Privacy Policy for Pharmacovigilance, Cosmetovigilance, and Medical Device Vigilance Data, and Clinical Studies

This Privacy Policy contains important information with regard to the processing of your personal data by Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH and Biofrontera AG, all located at Hemmelrather Weg 201, 51377 Leverkusen, Germany (hereinafter jointly referred to as "***Biofrontera***", "***us***", "***our***" or "***we***") in the context of the safety of drugs, medical devices and cosmetics, the processing of medical inquiries, the management of product complaints and the performance of clinical trials. The processing is based on our obligations under applicable data protection laws, in particular the EU General Data Protection Regulation ((EU) 2016/679) ("***GDPR***").

Pursuant to Art. 4 No. 1 of the GDPR, personal data means any information relating to an identified or identifiable natural person. This includes information such as your name, your address, your telephone number and your date of birth, which can be assigned to a specific person with reasonable effort (hereinafter referred to as "***data***").

Because humans have a wide variety of biological responses to drugs, medical devices or cosmetics, and only a limited number of test persons participate in clinical trials, not all adverse events and side effects associated with the use of drugs and medical devices can be detected during clinical development - not even by the most extensive clinical trials. Biofrontera develops and sells prescription drugs, medical devices and cosmetics. We process data for pharmacovigilance, cosmetovigilance, and medical device vigilance purposes to ensure the safety and global monitoring of all products, to protect public health and to ensure a high standard of safety of Biofrontera products. Pharmacovigilance, cosmetovigilance, and medical device vigilance encompasses activities focused on identifying, assessing, understanding, and preventing adverse effects, side effects and incidents (hereinafter referred to as the "***adverse events***") associated with pharmaceutical products, including prescription drugs, medical devices, and cosmetics. Pharmacovigilance, cosmetovigilance, and medical device vigilance obligations require us to document adverse events and, where required, report the information to the relevant regulatory authorities.

In addition, the development of new drugs or medical devices is only possible with the help of clinical trials. These are necessary to gain or expand knowledge about the efficacy and tolerability of drugs and medical devices. This is why the legislator stipulates that new drugs and medical devices must be clinically tested. If you take part in clinical trials, it is necessary to process your data and report it to the responsible supervisory authorities.

Processing of your data

1. **Pharmacovigilance, cosmetovigilance, and medical device vigilance (events, other notifications, and reports)**

   We may need to process the following data:

   1.1. about the patient:

   - contact information, such as patient's name and/or initials, address, phone/fax/email or other contact information;
   - demographic information such as date of birth, age group, gender, weight or height;
   - information on health, information on pregnancies – where applicable, racial or ethnic origin;
   - date of treatment, medical history and health status and other medical information provided by you, e.g.:
     - use details of the Biofrontera product suspected of having caused the adverse event, including the dose, the underlying indication for the treatment, and details of the treated body parts;
     - information on photodynamic therapy (PDT) when using our drug Ameluz® 78 mg/g gel;
     - details of any other drugs, cosmetics or products you are taking or using or were taking or using at the time of the adverse event, including the dose you were taking, using or which has been prescribed for you, the duration of taking the drug or cosmetic, the reason for taking the medicine or cosmetic and any subsequent changes of your therapy;
     - details of the adverse event that affected you, the treatment you received due to this adverse event, the potential impact of the adverse event on your health and other information about your medical history that is considered relevant by the reporter, including documentation necessary to evaluate the report, such as laboratory reports, medication history, patient history and other documents as appropriate.

   1.2. About the notifying person:

   - contact information, such as name and/or initials, address, phone/fax/email or other contact information;
   - job title (this information may influence the questions you are asked depending on the assumed level of medical knowledge about the adverse event).

2. Medical inquiries

If you contact us with a question about Biofrontera health products, we may process the following data about you:

- contact information such as name, address, telephone/fax/mobile phone/email/ or other contact information;
- information as part of your inquiry;
- information about health, racial or ethnic origin.

3. Clinical trials

Regarding the data that is collected and processed about you in the context of clinical studies, a distinction must be made between:

- data by which you can be directly identified (e.g. name, date of birth, address, photos, etc.);
- pseudonymised (encrypted) data, in which all information that allows direct conclusions to be drawn about your identity is replaced by a code (e.g. a number) or (e.g. in the case of image recordings) made unrecognisable. This means that the data can no longer be assigned to your person without additional information and without disproportionate effort;
- anonymised data that can no longer be traced back to you personally.

The encryption code is kept strictly separate from the encrypted data records and is only stored by us. The data is protected against unauthorised access.

4. Purposes of the data processing

As part of the fulfilment of our **pharmacovigilance, cosmetovigilance, and medical device vigilance** obligations, we may process your data to:

- investigate the adverse event;
- contact you to obtain further information about the adverse event you have reported;
- to compare the information on the adverse event with information on other adverse events reported to Biofrontera and, on this basis, to analyse the safety of a production batch or an active substance of the Biofrontera product; and
- submit required reports to the competent regulatory authorities so that they can analyse the safety of a production batch, the Biofrontera product together with reports from other sources;

When publishing information about adverse events (e.g. case studies and summaries), we remove any identifying personal information to protect the identity of data subjects.

If you contact us with a **medical inquiry** about Biofrontera products, we may process your data to

- process your inquiry;
- contact you for follow-up questions and clarification purposes;
- analyse the content of your request;
- ensure the quality of our services;
- give you an answer to your question.

In the case of conducting **clinical trials** on you as a test subject, we process your data to

- conduct statistical planning, systematic review and careful evaluation of new drugs and medical devices. This is the only way we can reliably determine how effective and how well tolerated drugs and medical devices really are;
- gain confidence in dealing with treatment methods;
- fulfil the strict regulations and established procedures as a manufacturer of such products;
- answer scientific questions and improve medical treatment.

