Manual

Swissmedic Portal – User manual for partners

ID-Number:	SMCPF-0001
Version:	1.0
Valid from date:	17.02.2025

1 Summary

The Swissmedic Portal is the new collaboration platform from Swissmedic.
The web-based application offers business partners of Swissmedic self-service access to official services in digital form.
The Swissmedic Portal also contains a protected customer area where available and released data can be viewed based on user roles and permissions.
This user manual is a guide for external users/partners of the Swissmedic Portal.
Please read the step-by-step instructions carefully and follow the instructions given if you are unsure.
The table of contents shows the relevant actions, categorised by chapter.

Table of content

2 Swissmedic Portal – A brief explanation

The Swissmedic Portal is based on a context-sensitive structure. A context is listed as a portal tab in the Swissmedic Portal tab bar and shows a specific business context (either data view or process view).

The navigation is designed to be intuitive and allows you to switch between different contexts by selecting the relevant tab.

When you access the Swissmedic Portal, the available data structure is displayed in accordance with your user profile. Within this structure, you can navigate to business data and view the corresponding content, and you can also initiate specific actions (processes).

The Swissmedic Portal is being developed and expanded, which is why the currently available functions are still limited. However, the range of functions will be continuously enhanced with each new version.

This user manual will be updated with each new version of the Swissmedic Portal, so that you will always have access to the latest instructions for the available functions.

3 Functionalities of the Swissmedic Portal

This chapter describes the basic controls and operations.

3.1 Start the application

The Swissmedic Portal is a web-based application and can be accessed using any up-to-date web browser.

➢ Save this URL as favorite within your browser.	URL: **www.portal.swissmedic.ch**

3.2 Login Sequence

The Swissmedic Portal requires a secure log-in and uses the eIAM log-in procedure of the Swiss federal administration.

After calling the URL above, the login sequence selection window is displayed. ➢ Click on the **tile** representing your usual login sequence.	
You will be asked to your registered e-mail address. ➢ Enter your e-mail address in the field and confirm by clicking **'Continue'**.	
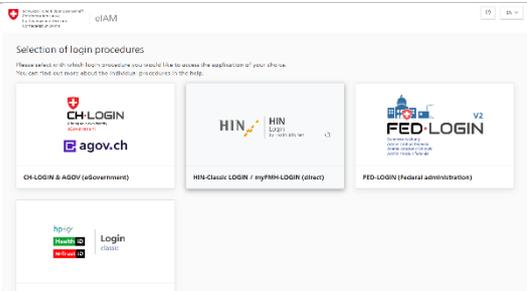
🔵 *If you do not yet have a registration, click on the page on 'Create account' and follow the instructions.*	
You are now being asked to enter your password. ➢ Enter your password in the field and confirm by clicking on **'Login'**.	
You are now being asked to confirm your identity using two-factor authentication (2FA). ➢ Enter your 2FA confirmation code in the field and confirm by clicking **'Continue'**.	
After successfully completing the log-in procedure, you will automatically be redirected to the Swissmedic Portal Application.	
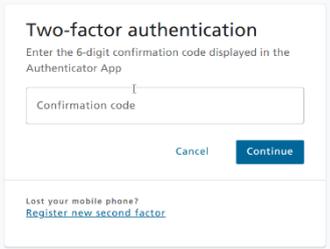
3.3 Profile selection – User with multiple profiles (Mandates)

If you work for several companies, you will or have already a multiple profile.

In this case, a selection of your available profiles will be displayed when you log in to the Swissmedic Portal. ➢ Select the desired profile by tapping the tile and confirm your selection by tapping **'Use profile'**.	
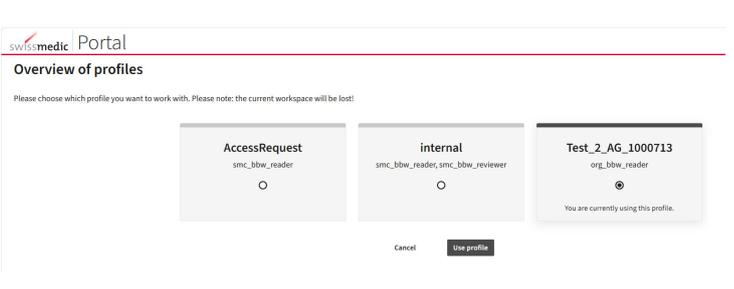
3.4 Company view – Starting page after login

Once you have successfully logged in to the Swissmedic Portal, you will see the initial view.

