

Guidance document
swissdamed Privacy Notice and Terms of Use

Identification number: BW630_40_870

Version: 1.0

Valid from: 06.08.2024

List of contents

1	Terms of Use	2
1.1	Content of swissdamed	2
1.2	Liability	3
1.3	References and links	3
1.4	Copyright	3
1.5	Languages	3
2	Privacy Notice	4
2.1	Person responsible for data processing	4
2.2	Storage for the purpose of web analysis	4
2.3	Procurement and processing of personal data	4
2.4	Purpose of data processing and legal basis	4
2.5	Retention and erasure	5
2.6	Cookies	6
2.7	Social networks and other third-party services	6
2.8	Data transfer and data transmission abroad	7
2.9	References / External services and links / Content	7
2.10	Your rights	7
2.11	Data security	8
2.12	Scope	8

1 Terms of Use

1.1 Content of swissdamed

swissdamed is the medical devices information system operated by Swissmedic in order to discharge its responsibilities specified in Art. 62c of the Therapeutic Products Act (TPA; 812.21) and Art. 83 ff. of the Medical Devices Ordinance (MedDO; SR 812.213). swissdamed is designed to be a web application that enables economic operators to register their details and medical devices¹ and to give the public access to information about economic operators and medical devices. swissdamed is aimed at the public, economic operators, healthcare institutions and authorities.

swissdamed consists of a publicly accessible section (public) and a protected section for economic operators and authorities (restricted) that cannot be viewed by the public.

Economic operators are given access to their account by Swissmedic upon application. The economic operators can then update their data and information relating to their medical devices available in Switzerland.

¹ In this context, the term medical device also includes in vitro diagnostic medical devices and the groups of products stated in Annex 1 MedDO (SR 812.213).

The publicly accessible data can be viewed in the public section of swissdamed.

1.2 Liability

The economic operators are basically responsible for ensuring that their data in swissdamed are correct, complete and up to date.

The economic operators are required to check the correctness of their data on publication.

Swissmedic does not systematically check the data to ensure that the information is correct, accurate, up to date, reliable and complete.

In addition to deficiencies in content, the data may also contain technical inaccuracies or typographical errors.

Swissmedic expressly reserves the right at any time to modify, delete, add comments to, or temporarily not publish all or part of the content unannounced.

Liability claims against Swissmedic for losses of a material or immaterial nature arising from the access or use / non-use of the published information, misuse of the connection or due to technical faults of swissdamed are excluded.

1.3 References and links

Swissmedic is not responsible for references and links to or from websites or web services of third parties. Such websites are accessed and used at the user's own risk and responsibility. Swissmedic expressly declares that it has no influence whatsoever on the design, content, security or offerings of the linked sites. The respective third party is entirely responsible for the information and services on linked websites.

No responsibility is accepted for such websites or web services.

1.4 Copyright

Copyright, Swissmedic.

Downloading or copying content, images, photos or other files does not transfer any rights regarding the content.

The copyright, trademark and all other rights to content, images, photos, data or other files in swissdamed belong exclusively to Swissmedic or the respective economic operators. The reproduction of any elements requires the prior written consent of the copyright holder.

1.5 Languages

The web application is available in German, French, Italian and English. Swissmedic provides information on the use of the web application in all these languages.

The respective economic operators decide on the language in which their information is published. No information is translated by Swissmedic. Swissmedic accepts no responsibility or liability for inconsistencies, misinterpretations or similar that may arise from the translation or (linguistic) interpretation of the published information.

2 Privacy Notice

This Privacy Notice informs you about the nature, scope and purpose of the collection and use of personal data on swissdamed (hereafter also referred to as web application) and provides information about your rights. These rights are based on the applicable data protection laws.

This description of the procurement and processing of personal data is not exhaustive. Other privacy notices/statements/policies or general terms and conditions, user agreements and similar documents may regulate specific circumstances.

2.1 Person responsible for data processing

Responsible for the data processing on swissdamed and contact person for data protection issues (unless otherwise stated in individual cases):

Swissmedic, Medical Devices Surveillance Sector, Hallerstrasse 7, 3012 Bern

2.2 Storage for the purpose of web analysis

When swissdamed is accessed, the following data are stored in log files: IP address, date, time, browser request and information transmitted on the device used, incl. operating system and browser. These data are analysed with analysis tools. The data are stored and processed in Switzerland.

2.3 Procurement and processing of personal data

The processing of personal data in swissdamed is limited to the data required to provide a properly functioning website or web application and user-friendly content and services, or to the data that you have actively made available to us. When you enter data in swissdamed (e.g. assignment account), we process the data that you provide to us to the extent that this is required to fulfil the purpose of processing or to complete the assignment. Mandatory fields are marked as such if this information is necessary for the fulfilment of our statutory task or your request.

