

Guidance document
swissdamed Service Agreement

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Abbreviations

CHRN	Swiss Single Registration Number according to Art. 55 MedDO ¹ / Art. 48 IvDO ²
PRRC	Person responsible for regulatory compliance
MedDO	Medical Devices Ordinance
IvDO	Ordinance on in Vitro Diagnostic Medical Devices

1 Subject matter

This service agreement describes the general legal framework for the use of the web application swissdamed, which is provided by the Swiss Therapeutic Products Agency (hereafter "Swissmedic").

2 Scope

The service agreement is intended for legal and natural persons who are domiciled in Switzerland and must be registered under Art. 55 MedDO or Art. 48 IvDO.

Based on the Customs Treaty³ between Switzerland and Liechtenstein, the terms "domiciled in Switzerland" and "on the market in Switzerland" refer to the common market of Switzerland/Liechtenstein (customs union), if the devices are placed on the market in accordance with MedDO / IvDO.

Economic operators based in other countries (excluding Liechtenstein) cannot be registered in swissdamed.

3 Services and responsibilities of Swissmedic

3.1 General

swissdamed is the medical devices information system operated by Swissmedic in order to discharge its responsibilities under MedDO/IvDO. Economic operators can register themselves using swissdamed. On completion of registration, Swissmedic issues the CHRN to the economic operators via swissdamed. Swissmedic specifies the details for providing and operating swissdamed. Swissmedic endeavours, but cannot guarantee, to make swissdamed available to the public and the registered economic operators at all times and in a fault-free condition. Swissmedic reserves the right, at any time and without consulting the registered economic operators, to interrupt, modify, supplement or restrict the processes, structure or functions of individual, several or all functions of swissdamed. It informs the affected registered economic operators, if possible in advance, about the details as necessary. While failures and errors are rectified as quickly as possible, Swissmedic decides on the timing of the troubleshooting at its own discretion. Depending in each case on the duration of the

¹ Medical Devices Ordinance (MedDO; SR 812.213)

² Ordinance on In Vitro Diagnostic Medical Devices (IvDO; SR 812.219)

³ Treaty between Switzerland and Liechtenstein on the Accession of the Principality of Liechtenstein to the Swiss Customs Area (SR 0.631.112.514)

failure or interruption, and depending on the complexity of the error or problem, Swissmedic provides relevant information via its official website www.swissmedic.ch.

3.2 Structure of swissdamed

swissdamed will, in future, consist of two interconnected areas, one that is made available only to registered companies and the relevant authorities (restricted section), and a public section where information is published on the economic operators and, subsequently, on the devices.

The restricted section consists of the following modules:

- Basic registration of legal or natural persons (companies) and registration of economic operators
- Registration of the devices (still in development)

The public section is available to the public as a website. The following information on the registered economic operators is published in the public section:

- Role of the operators (“actors” in swissdamed)
- CHRN
- ID mandate, incl. name of the mandate, address and start and end of the mandate.
- UID
- Name of the company
- Address of the company
- Contact details for the company (telephone, e-mail, website)
- PRRC (first name, last name, address and contact details)
- Status of the economic operator

The rest of the data for economic operators stored in the swissdamed database (restricted section) is not published and can be viewed only by the economic operator and the relevant authorities.

3.3 Distinction

swissdamed serves the same purpose in Switzerland as EUDAMED does in the European Union. The data in swissdamed must be updated by the registered companies themselves. swissdamed is not synchronised with EUDAMED.

Since the Mutual Recognition Agreement (MRA)⁴ has not been updated, Swissmedic does not have access to EUDAMED data that are not publicly available.

swissdamed currently only enables economic operators to be registered.

The issuing of the CHRN does not constitute a certificate of conformity, an officially reviewed registration of the devices placed on the market by the economic operators, or an assessment of the quality of these devices.

The provisions concerning the registration of devices (Art. 17 para. 5 MedDO / Art. 16 para. 5 IvDO) will come into force at a later date (Art. 110 MedDO / Art. 91 IvDO).

⁴ Agreement between the Swiss Confederation and the European Community on the mutual recognition of conformity assessments (Mutual Recognition Agreement, MRA)

3.4 Basic registration of companies and registration of economic operators (Module 1):

For the basic registration, the applying company must register itself via the web application swissdamed (www.swissdamed.ch).

In a second step, the economic operator can complete and submit the online registration form for the desired role as economic operator (e.g. manufacturer, authorised representative, etc.).

No applications submitted on paper or via e-mail will be accepted.

3.4.1 Technical requirements for the basic registration of a company

A [CH-LOGIN](#)⁵ is required for the registration of a company in swissdamed. The CH-LOGIN is a login procedure provided by the standard eIAM service of the Federal Administration. The terms of use of eIAM apply.