You see the company associated with your profile as a **context tab** (yellow).	

ⓘ The number shown corresponds to your company reference at Swissmedic. ⓘ The name displayed corresponds to the company name registered with Swissmedic.	
A **page header** and **page navigation** are displayed in the context tab. ⓘ The page header (yellow) contains further information on the displayed context. ⓘ The page navigation (green) shows the available data structure and allows you to navigate within the business context.	
ⓘ With the **arrow icon**, the side navigation can be temporarily hidden on the left and then extended again if needed.	
If the company has one or more types of establishment licences, these will be listed in the side navigation (see picture above). ➢ Click on the corresponding page navigation entry to display the desired type of licence (if only one type is available, it will be displayed immediately). ⓘ Further information on establishment licences can be found in the next chapter of this manual.	
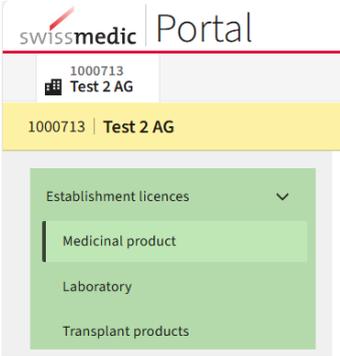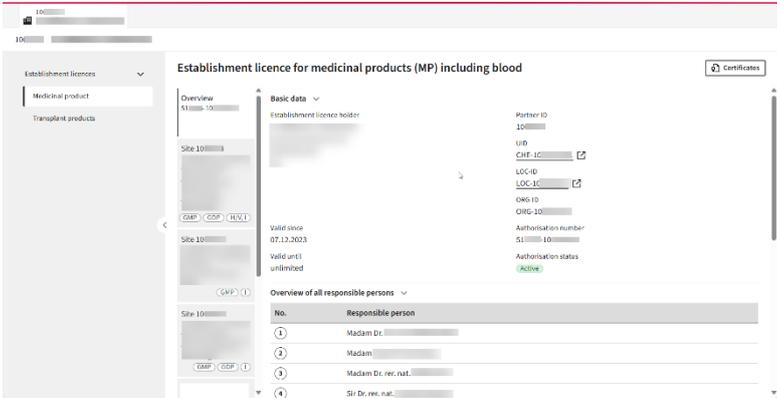
3.5   Establishment licence – Context page

The Swissmedic Portal provides access to a range of business data context pages. One of these contexts is the establishment licences.

There are three types of **establishment licences**, for which the data is all displayed according to the same structure.

- ℹ️ Medicinal product
- ℹ️ Laboratory
- ℹ️ Transplant products

- ℹ️ The currently selected establishment licence is highlighted in white in the side navigation.
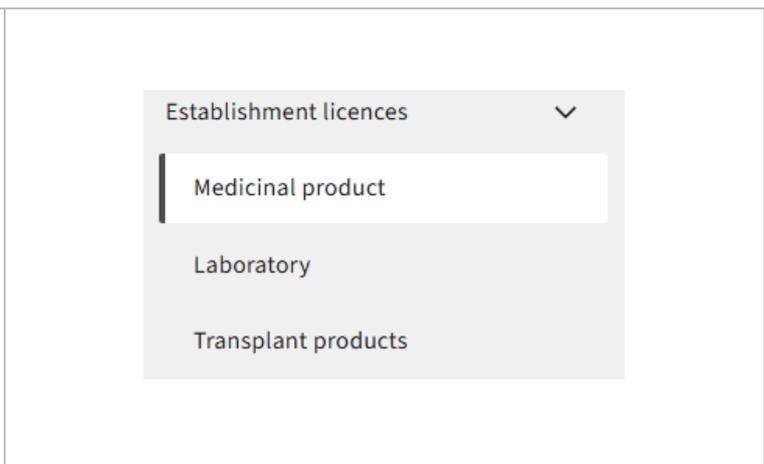
The content page associated with the selected page navigation entry has a sub-navigation (Mega-Tabs).

In these **Mega-Tabs**, you can switch between the overview and the available locations.

