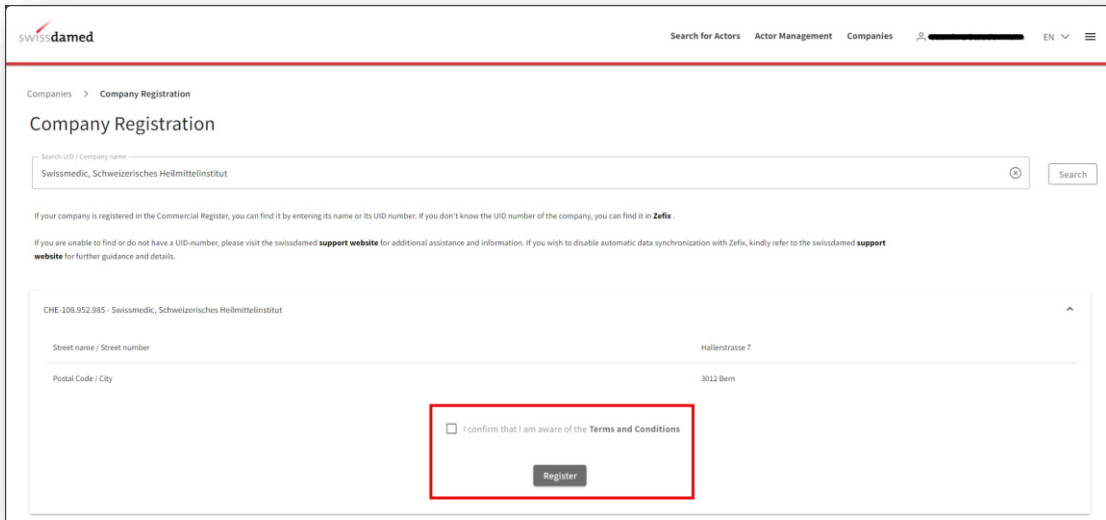
1. Go to the “Companies” tab and click the button “Register new Company”.



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).

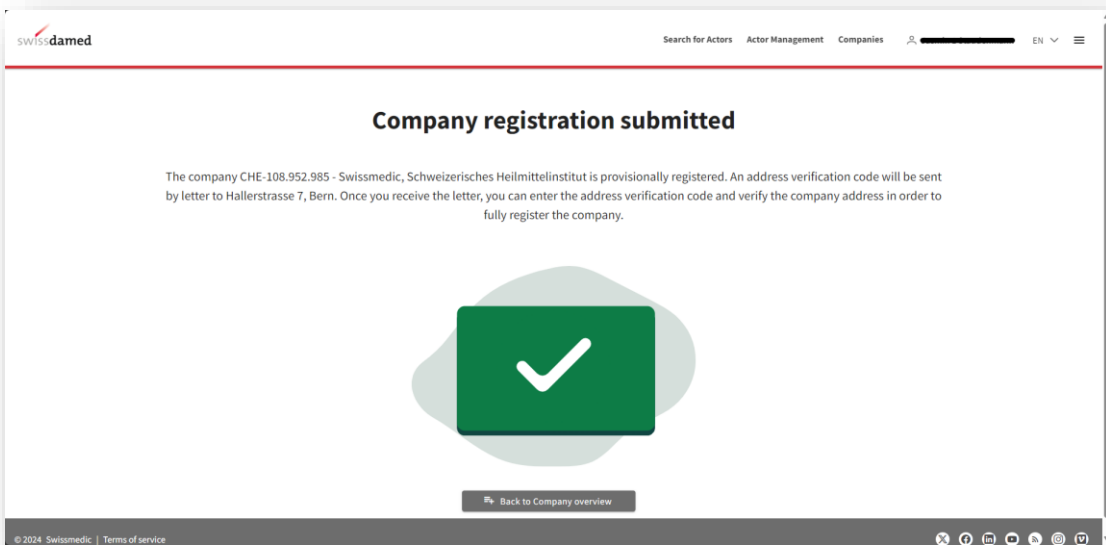


3. Select the desired company, tick the box “I confirm that I am aware of the Terms and Conditions” and click on “Register”.



4. A confirmation should appear 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.

Your verification code

Good day [REDACTED]

You recently registered the company in swissdamed.

Please confirm this using the code below. This code will expire after **30 days**.

By entering the code, you confirm that you are working for the company concerned.

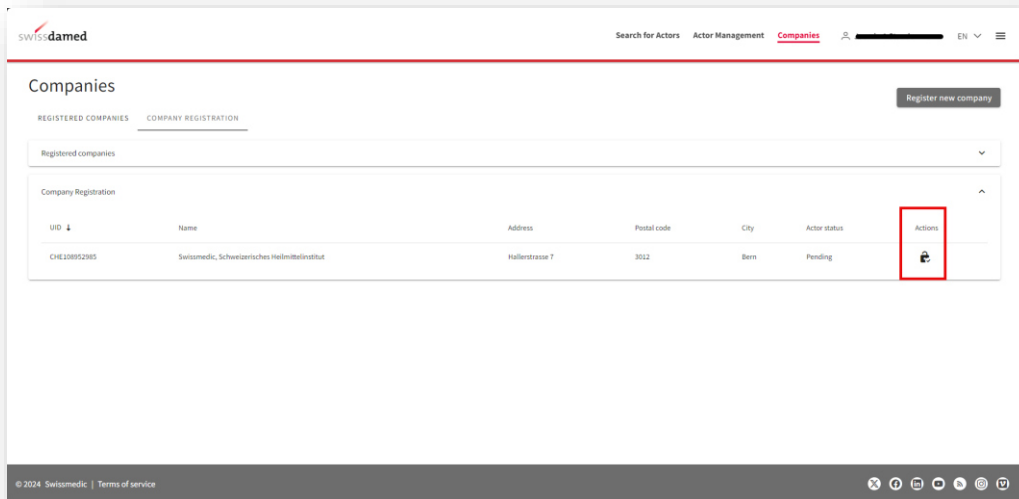
Step 1: Open [REDACTED] in your browser

Step 2: Log in using your username and password

Step 3: Under "Companies" in the "Company registration" tab, select the registered company and enter the following verification code: [REDACTED]

Step 4: Once validation has been confirmed, you have to log in again as described in swissdamed. Otherwise, your company will not yet be visible in the "Registered companies" tab

- Once you received the letter, log in to swissdamed, go to "Companies" and then "Company Registration" tab and click on the padlock symbol of the corresponding company.



- Enter the Company verification code you received by letter and click on "Submit".

Enter Company Verification Code

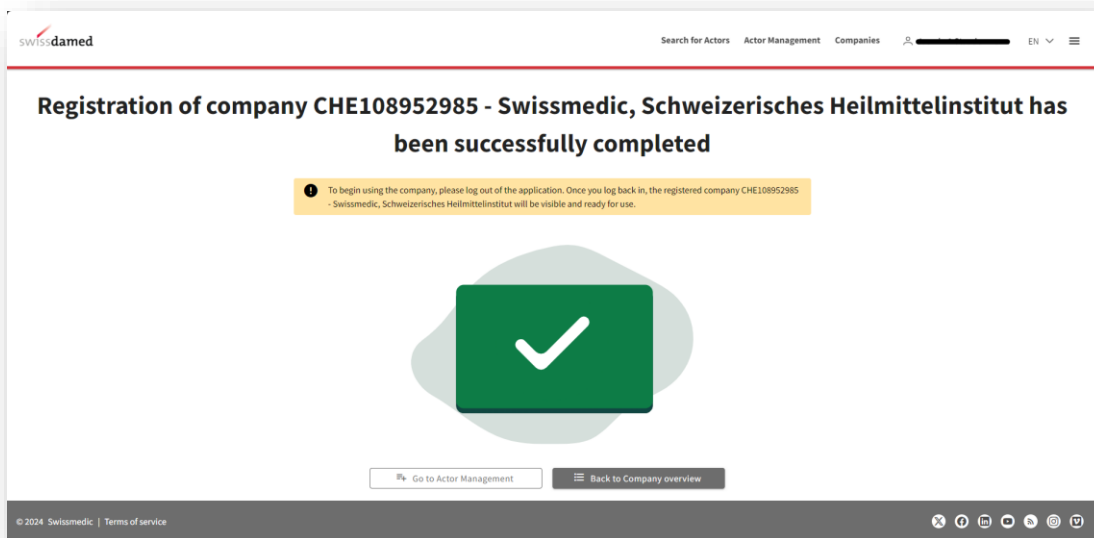
You created a Registration Request for the following company:

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".

