

Privacy notice for reports on adverse reactions to products

In this privacy notice, we wish to inform you about the nature, scope and purpose of the personal data we process when handling your report of an adverse reaction to our products.

The controller within the meaning of Art. 4(7) GDPR is Melisana AG, Grüngasse 19, 8004 Zurich (hereinafter: "we" or "us").

I. I. Categories of personal data that we process

We process the personal data you provide as part of your report if you inform us of possible side effects or quality defects concerning our products.

You are not obliged to provide us with your personal data, but without it, we may not be able to fully process your report.

II. Purposes and legal bases of data processing

We process the above data exclusively in order to comply with our legal obligations under laws and regulations on medicinal and medical products etc.

The legal basis for this is Art. 6(1)(1)(c) and Art. 9(2)(i) GDPR in conjunction with the aforementioned legal standards.

III. Recipients or categories of recipients of your data

At our company, only those employees who need your personal data to fulfil our contractual and legal obligations will have access to it. Your data will only be passed on to external parties if this is permitted or required by law or if you have given your consent.

The categories of external recipients of your data are listed below:

- Affiliated companies within our group of companies, where they act as service providers for us and provide e.g. IT services so that we can provide our services, or if they require the data to fulfil our contractual and legal obligations.
- Private entities outside the group of companies, such as, in particular, service providers that record adverse reaction reports, or IT service providers that store data and assist with systems administration and maintenance, plus file archiving and shredding companies.
- Public bodies and institutions, where we are legally required to do so. For example, our legal obligations include notifying the competent state authorities to which the Klosterfrau Group companies are accountable about any reported quality defects in our products.

IV. Transfer to third countries

Data are only transferred to countries outside the EU or the European Economic Area EEA ("third countries") if this is necessary in order to manage our contractual relationships, or is permitted or required by law (e.g. reporting obligations under tax law), or if you have given us your consent, or as part of order processing. When we use service providers in third countries, they are required to comply with the level of data protection in Europe by agreeing to the EU Standard Contractual Clauses. Alternatively, we transfer the data based on an adequacy decision by the European Commission. Further information can be obtained from our data protection officer.

V. How long we store your personal data

We only process your personal data for as long necessary to fulfil its specific purpose. We then delete it unless we are required to store it for a longer period.

For product safety reasons we are required to store data concerning safety-related events for up to ten years after the product marketing authorisation ends. This is for testing purposes due to legal requirements, depending on the status of the product as a medicinal product, medical device, cosmetic or foodstuff.

In addition, we are subject to various retention and documentation obligations, in particular under the Swiss Code of Obligations (Obligationenrecht, OR). The retention and documentation periods stipulated in the OR are up to ten years beyond the end of the business relationship or the pre-contractual legal relationship.

Furthermore, special statutory provisions may require a longer retention period, e.g. the preservation of evidence under statutory limitation periods.

If the data are no longer required for the fulfilment of contractual or legal obligations and rights, they are routinely deleted unless we temporarily need to process it further in individual cases to fulfil the purposes listed above.

VI. No automated individual decision-making (including profiling)

We do not use any procedures for purely automated decision-making in individual cases (including profiling) as provided for in Art. 22 GDPR.

If we do use such a procedure in individual cases in the future, we will inform you of this separately.

VII. Your data protection rights

Under certain conditions, you can exercise your data protection rights with us

- **Right of access**

You have the right to request confirmation from us at any time as to whether we are processing personal data concerning you. If this is the case, you have the right to access information about this personal data and certain other information (including processing purposes, categories of personal data, categories of recipients, planned storage period, your rights, the source of the data, the use of automated decision-making and, in the case of transfer to a third country, the appropriate guarantees).

- **Right to rectification**

You have the right to demand that we rectify the personal data stored about you if it is inaccurate or incorrect.

- **Right to erasure**

Under certain conditions, you have the right to demand that we erase personal data concerning you without undue delay. In certain cases, the right to erasure does not apply: for example, if the processing of personal data is necessary (i) to exercise the right of freedom of expression and information, (ii) to comply with a legal obligation to which we are subject (e.g. statutory retention obligations) or (iii) to establish, exercise or defend legal claims.

- **Right to restriction of processing**

You have the right to demand that we restrict the processing of your personal data.

- **Right to data portability**

Under certain conditions, you have the right to receive the personal data concerning you, which you have provided to us, in a structured, commonly used and machine-readable format.

- **Right of withdrawal**

You have the right to withdraw your consent to the processing of personal data at any time with effect for the future.

Information about your right to object under Art. 21 GDPR

You have the right to object at any time, on grounds relating to your particular situation, to the processing of your data based on Art. 6(1)(1)(f) GDPR (data processing based on a balancing of interests). This also applies to profiling based on this provision within the meaning of Art. 4(4) GDPR.

If you object, we will no longer process the personal data unless we can demonstrate compelling legitimate grounds for the processing which override your interests, rights and freedoms or for the establishment, exercise or defence of legal claims.

You can address enquiries regarding the exercise of your aforementioned data protection rights to us either using the contact details of the controller as provided above, or by email to info@melisana.ch, or by contacting our external data protection officer using the following contact details:

Mr Alexander Bugl, Bugl & Kollegen Gesellschaft für Datenschutz und Informationssicherheit mbH, Eifelstraße 55, 93057 Regensburg, Germany Tel. +49 941-630 49 789, email: Datenschutz.buglundkollegen@klosterfrau.de.

You also have the right to lodge a complaint with a supervisory authority, in particular in the Member State of your habitual residence, place of work or place of the alleged infringement if you consider that the processing of personal data relating to you infringes the GDPR.

Last updated: September 2023