- ℹ️ Select the Mega-Tab 'Overview' (yellow) to see an overview of the scope of the licence. The licence number is listed in the Mega-Tab.
- ℹ️ The 'Location' Mega-Tabs (green) allows you to view the details of the location. The location designation and number, as well as the 'GxP' & 'H/V,I' badges, are listed in the Mega-Tab.
- ℹ️ The 'GMP' badge is displayed if the location includes manufacturing activities.
- ℹ️ The 'GDP' badge is displayed if the location includes distribution activities.
- ℹ️ The 'H/V, I' badge is dynamically displayed and always includes the largest common combination.
- ℹ️ No badges are listed in the Mega-Tabs for type laboratory establishment licences.
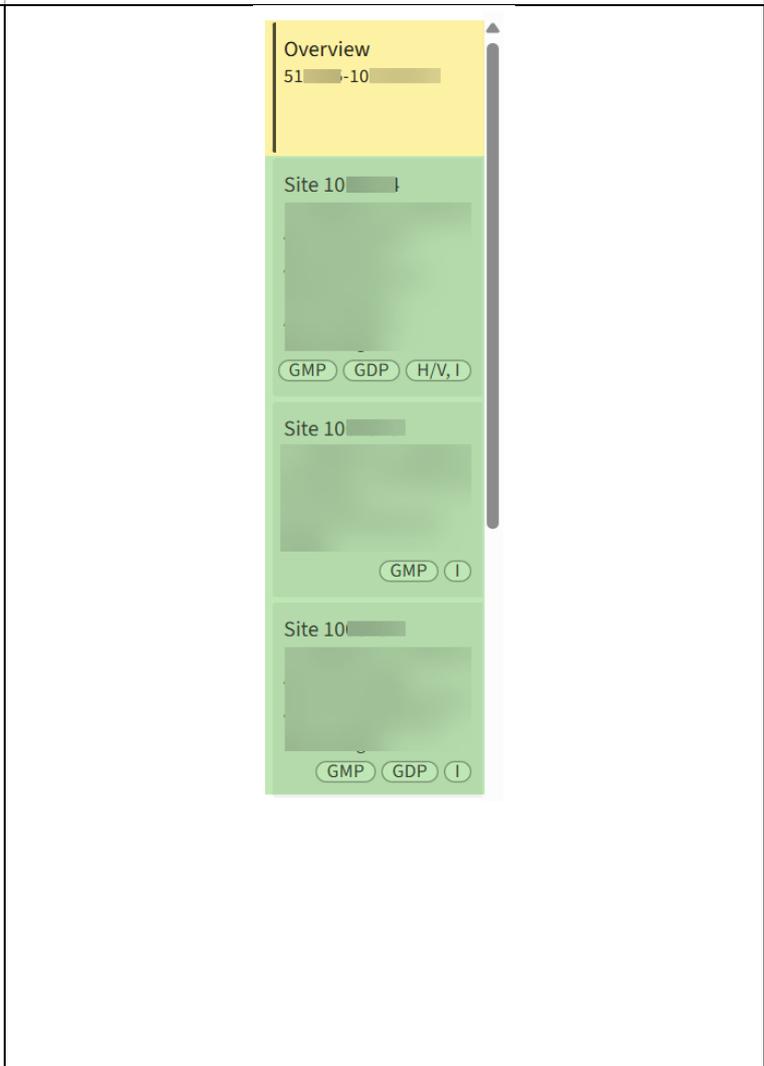
3.5.1 Establishment licence – Overview

The **overview** of the establishment licence consists of three sections.

🛈 Section 1:
Basic data, on the establishment licence and the licence holder including different Id-numbers and corresponding links to internationally shared databases.

🛈 Section 2:
Overview of the responsible person / laboratory management, list of all FVP / FVL belonging to the establishment licence.

🛈 Section 3:
Summary of activities, sites and FVP, overview matrix in which the sites (horizontal) and the main activities (vertical) are linked by the FVP.

3.5.2 Establishment licence – Site detail

The **detail page for the site** also consists of three sections.

🛈 Section 1:
Site Information, includes details about the listed site such as the last inspection date or compliance status.

🛈 Section 2:
Responsible person, with tiles of the FVP / FVL belonging to the location (clicking on the tile filters the list of activities).

ⓘ Section 3: Authorisation scope, includes the detailed list of activities associated with the site, including the remarks.	Authorisation scope ∨ | No.	Operations	Scope	RP
---	---	---	---
∨ 1	MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)		
∨ 1.2	Non-sterile products		
∨ 1.2.1	Non-sterile products (processing operations for the following dosage forms)		
1.2.1.8	Other solid dosage forms	H/V, I	
1.2.1.13	Tablets	H/V, I	
1.2.2	Batch certification (technical release)	H/V	
∨ 1.5	Packaging		
∨ 1.5.1	Primary packaging		
1.5.1.8	Other solid dosage forms	H/V, I		

3.6 Profile Menu (My Profile)

The Swissmedic Portal has a profile menu from which you can access a range of useful links and settings.