Verification Code

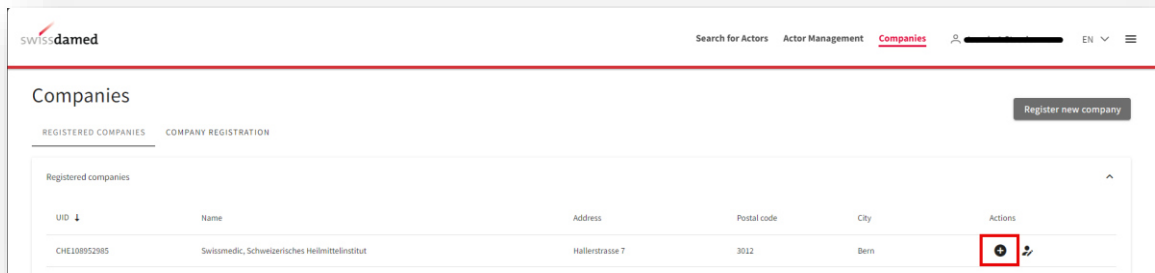
8. A confirmation should appear telling you that the registration of your company has been successfully completed. The text above the icon explains what to do next: *“To begin using the company, please log out of the application. Once you log back in, the registered company CHE123456789 - XXX will be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



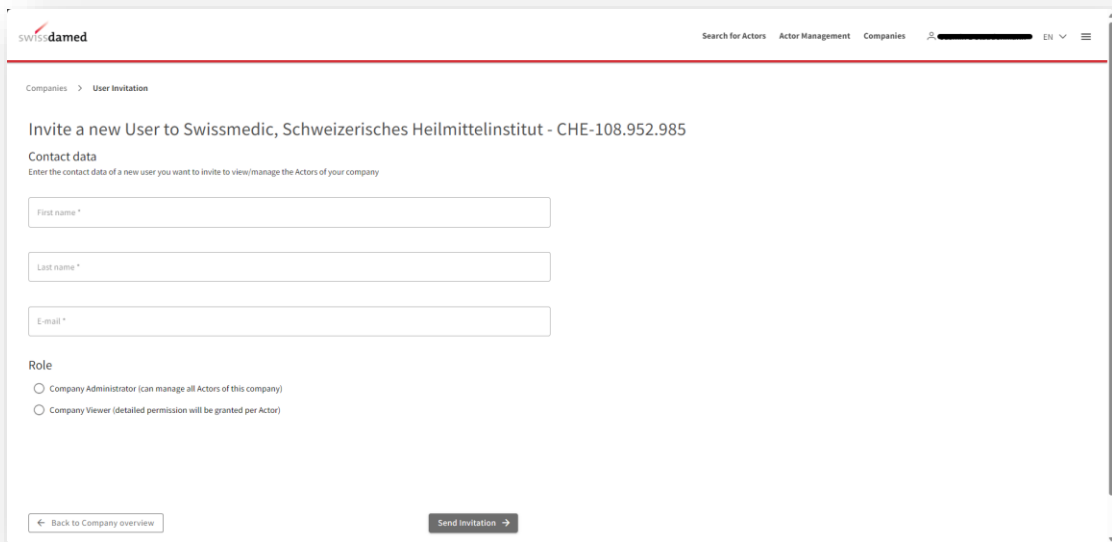
9. After login back to the application, the company should be in the list of the “Registered Companies” in the “Companies” tab.

3.1.1 Add User(s) to the Company

1. Go to tab “Registered Companies”, where you will see your company. Click the icon “+” on the right of your company to “invite new user”.



2. Enter the first name, the last name and the email address of the user you want to invite and choose the company role you want to assign to that person. When everything is filled, you can click on the “Send invitation” button below.

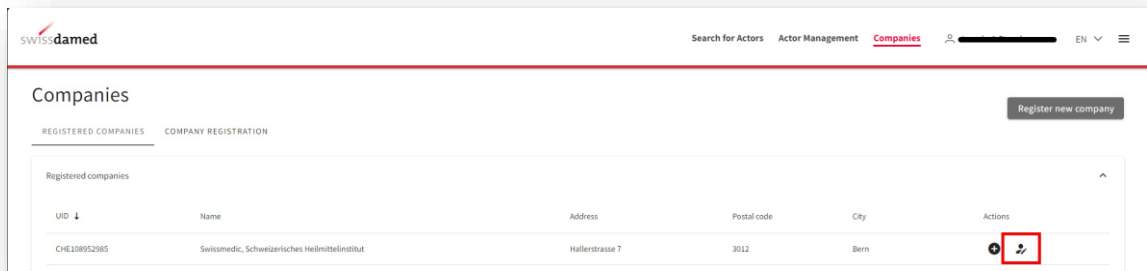


3. After sending the invitation, the invited user will get an email where the onboarding procedure will be explained (if the invited user does not yet have a CH-LOGIN account). The person will have to follow the instructions by using the link and code provided.

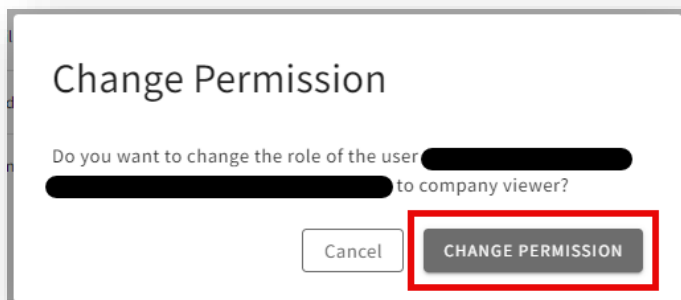
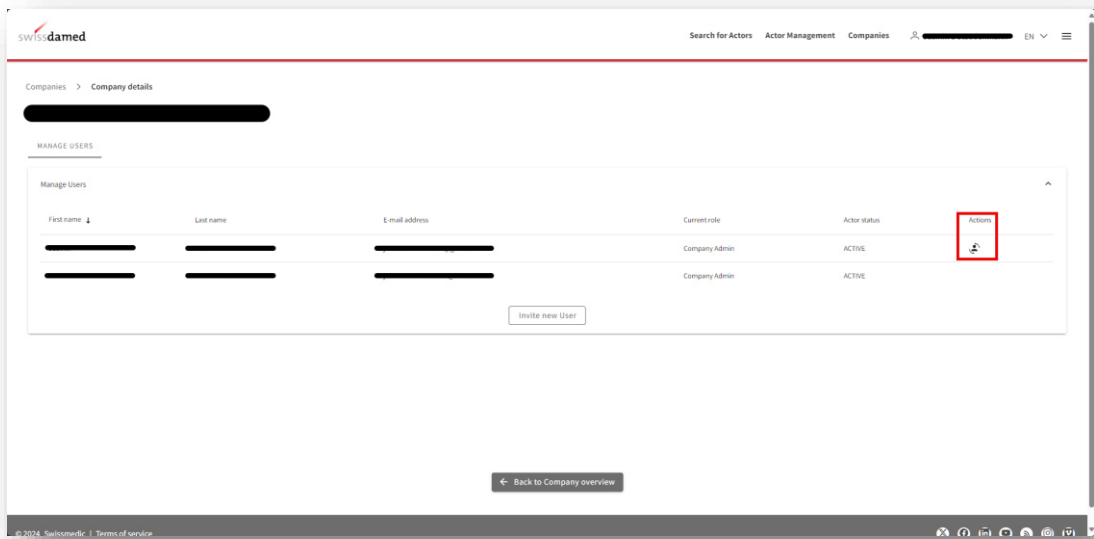
If the user already has an CH-LOGIN account, the mail will contain information about the invitation and the new role in the company.

3.1.2 Manage company users

1. Once the user is onboarded, his status can be checked in the actor management table on the company tab, 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 desired user.

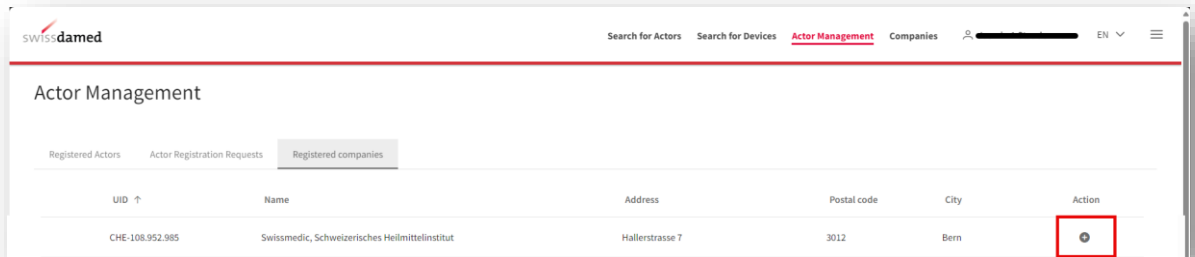


3.1.3 Change data of a company

1. The General information as address and UID of the company can't be changed, because this is an excerpt of the Swiss commercial register
2. If your company has not a UID, please contact the swissdamed Team for support.

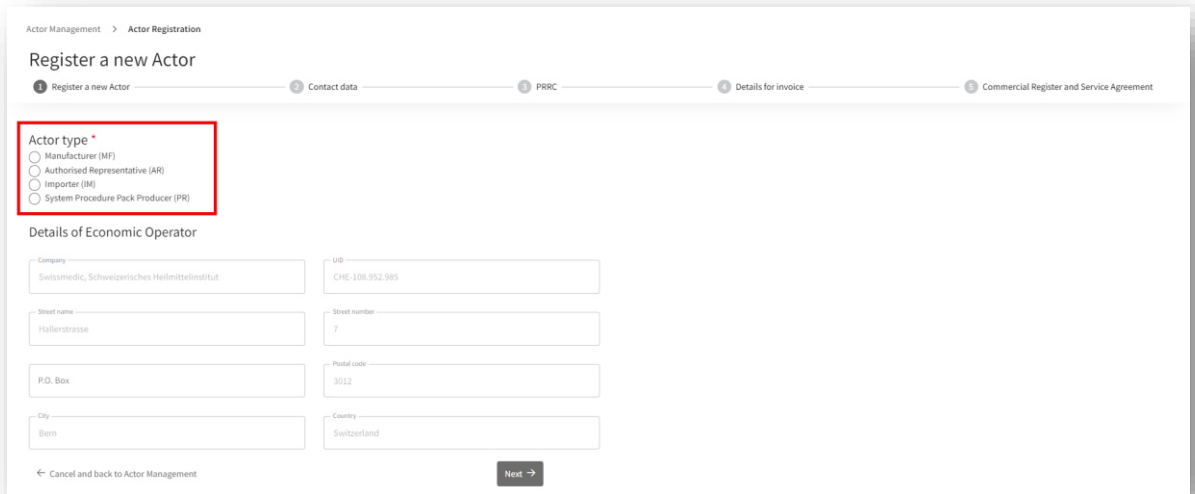
3.2 Register an Actor

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



**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 to assign you a role.*

2. Choose an Actor Type and fill in the form with your details for each stage. 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