For the basic registration, the company's address details must be taken from the Central Business Name Index of the Federal Registry of Commerce (Zefix), provided the company is registered in the commercial register. Consequently, the company's address can be changed only in the commercial register, not in swissdamed. If the address details for a registered company connected to Zefix are changed, this change is automatically imported into swissdamed. The registered company will be informed of the change of address details before they are definitively imported into swissdamed. Swissmedic is not responsible for the operation of the Zefix internet platform or for the data retrieved via Zefix.

For companies from Liechtenstein or natural persons without an entry in the commercial register, or if the company does not wish to be connected, swissdamed offers a registration process without connection to Zefix.

3.4.2 Registration of economic operators

After a successful basic registration, a company can register as an economic operator and thereby trigger an application for the issuing of a CHRN for this role. A separate application must be submitted for each role undertaken (manufacturer, authorised representative, importer, etc.). If all the legal requirements are met, the CHRN is issued.

3.4.3 Inactivation of a registration of an economic operator

The registration of an economic operator is inactivated in the following cases:

- If the economic operator inactivates its registration itself.
- If the company's linked ID entry in Zefix has the status of “deleted” (automatic).
- If, during registration or the subsequent use of swissdamed, misuse was suspected or proven, Swissmedic reserves the right to inactivate the registration (see section 5).

In the event of an inactivation, the registration entry is preserved in swissdamed. Inactivated economic operators can no longer operate certain functions or manage their data themselves. (e.g. registration of new medical devices). The inactivation is published in the public section of swissdamed.

⁵ CH-LOGIN FAQ - eIAM, Identity and Access Management, Confederation

If a registered company, user or actor (economic operator) is no longer active in this sector, the profile can be inactivated. Even in the event of an inactivation, the data remain stored in the system until Swissmedic has completed its tasks.

3.4.4 Account administrator

The user who registers the economic operator automatically becomes the administrator (admin) for this actor. The admin can subsequently invite, and assign rights to, new users. An admin can assign rights at company level and / or the level of the economic operators. The admin is responsible for the administration of users.

The admin is responsible for ensuring that the data entered in swissdamed are correct.

Several individuals can perform the role of admin within a company or for an economic operator.

3.5 Device registration (Module 2):

The registration of devices is currently still in development.

3.6 Responsibility of Swissmedic (exclusion of liability)

Swissmedic does not guarantee the availability or reliability of the web application swissdamed, or of applications or registers integrated in, or connected to, swissdamed, or the completeness, authenticity and integrity of the stored data or the data transmitted via its system or the internet. Swissmedic expressly reserves the right to modify, delete or temporarily not publish all or part of the information in swissdamed completely or partially unannounced.

Despite taking the appropriate protective measures and responding to relevant signs, Swissmedic cannot rule out the possibility of swissdamed or its data being used for improper purposes.

Furthermore, Swissmedic cannot – despite taking appropriate protective measures – provide any guarantee or warranty that swissdamed is safe from hackers, viruses or other attacks of any kind. Swissmedic will accept no responsibility for losses arising from improper use of swissdamed by a registered company or third parties.

Swissmedic shall not be liable for losses arising from the improper or negligent use of swissdamed, particularly losses attributable to the failure of a registered company or third parties to exercise their due diligence obligations. Swissmedic shall also not be liable for losses suffered by a registered company as a result of transmission errors, technical shortcomings, interruptions, faults or errors in data. In the event of claims, regardless of their legal basis, Swissmedic shall only be liable for losses caused by its own actions or those of its employees in breach of a fundamental official duty or deliberately.

Swissmedic excludes any liability for its auxiliaries and individuals mandated by it, where legally permissible. Liability for indirect and consequential losses is also excluded, where legally permissible. If Swissmedic may nevertheless be considered liable, such liability shall be subject to Art. 80 of the Therapeutic Products Act (TPA; SR 812.21) in conjunction with Art. 19 of the Government Liability Act (GLA; SR 170.32).

Swissmedic reserves the right to modify its services in relation to swissdamed at any time. Modifications will be announced by Swissmedic in a suitable manner.

4 Obligations and responsibilities of registered companies

4.1 Obligations of registered companies

Registered companies are obliged, during registration and in other usage operations (e.g. changes), to provide complete and accurate information and to ensure that all information is correct and up to date. This responsibility applies to data in both the restricted and public sections of swissdamed and, in addition to details relating to the company and economic operators, to device registration as soon as this module becomes available.

If the address is automatically synchronised with Zefix, the economic operator is exempt from the obligation to report address changes separately, since this obligation is fulfilled by the address change in Zefix. All the timelines for reporting still apply.

The obligation to update the other details (e.g. contact person) still applies.

The registered company undertakes to use swissdamed in compliance with Swiss law and in accordance with the relevant provisions. The registered company is responsible for taking appropriate measures to protect its IT infrastructure and the terminals used to access swissdamed against unauthorised access and misuse by third parties. If the registered company notices an error (in the data or, for example, unauthorised access by third parties) in use, it shall notify Swissmedic immediately. If, as a result of an error, the registered company gains access to confidential or legally protected information, it shall not be allowed to distribute, reproduce or use said information in any other way.