3.6.1 Opening the profile menu

The profile menu can be opened as follows. ➢ Click on the **profile icon** at the top right of the Swissmedic Portal (My Profile).	

3.6.2 Profile information (Active profile)

In the displayed profile menu, your active profile ('Logged in as') is displayed at the top of the menu. ⓘ Username according to eIAM profile ⓘ Company affiliation ⓘ Designated role	Logged in as username company affiliation designated role

3.6.3 User settings - e.g. Change language

Within the displayed profile menu, ➢ Click on «**User settings**» to access the corresponding context page.	
In the future, this context tab will offer various setting options for your user profile. For now, however, you will find the language setting here. ➢ Select your preferred language (click on the radio button). The language will change immediately and remain stored in the profile.	
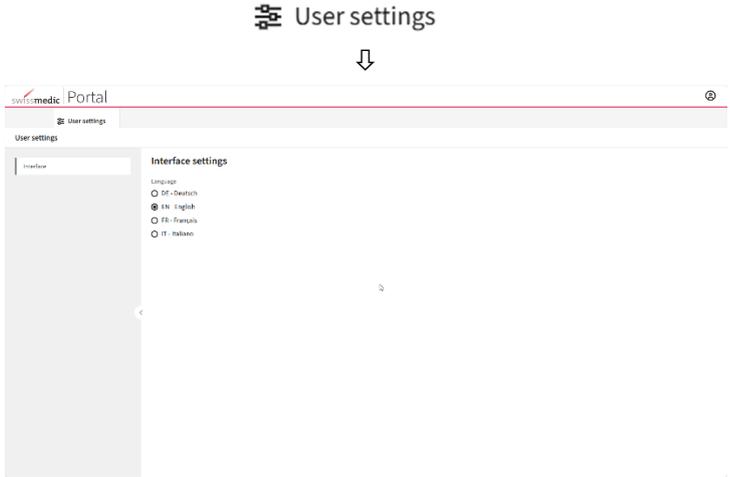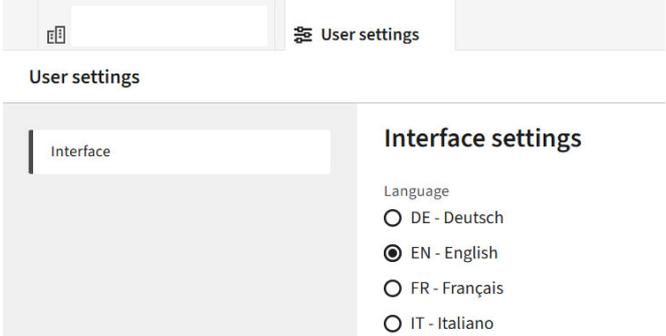
3.6.4 eIAM user profile (Corresponding link)

| In the displayed profile menu, you can jump to your eIAM user profile.

➢ Click on the entry in the profile menu **'eIAM user profile'**.
➢ A new browser tab will automatically open.
➢ Select the appropriate log-in procedure tile.
➢ After successful authentication, you will see your eIAM account. | |
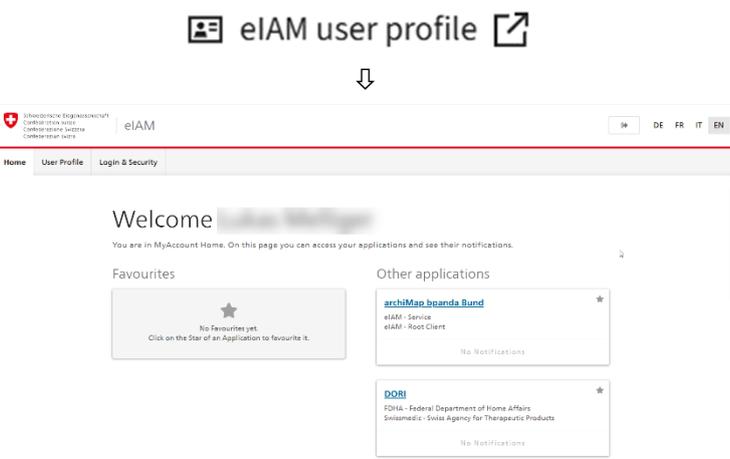
3.6.5 Terms of use (Corrsponding link)