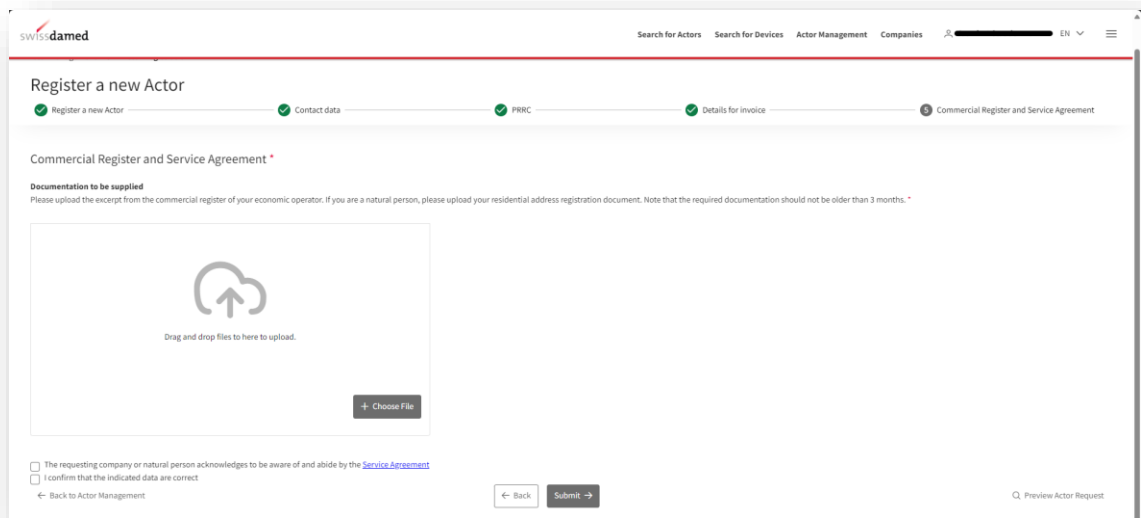
P.O. Box: Postal code: 3012

City: Bern Country: Switzerland

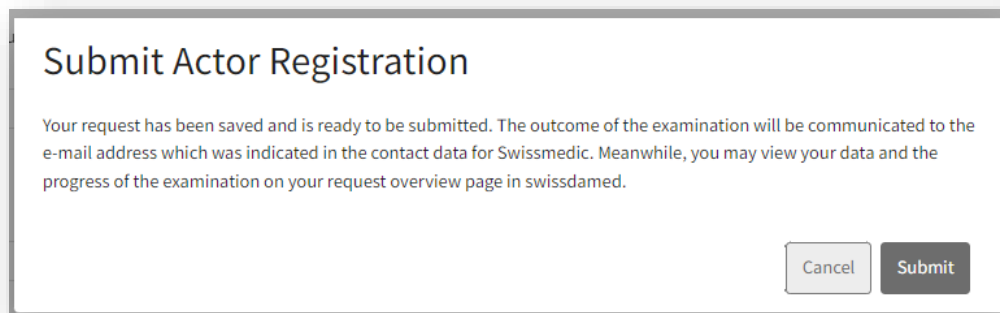
← Cancel and back to Actor Management Next →

3. On the last step: Upload your Excerpt from the commercial register or, agree to the Service Agreement and confirm that the indicated data are correct.

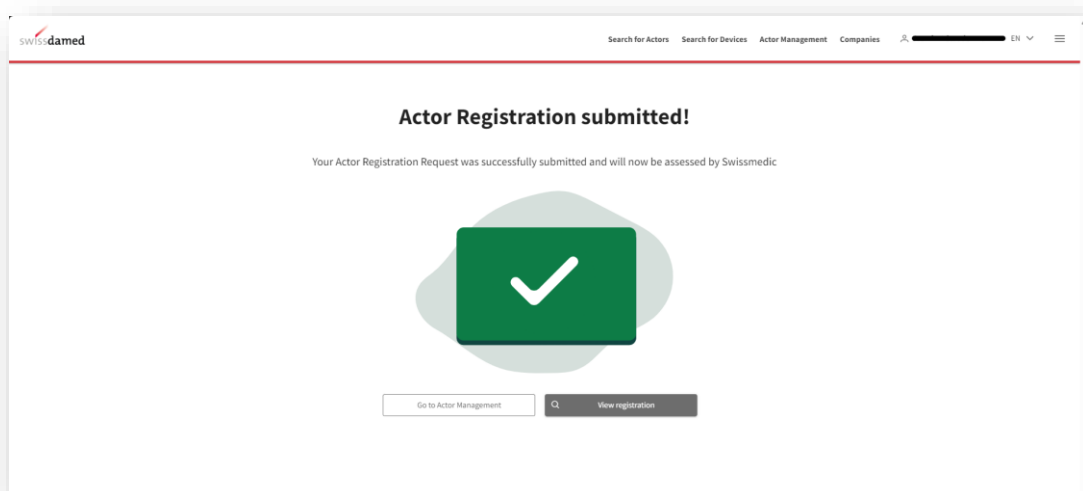
If you are a natural person, please upload your residential address registration document. Note that the required documentation should not be older than 3 months.



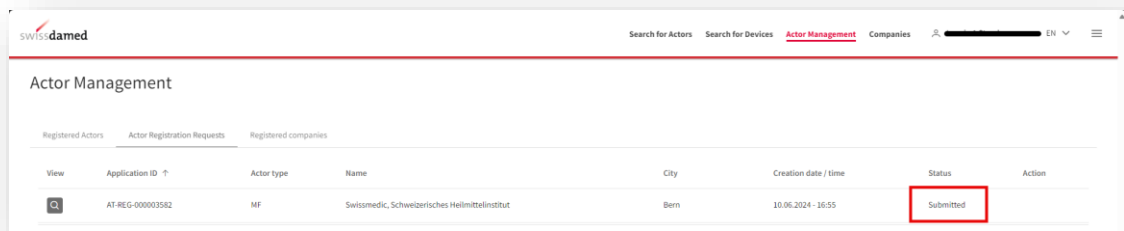
4. Submit the Actor Registration Request to Swissmedic by clicking on the “Submit” button.



5. If the demand was successfully submitted, a confirmation should appear. Swissmedic will check the request and assess it.



- In the meantime, the status of your request can be checked on the “Actor Registration Requests” overview in the “Actor Management” tab.

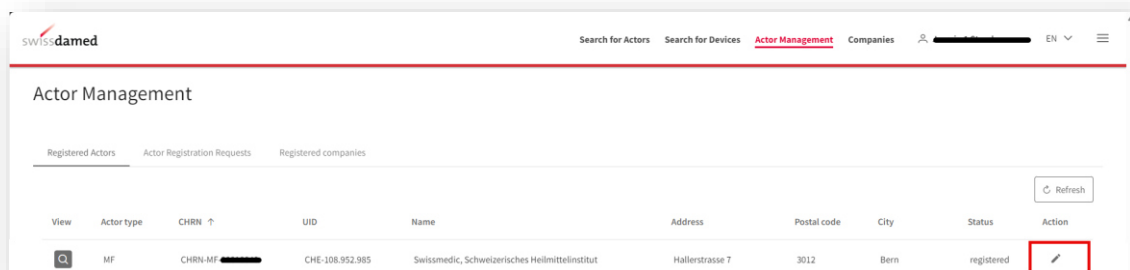


- Once your request has been assessed, you will receive an email with the status of your request.

If your request is accepted, your request will on the “Actor Registration Requests” overview in the “Actor Management” tab will get the status “Approved” and your actor will be available in the “Registered Actors” tab with the status “Registered”.

If your request needs correction, your request will still be on 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 (pen icon in the action column).

If your request is refused, your actor will be displayed on 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 on the “Registered Actor” 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 chapter 3.1.1 of this user guide.

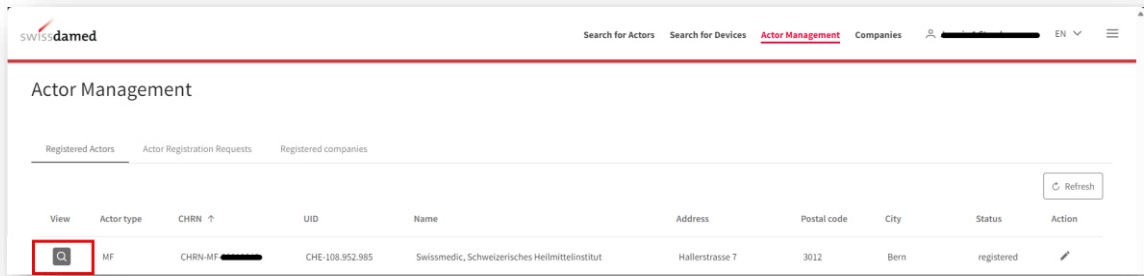
As soon as the desired user is registered in the company, he will automatically appear in the user list of the actors of that company. The following table is showing which role will be automatically given on actor level to the company users.