4.2 Responsibilities of the registered company

The registered company bears full responsibility for protecting the confidentiality of and securely managing the access data for swissdamed. It is also responsible for protecting the access data against misuse by third parties. Swissmedic will hold the registered company responsible for any use of accesses by employees or third parties and for the content of the information that is transmitted or processed by the registered company (including its employees) or third parties. Swissmedic regards users who access the system using valid access data as being authorised to do so by the legitimised registered company. Transactions by such users and data transmitted by them are considered by Swissmedic to have been authorised by the legitimised registered company and therefore legally binding. The registered company shall be liable for all losses arising from any violation of its obligations.

5 Exclusion from use of the restricted section of swissdamed

5.1 Blocking at the request of the registered company

If the registered company has any indications that unauthorised individuals have gained, or could gain, access to an account, the registered company or the Administrators shall block the account in question immediately. If the registered company is unable to block the account in question itself, it

shall immediately arrange for the account to be blocked by Swissmedic (notification to Swissmedic). Blocking can cover individual or all accounts, complete access or individual services. The registered company bears full responsibility for any losses arising from the unauthorised access to its account.

Contact address for account blocking by Swissmedic: [Support swissdamed \(swissmedic.ch\)](mailto:Support.swissdamed@swissmedic.ch)

5.2 Blocking by Swissmedic

If Swissmedic or its mandated system operators notice any irregularities in the use of the swissdamed services, Swissmedic can, on its own initiative, temporarily block individual accounts, all swissdamed services or affected swissdamed services without notice. In particular, blocking may occur if:

- the registered companies fail to comply with this service agreement,
- the access credentials are improperly used or distributed
- a threat from malicious software is identified or
- Swissmedic informs the registered company affected by the blocking promptly and in the appropriate manner.

6 Fees/costs

The services provided by Swissmedic in relation to the registration of economic operators and the issuing of the CHRN are subject to fees in accordance with the Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic; SR 812.214.5).

Fees are even charged if the application for registration is rejected.

7 Invoicing and terms of payment

Invoices will be issued solely to an invoicing address in Switzerland or Liechtenstein and will be sent immediately after the service has been provided, i.e. after the CHRN has been issued on swissdamed.

7.1 Advance payments

Swissmedic may require an appropriate advance payment of part or all of the expected fee from persons subject to payment of fees in justified cases, particularly in case of payment arrears or if debt collection proceedings are ongoing⁶.

8 Data protection and archiving

Unless otherwise provided for, Swissmedic shall treat in confidence information that is not generally known and that is disclosed to it during the provision of the swissdamed service. Such information will not be forwarded to third parties without the consent of the registered company. This does not apply to the disclosure of information to third parties that were commissioned by Swissmedic to provide services in connection with the operation of swissdamed. Swissmedic will process personal data provided by a registered company only for the corresponding intended purposes. The data privacy

⁶ Art. 10 GFeeO (SR 172.041.1)

statement and the swissdamed terms of use⁷ provide information about the nature, scope and purpose of the collection of personal data on swissdamed and about the rights of the individuals concerned.

The following data are saved to log files during the use of swissdamed. The log files typically contain information such as the access time, IP address, browser used or the operating system used.

The retention and archiving of the saved and published data are based on Swissmedic's statutory retention and archiving obligations.

8.1 Consent concerning the disclosure of information to foreign authorities by Swissmedic

By accepting this agreement, the registered company consents to Swissmedic providing foreign authorities with information about CHRNs that it has issued, without consulting the registered company and at the foreign authorities' request, e.g. in order to verify the authenticity or validity of the CHRNs if there is a suspicion that they may be counterfeit.

9 Validity and modifications to the service agreement

This latest version of this service agreement is published online and can be viewed at <https://www.swissmedic.ch/swissmedic/en/home/medical-devices/medizinprodukte-datenbank/swissdamed-ueberblick.html>

Swissmedic reserves the right to amend or supplement this service agreement as required. Registered companies are informed of amendments and additions in a suitable manner, and these must be expressly accepted by the registered company during the next login.

10 Contact

Swissmedic, Swiss Agency for Therapeutic Products
Medical Devices Surveillance Sector
Medical Devices Operations Division

Further information on swissdamed can be found on the Swissmedic website at:
<https://www.swissmedic.ch/swissdamed>

11 Applicable law and place of jurisdiction

The contractual relationship is subject solely to Swiss law. The place of jurisdiction is Bern.

⁷ See the swissdamed terms of use

12 Final provisions

Should individual provisions of the service agreement prove to be invalid or illegal, this shall not affect the validity of the service agreement as a whole.

Change history

Version	Change	sig
1.0	First version	sin