In the displayed profile menu, you can view the terms of use for the Swissmedic Portal (and Swissmedic applications in general). ➢ Click on the entry in the profile menu **'Terms of use'**. ➢ A new browser tab with the terms of use on the Swissmedic homepage will open automatically.	
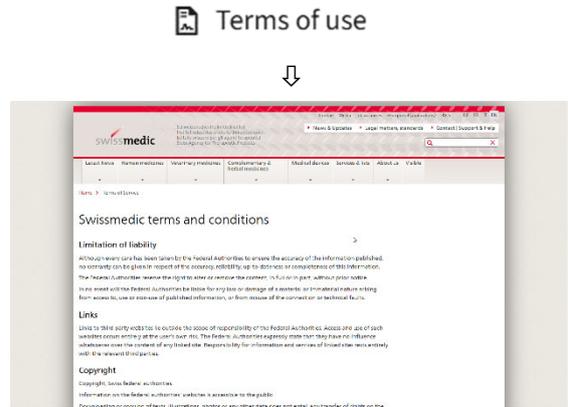
3.6.6 Support (Corrsponding link)

You can access the external support page for the Swissmedic portal via the displayed profile menu. ➢ Click on the **'Support'** entry in the profile menu. ➢ A new browser tab with the support form on the Swissmedic homepage will automatically open.	
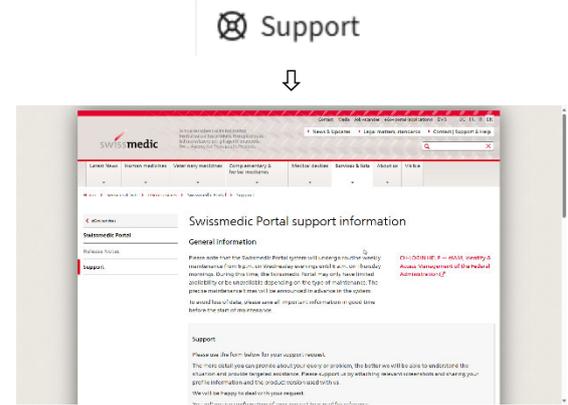
3.6.7 Accessibility (Corrsponding link)

In the displayed profile menu, you can access the information page on accessibility for the Swissmedic portal. ➢ Click on the entry in the profile menu '**Accessibility**'. ➢ A new browser tab with the information page will open automatically.	
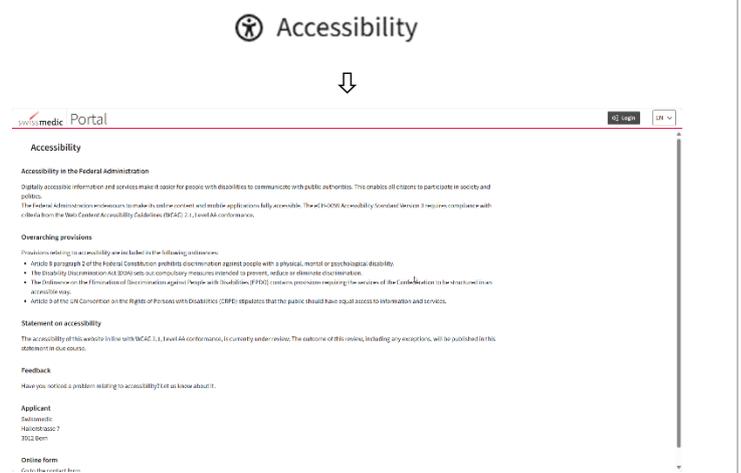
3.6.8 Profile switch – In case of multiple profiles (Mandates)