Company role given	Actor role automatically given
Company-admin	Actor-admin
Company-viewer	None

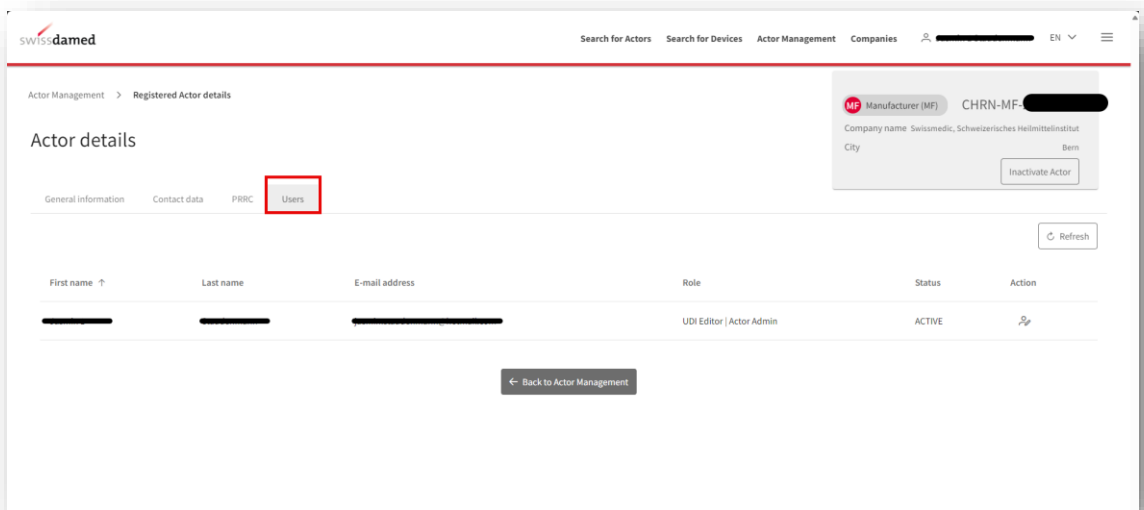
3.2.2 Manage actor users

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

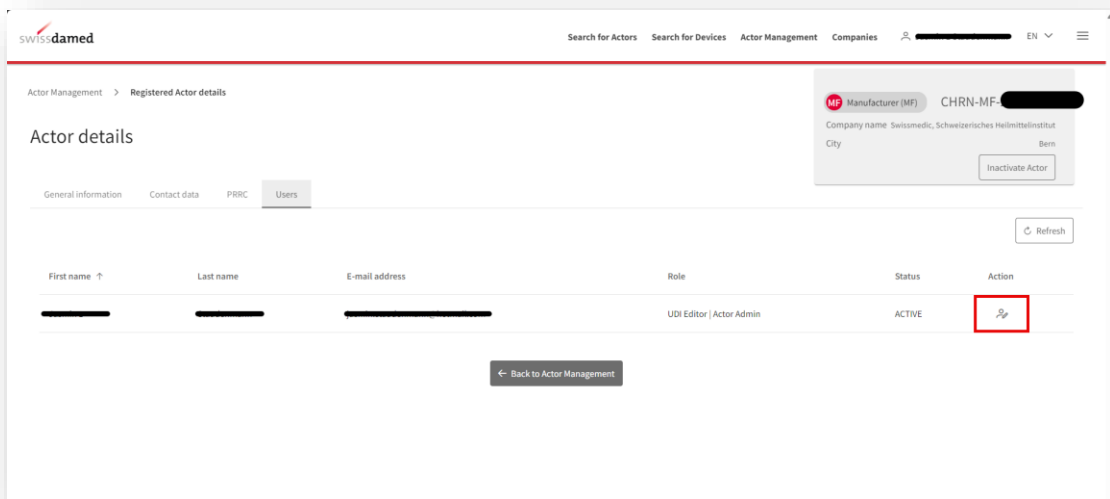
1. Open the Actor Details of the desired actor by clicking on the magnifier icon.



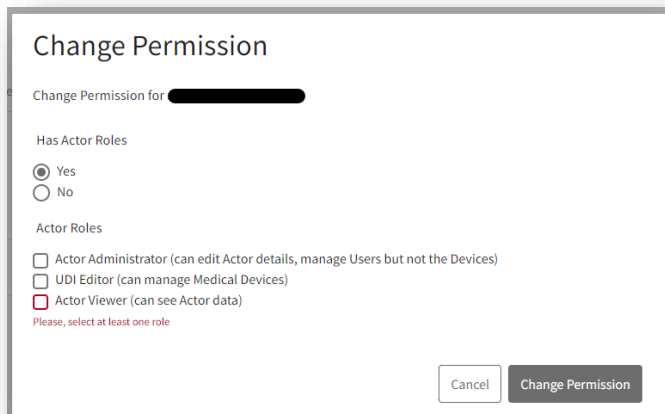
2. Once in the Actor detail's view, open the "Users" tab. All users from the company are listed there with their role and status.



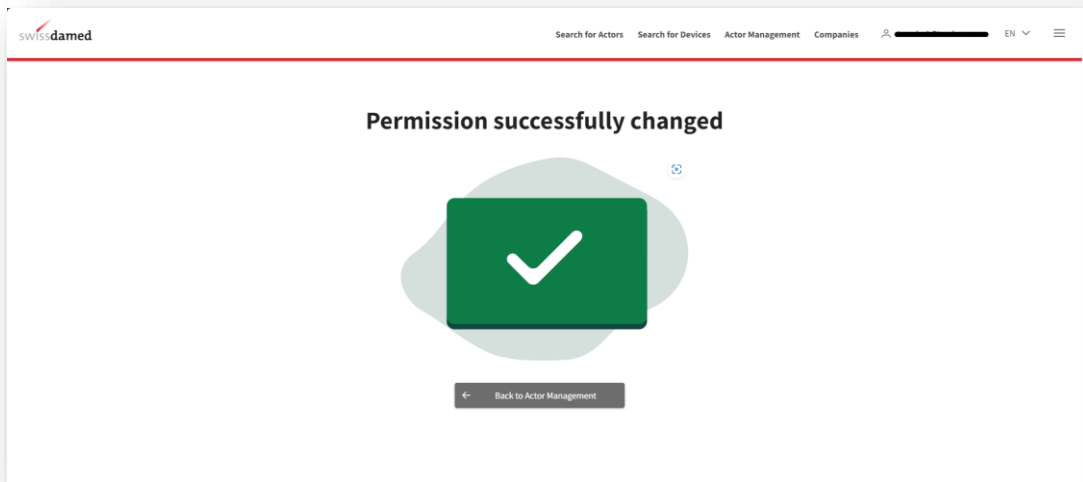
3. If you want to change the role of one of the actors, click on the action button "change permission" (character icon on the right)



4. Add or remove a permission by choosing if the selected user should have an Actor Role or not and if yes which one (multiple choice allowed). For example, “Actor Viewer”. Click on the “change permission” button to validate your choice.



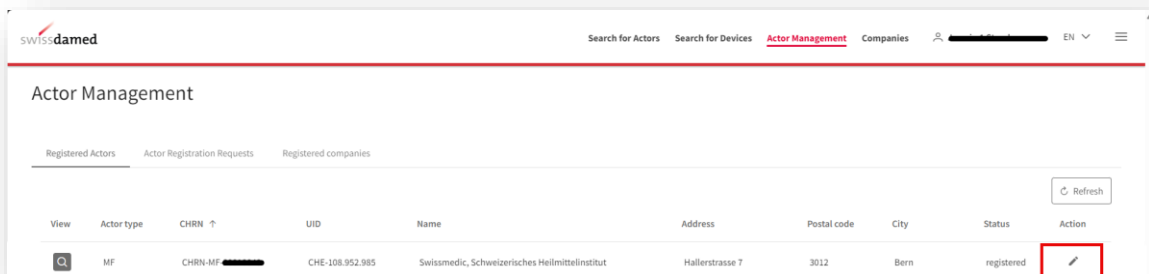
5. If the change of role was successful, a confirmation should appear.



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.

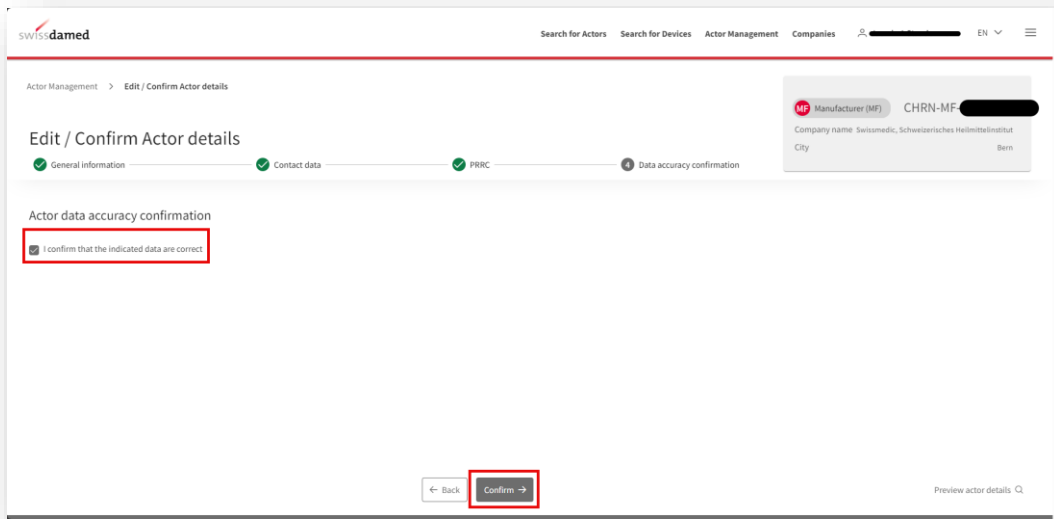
1. Click on the pen icon on the right of the actor you wish to update.