The following data are procured and processed in this connection:

- Contact details of a company (name, address and UID number)
- Contact details of an actor (language, telephone number and e-mail address)
- Contact details of an actor's contact person (name, telephone number and e-mail address)
- Contact details of the PRRC (person responsible for regulatory compliance: name, telephone number, e-mail address)
- Contact details of the mandates (company name, address, e-mail address, effective date)
- Contact details of a user (name and e-mail address)

If you have given us your consent to process your personal data for specific purposes, we process your personal data within the scope of, and based on, this consent if we require a legal basis and have no other option. Consent that has been granted may be withdrawn at any time, although this will not affect any data processing that has already taken place.

2.4 Purpose of data processing and legal basis

Laws and ordinances specify what data of yours we can process and in what form.

According to Art. 55 para.1 MedDO, the personal data of contact persons and PRRCs must be stated in swissdamed. The entered data are used to fulfil our duties, in particular to ensure the safety of medical devices, as well as their vigilance and surveillance (see Art. 62c para. 1 TPA).

Swissmedic will verify the information provided by the economic operators and assign them a Swiss single registration number (CHRN) (Art. 55 para. 4 MedDO).

Non-personal data may be used for the independent assessment of long-term device safety or performance or of the traceability of implantable devices (Art. 91 MedDO).

In addition, Swissmedic also processes personal data within legal limits for the following purposes:

Swissmedic and the third parties it commissions are authorised to process personal data that they require for performing all the tasks assigned to them by this ordinance. Specifically, these include:

- a. health data acquired in the course of market surveillance and vigilance;
- b. data documenting the reliability and professional qualifications of vigilance contact persons (Art. 67 para. 2) or persons responsible for compliance (Art. 49 and 52) (Art. 79 MedDO).

The medical devices information system contains the following data (Art. 85, para. 1, let. a, b, g, and h MedDO):

- device data;
- data on economic operators;
- data that can be used to manage and adapt the medical devices information system (system data);
- authentication data, assigned user roles and basic settings for using the medical devices information system (user data).

The medical devices information system can be used to obtain data referred to in Art. 85 MedDO from the European Database on Medical Devices and from cantonal electronic systems; it may also submit data to Eudamed and cantonal systems (Art. 86 MedDO).

Swissmedic may publish the following in the medical devices information system (Art. 90, let. a, b, f, and j MedDO):

- device data, as specified in Part B of Annex VI to EU MDR;
- information on economic operators and devices, as specified in Part A of Annex VI to EU MDR;
- information on certificates issued under Articles 28 and 42–44 (MedDO);

information on market surveillance measures, particularly recalls, on non-conforming devices and preventive health protection measures.

2.5 Retention and erasure

Swissmedic processes and stores your personal data for as long as needed to fulfil the contractual and legal obligations, or otherwise for the purposes pursued with the processing, as well as to satisfy the statutory retention and documentation obligations. It is possible that personal data are stored for

the period during which claims can be asserted against Swissmedic and insofar as Swissmedic is otherwise legally obliged or authorised to do so, or this is required for legitimate (business) interests (e.g. for evidentiary and documentation purposes).

The personal data collected by Swissmedic will be retained only for as long as needed to fulfil the respective purpose. Statutory requirements or other obligations may lead to a longer retention period.

2.6 Cookies

swissdamed uses cookies in order to make the visit to the web application more user-friendly and to enable certain functions to be used. Cookies are small text files stored on your computer. Most of the cookies used are deleted from your hard drive at the end of the browser session (these are known as session cookies). Other cookies remain on your computer so that you are recognised on your next visit (these are known as permanent cookies).

You can prevent cookies from being stored in your browser by restricting or disabling the storage and reading of cookies. If you block cookies, certain functions (e.g. language selection) may no longer work.

2.7 Social networks and other third-party services

Swissmedic manages various accounts and profiles on social networks (including X, Facebook, LinkedIn, Xing, Instagram, etc.), its own YouTube channels and various apps. These sites and services are provided and operated by third parties. Each of these sites has its own data protection rules.

Some third-party services, including YouTube, X, Instagram, etc., are also directly integrated in individual Swissmedic websites. These providers also use cookies. During the use of Swissmedic websites, user data are automatically transmitted to these companies, and the data protection rules of the respective provider expressly apply. Users must be aware that data may be collected and also forwarded to third parties via these services. If users simultaneously use an account of a service, the operator can assign this transmitted information directly to the respective personal account.