In the displayed profile menu, you can switch to the profile selection page so that you can select a different user profile. ➢ Click on the entry in the profile menu **'Change profile'**. You will then see an overview of your profiles and can select one (see also Profile selection – User with multiple profiles (Mandates)	⇄ Change profile ⇩ swissmedic Portal **Overview of profiles** Please choose which profile you want to work with. Please note: the current workspace will be lost! **AccessRequest** — smc_bbw_reader ○ **internal** — smc_bbw_reader, smc_bbw_reviewer ○ **Test_2_AG_1000713** — org_bbw_reader ◉ You are currently using this profile. Cancel Use profile
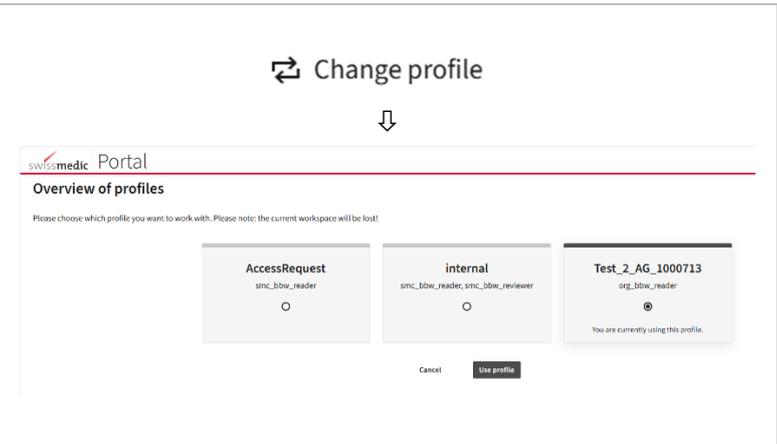
3.6.9 Logout

You can intentionally log out of the Swissmedic Portal via the displayed profile menu. ➢ Click on the **'Logout'** option in the profile menu. ➢ You will then see the logout page.	[↦ Logout ⇩ swissmedic Portal ⇥ Login EN ⌄ 🤚 **You have been successfully logged out.** You will be redirected to the homepage in a few seconds. Login again
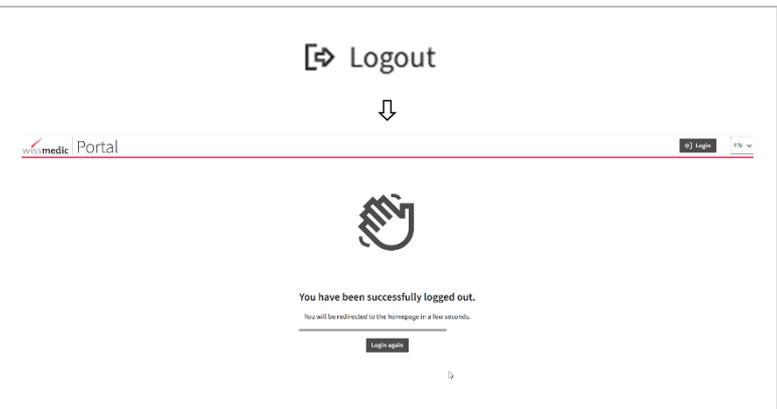
4 Business processes in the Swissmedic Portal

The Swissmedic Portal is the new Swissmedic collaboration platform. It enables digital interaction with business partners, and thus with you.

Our goal is to offer you a comprehensive self-service solution that allows you to easily manage and administer Swissmedic's official services.

We are continuously replacing previous processes and the associated PDF forms with the Swissmedic Portal and using newly structured data and process assistants.

In this section, you will find our digitised applications (requests) that you can process via the Swissmedic Portal.

4.1 Overview of the digital requests

Requests	Description
Fehler! Verweisquelle konnte nicht gefunden werden. Order, Establishment licences	*You order digital / paper-based proof of your business compliance in the form of a GxP certificate directly from the context of the establishment licence.*

4.2 GxP Certificate Order, Establishment licences

Navigate to the overview page for the desired establishment licence of your company.

➢ Click on the '**Certificates**' button (top right of the establishment licence) ℹ The order assistant is displayed as a dialogue window	
ℹ You now see two options: - Digitally view certificates - Order paper certificates ℹ View certificates digitally: You will be redirected to our SwissGMDP application and can generate and download the GxP certificates directly (free of charge). ℹ Order paper certificates: You will be guided through the ordering process and can order your GxP certificates in paper form for a fee. ➢ Click on the tile '**Order paper certificates**' and follow the step-by-step instructions of the order assistant.	
ℹ The order process consists of three steps, which are shown on the left. ℹ Each available location associated with the establishment licence is listed in the order assistant in step 1. ℹ A GxP category can only be selected if the corresponding activities are allowed to be carried out at the location. (see markings: yellow = GMP, green = GDP) ℹ If a site is non-compliant, no certificates can be issued for it. ℹ Please note the date of the last inspection before ordering, so that the corresponding certificate version meets your expectations.	