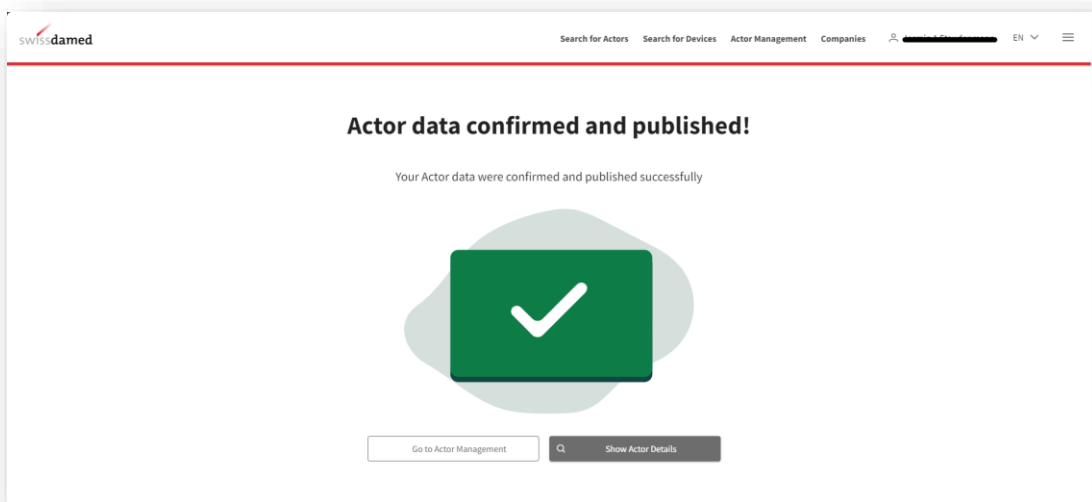
2. Change the data that needs to be updated. Confirm that your data are correct and submit your changes by clicking on the “Confirm” button.

Pay attention: you can't modify your company 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 didn't want to have the automatic synchronization between Zefix and swissdamed, your company has been manually registered by Swissmedic user. To update your company data in that case, please contact our support team.



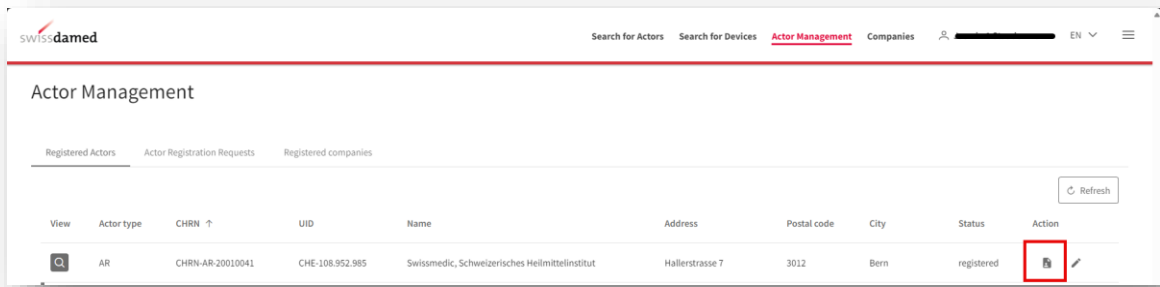
3. If the update was successful, a confirmation should appear.



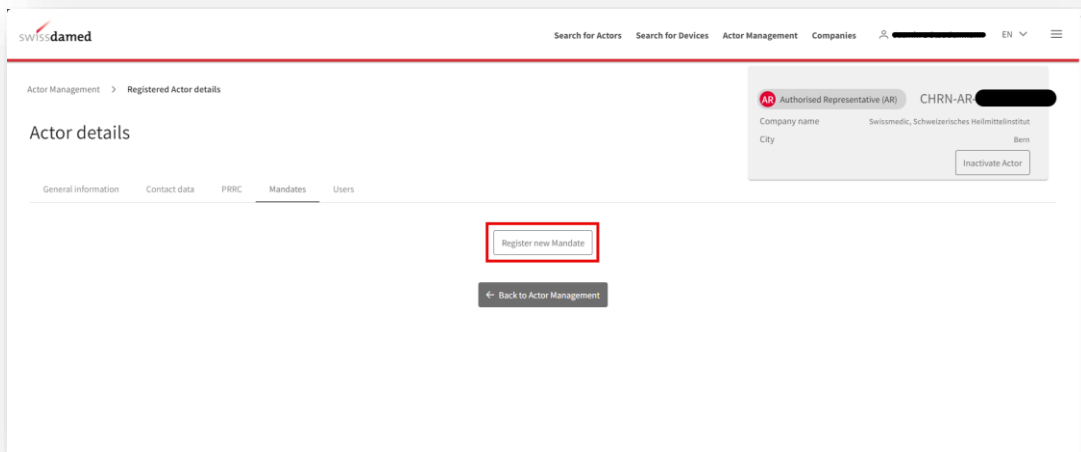
3.3 Register a mandate

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

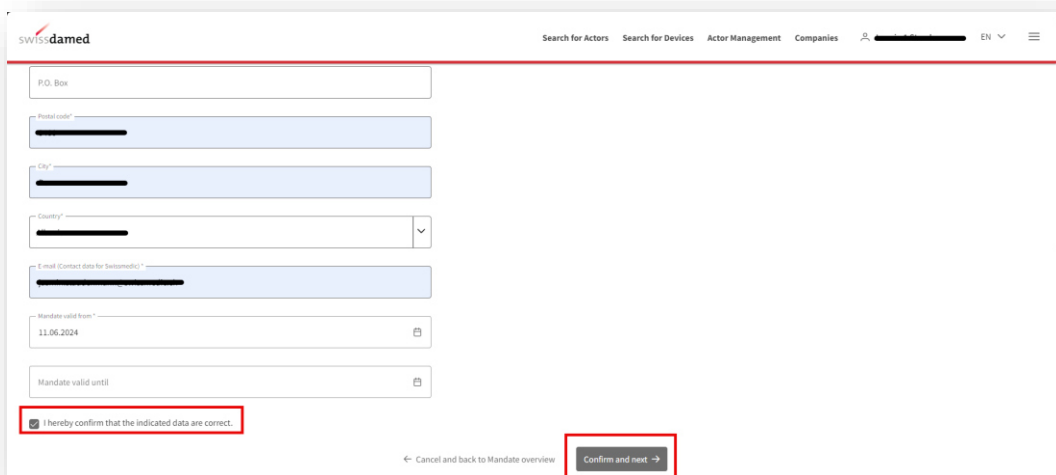
1. Go on the “Registered Actors” overview in the “Actor Management” tab. Click on the icon “Go to Mandates” of the authorized representative actor to whom you want to add a mandate.



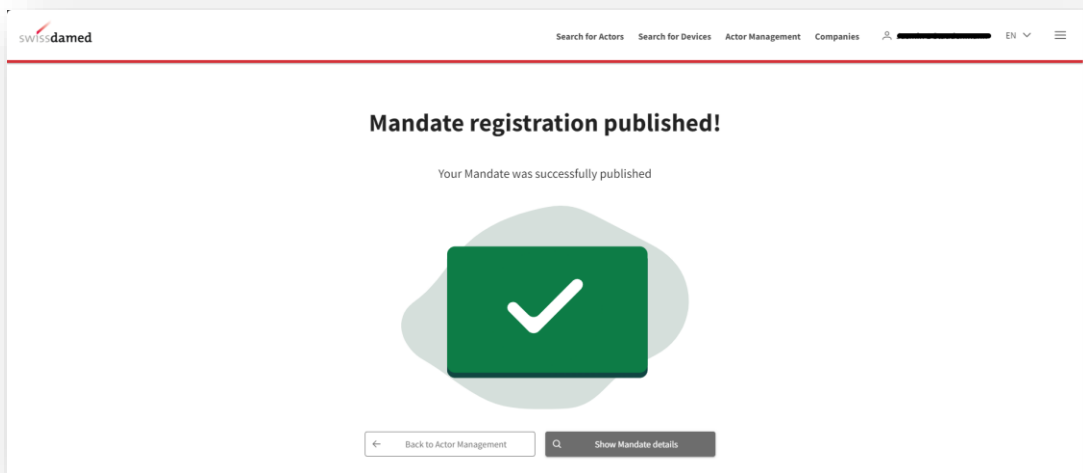
2. In the Actor Details, click on the “Register Mandate” button.



3. Fill in the form, confirm that the indicated data is correct and save the mandate by clicking on the “Publish Mandate” button at the bottom of the form.