Swissmedic has no influence on the collection of data or their subsequent use by these operators. Swissmedic cannot discern to what extent, where or for how long the data are stored, to what extent the operators comply with any erasure obligations, or what analyses or connections they undertake with the data, or to whom they send the data.

The most important services operated by third parties and used by Swissmedic are as follows:

LinkedIn: LinkedIn Corporation, 1000 W Maude Ave Sunnyvale, CA, 94085-2810 United States. You can find information on the management of user data in the LinkedIn Privacy Policy.

X: X Corp., 1355 Market Street, Suite 900 San Francisco, CA 94103, United States. You can find information on the management of user data in the Privacy Policy and the Cookies Guideline of X.

Facebook: Facebook, Inc. belongs to Meta. You can find information on the management of user data in the Meta Privacy Policy.

Instagram: Instagram, Inc. belongs to Meta. You can find information on the management of user data in the Meta Privacy Policy.

YouTube: As soon as you access a Swissmedic site with an embedded YouTube video, a link to the YouTube servers is established and plug-ins from YouTube (YouTube LLC, 901 Cherry Ave., San Bruno, CA 94066, USA; subsidiary of Google LLC) are used in some cases. YouTube is informed of the site that was visited and from which IP address.

Vimeo: Swissmedic publishes videos on Vimeo. Vimeo belongs to Vimeo.com, Inc., Attention: Legal Department, 330 West 34th Street, 10th Floor, New York, New York 10001, USA. You can find information on the management of user data in the Vimeo Privacy Policy.

eIAM and identity providers: eIAM is used for the authenticated access to swissdamed. Since eIAM is an identity provider, electronic identities mediated by third-part identity providers may be used. List of identity providers used:

- CH-Login
- Fed-Login

Pingen: online letter service for sending physical letters within Switzerland via Swiss Post. You can find information on the management of user data in the Privacy Policy of Pingen.

Sendgrid: (also known as Twilio SendGrid): We use Sendgrid from Twilio to send transactional emails. The service provider is the American company Twilio Inc. based in San Francisco, USA. Twilio uses your data, including in the USA. You can find more information about the data processed when using Sendgrid in the Twilio Privacy Notice.

Azure: Microsoft Azure is the cloud computing platform of Microsoft, belongs to Microsoft Corporation, One Microsoft Way, Redmond, WA 98052-6399, USA. You can find information on the management of user data in the Microsoft Privacy Statement. The web application is operated on Azure exclusively in server rooms located in Switzerland.

2.8 Data transfer and data transmission abroad

In principle, we use your personal data only within Swissmedic.

If, and insofar as, we use third parties in the fulfilment of contracts (e.g. service providers, IT providers), or in the event that we outsource certain data processing tasks (order processing), these parties receive personal data only to the extent required by the transmission for the corresponding service.

No data are transferred to agencies or persons outside the European Economic Area (EEA) or Switzerland, nor is any such transfer planned. The only exception is the use of Sendgrid, which is described under 2.7.

2.9 References / External services and links / Content

Swissmedic has no influence either on external sites to which swissdamed refers, or on external sites that refer to swissdamed. Therefore, Swissmedic cannot guarantee that the information included on such sites is correct or free of malware (e.g. viruses). The respective third party is entirely responsible for the information and services on linked websites or web services. No responsibility is accepted for such websites or web services.

2.10 Your rights

You have the right to request information about the processing of your personal data from the responsible operator. In this case please contact the above-mentioned responsible operator. Further rights such as the right to data erasure, data rectification, restriction of data processing and the right to data portability exist within the legally prescribed framework.

The following data are saved to log files during the operation of swissdamed. Log files typically contain information such as the access time, IP address, browser used or the operating system used. Consequently, swissdamed users do not have a right of objection in this regard. Every data subject is also entitled to assert their claims in court or to lodge a complaint with the competent data protection authority. The competent data protection authority in Switzerland is the Federal Data Protection and Information Commissioner (<http://www.edoeb.admin.ch>).

2.11 Data security

Within the application visit, swissdamed uses encrypted data communication based on TLS in conjunction with the highest encryption level supported by your browser. You can recognise that the transmitted data are encrypted by the locked position of the padlock or key icon in the address bar of your browser.

Swissmedic takes appropriate technical and organisational security measures during data processing to protect your data against accidental or deliberate manipulation, partial or complete loss, destruction or unauthorised access by third parties.

2.12 Scope

This Privacy Notice applies to the whole swissdamed web application. It may be changed or adapted at any time without prior notice. The current Privacy Notice can be viewed at [Overview \(swissmedic.ch\)](#).

This Privacy Notice is also available in German, French and Italian.

Change history

Version	Change	sig
1.0	First version	sin