➢ Enter the desired number of certificates per category and site in the input field. ➢ Confirm the entry with **'Next'.**	
ℹ In the second step of the ordering process, you can enter your order details. ℹ The delivery address can be selected from a list of available addresses or freely entered (see yellow marking). ℹ The billing address is pre-filled and cannot be changed. ℹ The recipient e-mail address is pre-filled and is taken from your user profile. You can add further recipients. ➢ Select a delivery address from the drop-down list by clicking on an entry. ➢ Enter a reference for your own tracking. The reference will also be shown on the invoice. ➢ Click on **'Next'** to confirm your entries.	
ℹ In the last step of the ordering process, a summary of the order will be displayed. ℹ You will see an order summary of all the number of certificates (unit price CHF 200.- according to the fee ordinance) and the total billing amount. ℹ The overview of order details according to step 2 is also listed. ➢ Please check all the information and correct any input errors. You can go back to the previous steps by clicking on 'Back'. ➢ If all the information is correct, you can order the paper certificates by clicking on **'Order'**.	
ℹ After clicking on the 'Order' button, your request will be transmitted. ℹ The successful transmission will be displayed in the application. ℹ You will automatically be redirected to the operating licence overview.	
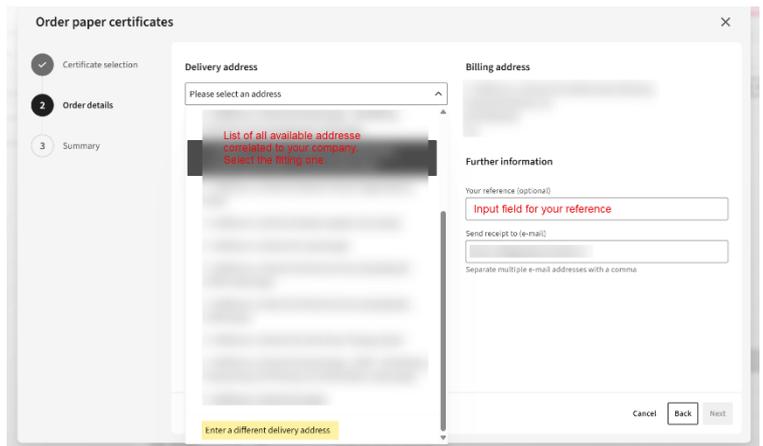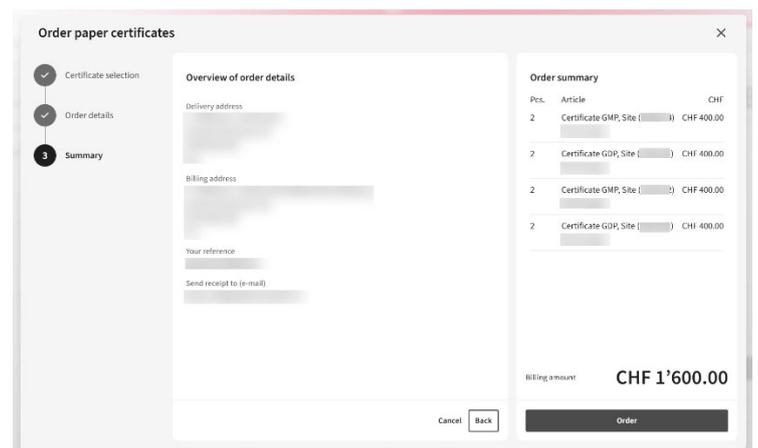
- ⓘ You will receive the order confirmation at the e-mail address you provided (as specified in step 2 of the order process).
- ⓘ This concludes the order process. You can now expect delivery of your certificate order by postal services.

Order confirmation 120000000268

N noreply <noreply@portal.swissmedic.ch>
An ✓

Dear

Thank you for your order!
We are pleased to confirm that your order has been placed and received successfully.

Order Details:

Order Number: 120000000268
Order Date: 10.02.2025
Delivery Address:

Your Reference: IrgendeineReferenz

Establishment Licence:

Site	# GMP	# GDP
-		
	2	2
Last Inspection: 31.03.2023		
-		
	2	2
Last Inspection: 12.04.2022		
Order summary, Amount CHF 1600.-	**4**	**4**

This email was generated automatically. Please do not reply to this email.
If you have any questions or need further assistance, please don't hesitate to reach out:
Support

Kind regards,
Swissmedic

Hallerstrasse 7
3012 Bern
Switzerland

Swissmedic