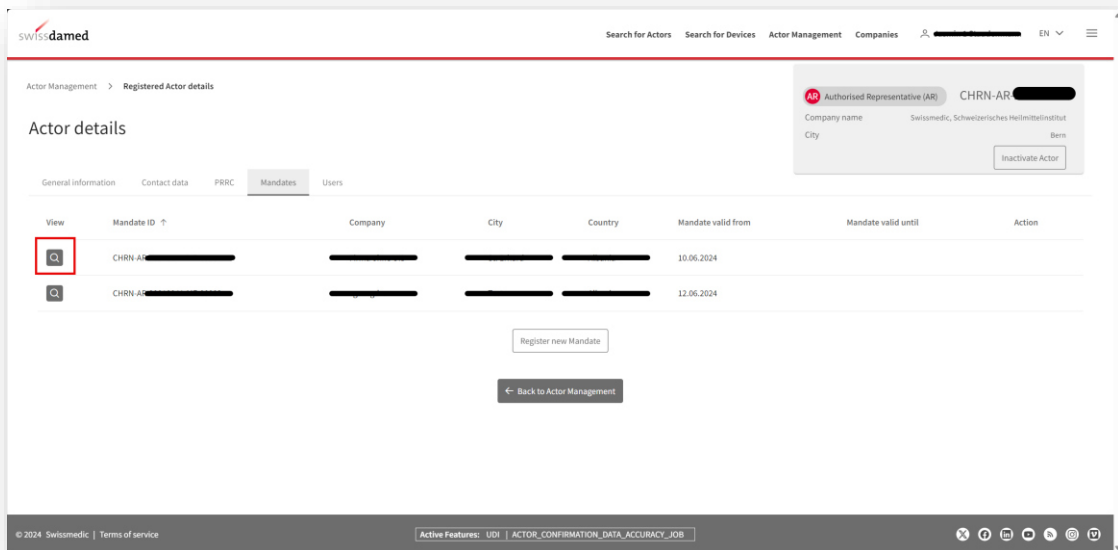
4. If the registration was successful, a confirmation should appear.



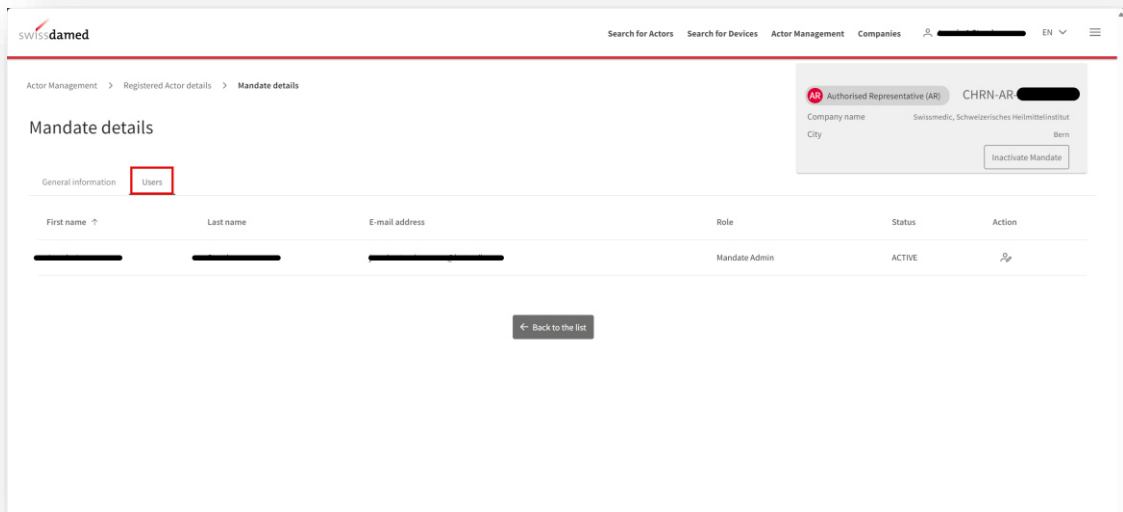
3.3.1 Manage mandate users

Once your mandate has been saved and is visible in the mandate overview, you can manage the user at mandate level. To manage the users at mandate level, follow these steps:

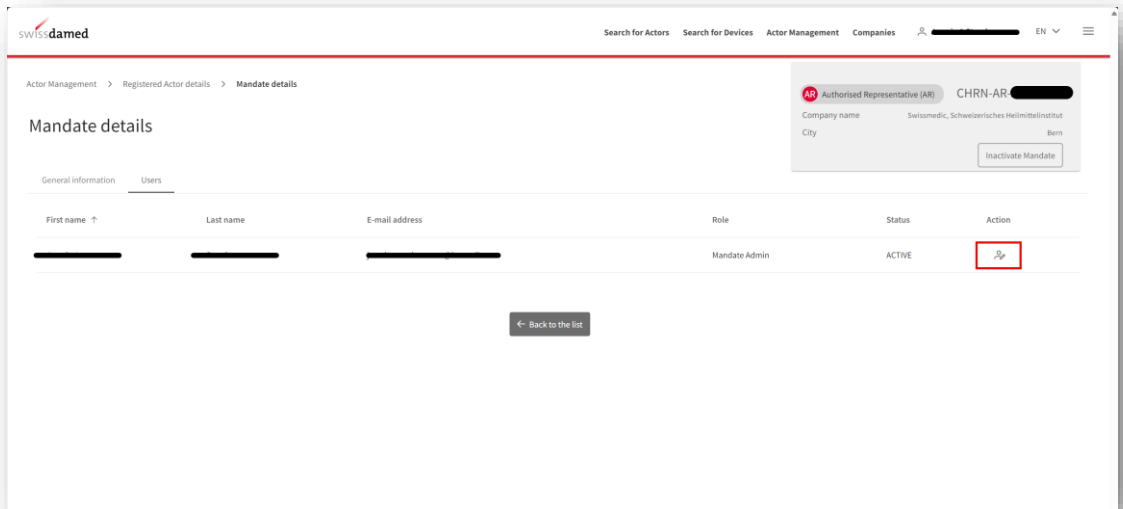
1. Open the Mandate Details by clicking on the magnifier icon next to the chosen mandate.



2. Go to the “Users” tab of the mandate details. The users of your company that have a role at actor level (actor admin or actor viewer) will automatically be listed there.



- As Mandate Admin you can manage the mandate users by clicking on the character icon to the right of the user whose role you wish to change.



- 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 [REDACTED]

Has Mandate Roles

Yes

No

Mandate Roles

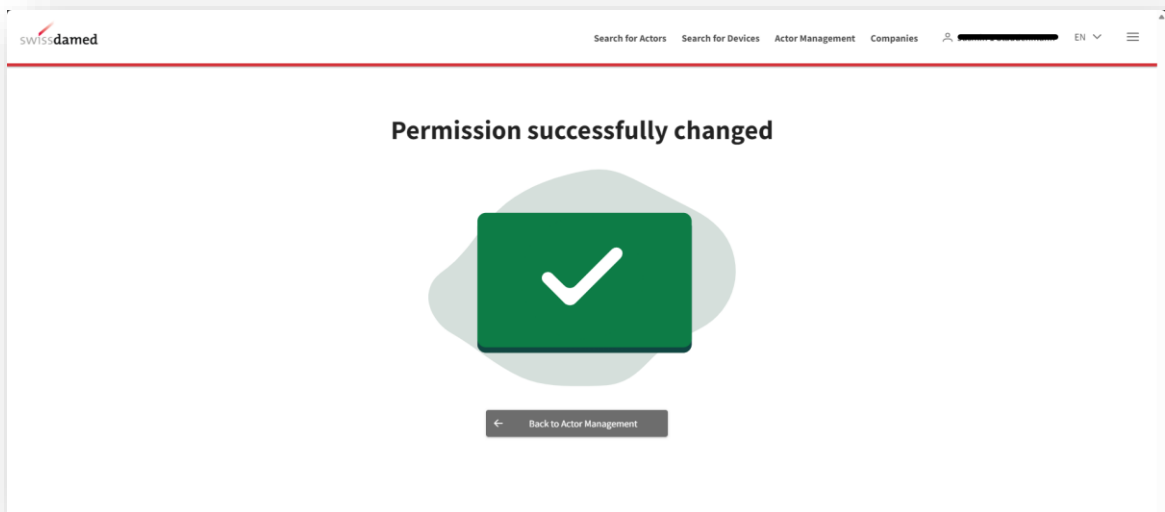
Mandate Administrator (can edit Mandate details, manage Users but not the Devices)

UDI Editor (can manage Medical Devices)

Mandate Viewer (can see Mandate data)

CANCEL
CHANGE PERMISSION

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



3.3.2 Add user(s) to the mandate

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

Once your mandate is visible on the “Mandates” tab of your authorized representative actor, other users can be added to the mandate. To be able to add a user to a mandate, the user you want to add must first be registered at company level. To do so, please follow the steps described in chapter 3.1.1 of this user guide.

As soon as the desired user is registered in the company, he will automatically appear in the user list of the actors of that company and on the corresponding mandates as well. The following table is showing which role will be automatically given on mandate level to the company users.

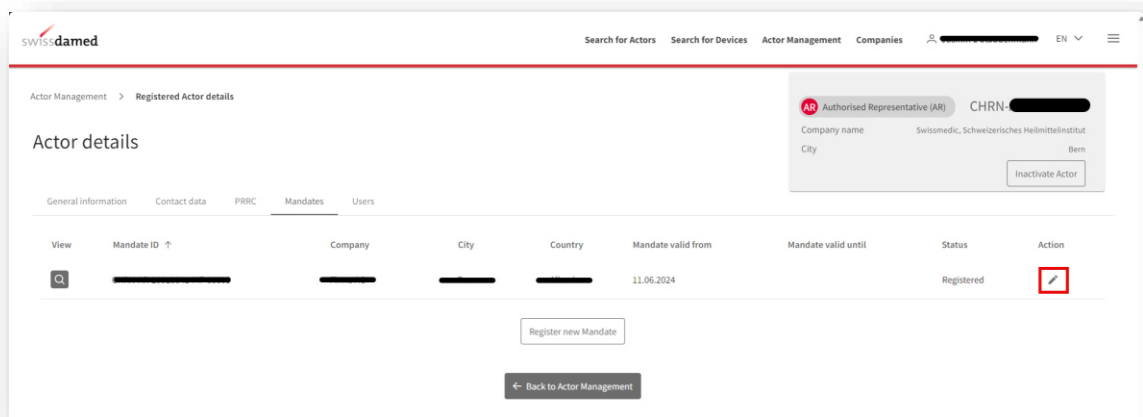
Company role given	Actor role automatically given	Mandate role automatically given
Company-admin	Actor-admin	Mandate-admin
Company-viewer	None	-

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 appears in the mandate users as well.

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 on the “Actor details” of the corresponding authorized representative (AR).

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



2. Change the data that needs to be updated. Confirm that the indicated data is correct and register your changes by clicking on the “Publish Mandate” button.

swissdamed

Search for Actors Search for Devices Actor Management Companies

P.O. Box

Postal code

City

Country

Email (Contact data for Swissmedic)*

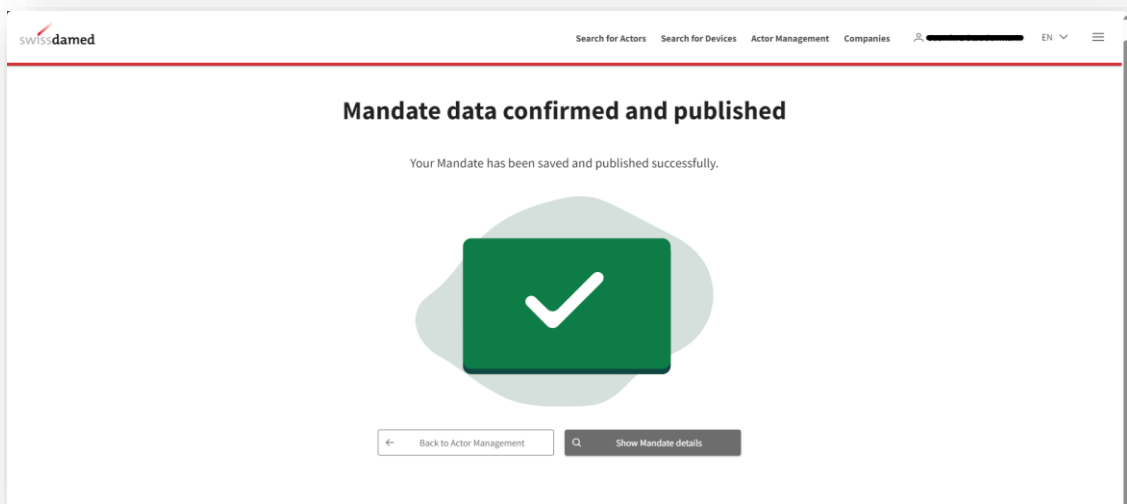
Mandate valid from 11.06.2024

Mandate valid until

I hereby confirm that the indicated data are correct.

← Cancel and back to Mandate overview **Confirm and next →**

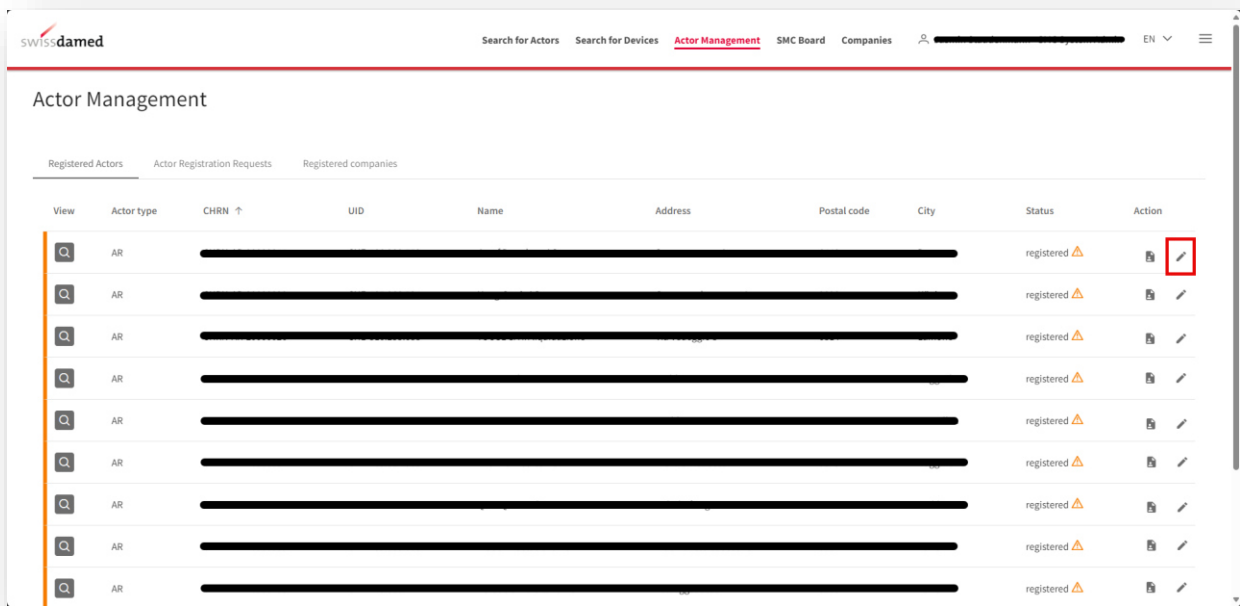
3. If the update was successful, a confirmation should appear.



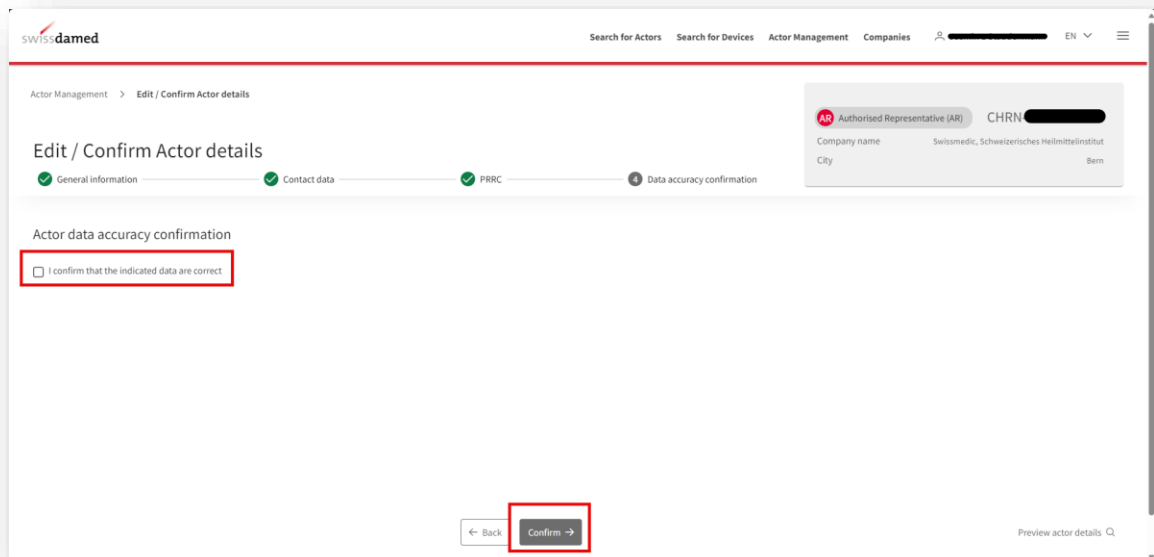
3.4 Validate your actor details

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

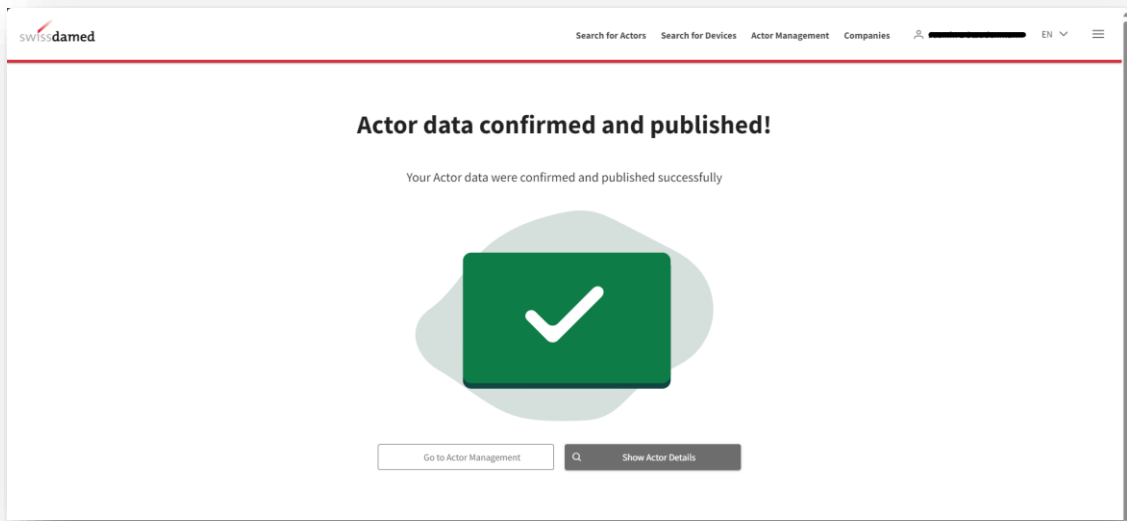
12 months after the creation of a new actor and then every 2 years, a mail from swissdamed is sent to the contact mail and the Actor Admin(s), asking them to confirm the actor data registered in swissdamed. The respective actor, by which the data needs to be confirmed, is marked (in orange) in the actor list.



1. To confirm or update your actor data, click on the pen icon on the right of the relevant actor.
3. Verify and change the data that needs to be updated. Confirm that your data are correct and submit your validation / changes by clicking on the "Confirm" button.



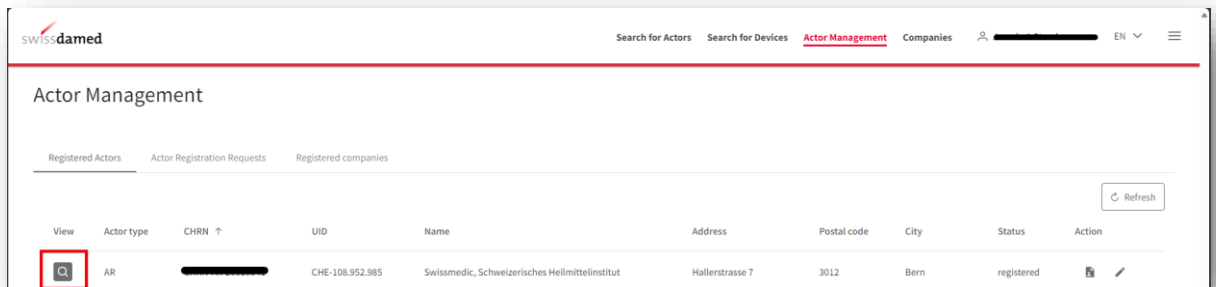
4. If the validation was successful, a confirmation should appear.



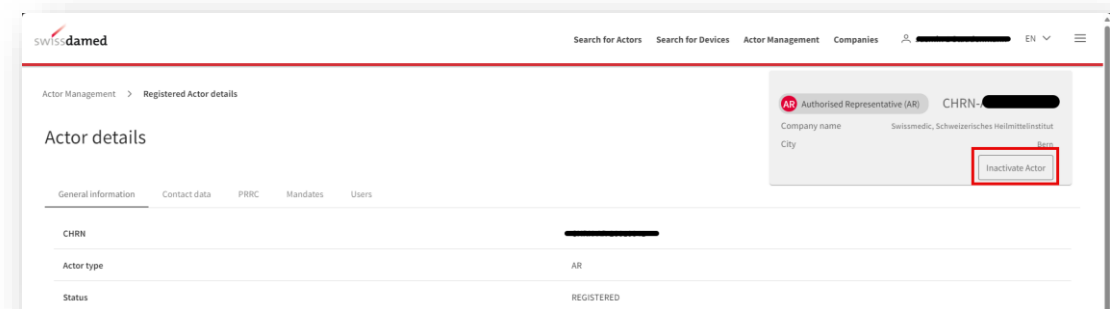
3.5 Inactivate an actor

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

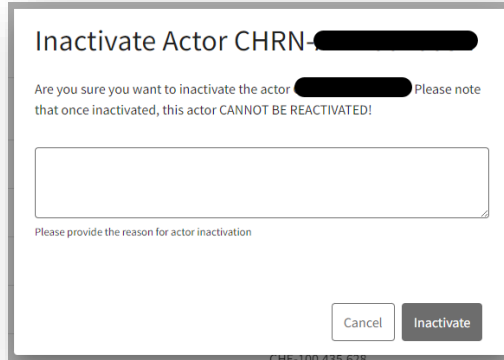
1. Go in the list of your “registered actors” in the “Actor management” tab and click on the magnifier icon on the left of the actor you want to inactivate.



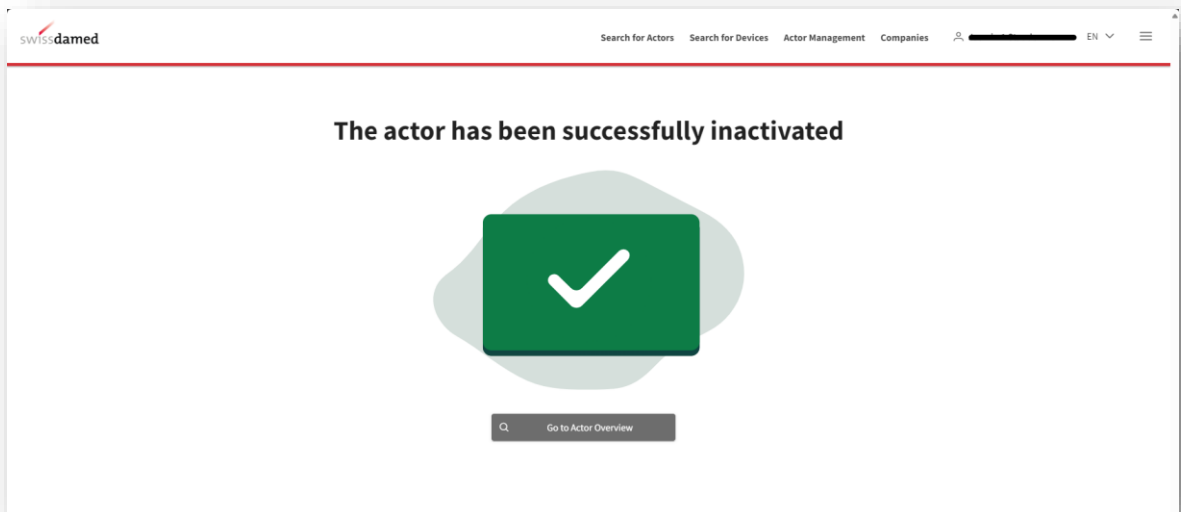
2. In the details of your actor, click on the “Inactivate actor” button in the grey box in the top right-hand corner



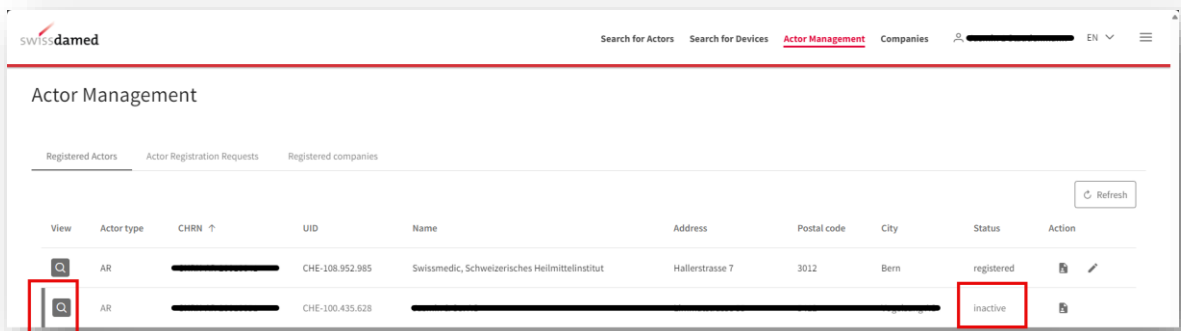
3. A confirmation window appears asking you to provide the reason for actor inactivation and to confirm that you really want to inactivate this actor. Please note that once inactivated, this actor CANNOT BE REACTIVATED!



4. If the inactivation is successful, a confirmation should appear.



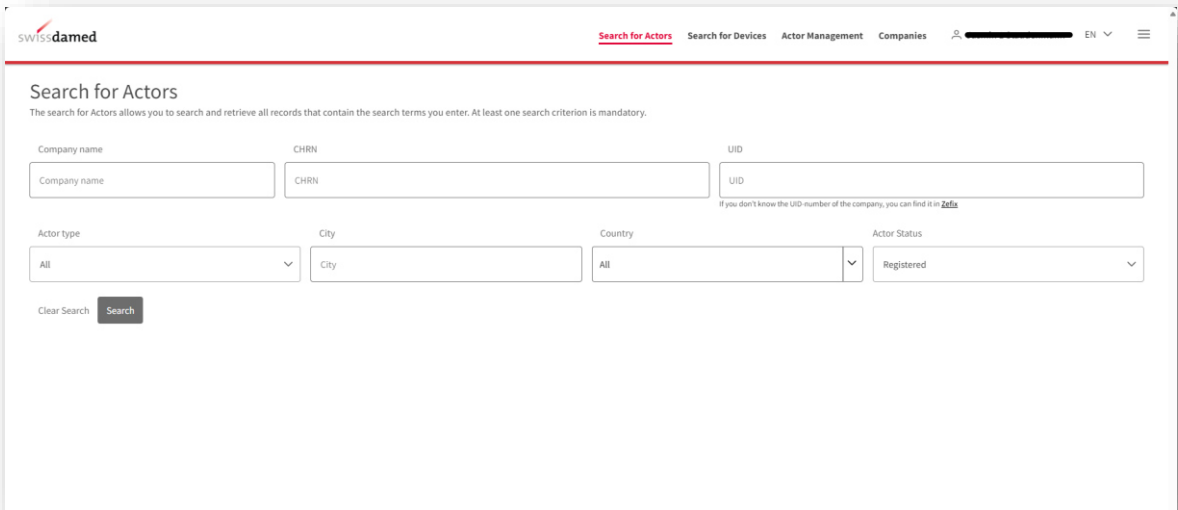
5. Inactivated actors are shown in grey in the list of the registered actors and an information box is added in the actor details as well.





3.6 Search for an actor

1. On the “Search for Actors” tab you have the possibility to search for an Actor by
 1. Company name (minimum 2 characters)
 2. CHRN (max. 16 characters) → Example: CHRN-MF-01234567
 3. UID (max. 15 characters)
 4. Actor Type
 5. City
 6. Country
 7. Actor Status



2. 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
1.0	First version for pilot swissdamed	lav / sin / red
1.1	Update for MDOD testing sessions	sin / stj