5. Recipients of your data

As part of the processing of data, we may transfer data to the following categories of recipients:

- to companies within the Biofrontera Group to analyse and process a reported adverse event. This applies to Biofrontera Bioscience GmbH (Medical Affairs department) and Biofrontera AG (pharmacovigilance) to manage the recording of reports and the creation of a log list as well as the reporting of adverse events
- to the competent supervisory authorities, regarding adverse events. In this case, your data will be pseudonymized;
- to third-party service provider who support the processing of adverse events on behalf of Biofrontera. The server of the service provider is located in Germany;
- to our service providers to whom Biofrontera submits data and who provide services on our behalf;
- to other pharmaceutical companies acting as co-distributors or other licence partners of the Biofrontera Group, if the pharmacovigilance, cosmetovigilance,

and medical device vigilance obligations for a Biofrontera product require such an exchange of safety information;

- to a legal successor of the business in the event of a sale, assignment, transfer or acquisition of Biofrontera or a specific Biofrontera product or division, whereby we will require the purchaser, assignee or transferee to process data only in accordance with applicable data protection laws;
- to law firms and/or consultants for any necessary support in legal decisions and for the pursuit or defence of legal claims;

In the case of clinical trials, the data is only passed on in encrypted or anonymised form. Only encrypted or anonymised data will also be used for any publications.

6. International transfers

As part of the processing of data for pharmacovigilance, cosmetovigilance, and medical device vigilance purposes, Biofrontera may transfer data to countries other than those in which the data was collected. Furthermore, due to the corporate structure and marketing strategy, it may be necessary for us to transfer your data to other companies within the Biofrontera Group. These may be so-called third countries with a low level of data protection.

For example, the US Food and Drug Administration (FDA) requires that reports on drugs that are also marketed in the USA are also sent to the FDA if these reports fulfil certain criteria. In this case, however, data is transmitted in anonymised form.

When transferring data internationally, Biofrontera takes care to do so only in accordance with applicable law. This is done, for example, by concluding special data protection contracts (e.g. standard contractual clauses) with the respective recipients or based on an adequacy decision (Art. 45 (1) GDPR).

The transfer of data collected in the EU to third countries may also be based on other legal basis, e.g. if this is necessary for important reasons of public interest (Art. 49 (1) lit. d) GDPR).

7. Security of your data

In accordance with Art. 32 GDPR, we have implemented appropriate and state-of-the-art technical and organisational measures to protect your data that is processed for the purposes stated above. These also include security measures and procedures that restrict access to data to those employees and teams who need this data to perform their work tasks.

We implement physical, electronic and procedural measures to protect data from accidental loss, destruction, damage and unauthorised access, use and disclosure.

Where appropriate and reasonable, we process data in anonymised or pseudonymised form.

8. Retention periods

We will process, store and archive your data in accordance with the legal and internal group requirements for storing and reporting information on pharmacovigilance, cosmetovigilance, and medical device vigilance. This includes, for example, the guideline on good pharmacovigilance practices.

Pharmacovigilance data shall be retained for the entire lifecycle of the product and for additional ten (10) years following its withdrawal from the market in the last country where it was marketed, or after the expiration of the marketing authorization.

Cosmetovigilance data and all related information required for inclusion in the Product Information File must be retained for at least 10 years from the date the last batch of the cosmetic product was placed on the market.

Medical device vigilance data: All relevant vigilance data must be retained for at least 10 years after the medical device was last made available on the European market.

Medical inquiries: After we have answered your inquiry, we will retain the information about the inquiry for as long as is necessary for record-keeping purposes and to comply with legal requirements. The inquiry will then be anonymised in accordance with the relevant data protection regulations. Medical inquiries containing information on adverse events will be handled in accordance with pharmacovigilance, cosmetovigilance, and medical device vigilance requirements.

Clinical trials: Archiving all medically relevant treatment records is part of the general medical documentation and retention obligations. In addition, the separate storage of pseudonymised data must also be carried out as part of the archiving purposes of clinical trial. The relevant legal framework regarding archiving results from numerous legal requirements (e.g. the German Medicinal Products Act (*AMG*), the Medical Device Regulation (*MDR*), etc.). Retention periods may vary depending on the applicable legislation for the clinical trial (e.g., 10 or 25 years). The so-called Trial Master Files (TMFs) require a

mandatory retention period of 25 years for clinical trials, to be maintained for as long as the corresponding drug's approval remains valid.

9. Legal basis for the processing of your data

Biofrontera processes information on adverse events in connection with Biofrontera products in accordance with the requirements of the applicable pharmacovigilance, cosmetovigilance, and medical device vigilance legislation.

The processing

- for **pharmacovigilance, cosmetovigilance, and medical device vigilance** purposes is conducted for reasons of public interest in public health, such as to ensure high quality and safety standards in healthcare and for drugs, medical devices or cosmetics pursuant to Art. 6 (1) lit. c) and e) GDPR and pursuant to Art. 9 (2) lit. i) GDPR in conjunction with pharmacovigilance, cosmetovigilance, and medical device vigilance legislation and local data protection laws. Furthermore, processing may take place in accordance with Art. 6 (1) lit. f) GDPR for the legitimate interest of Biofrontera to further improve our products;
- for the purposes of medical inquiries, we ask for your consent when you contact us (Art. 6 (1) lit. a) in conjunction with Art. 7 and Art. 9 (2) lit. a) GDPR). Art. 7 and Art. 9 (2) lit. a) GDPR), where possible and required by law. In addition, it is our legitimate interest to process your data to respond to your inquiry and to comply with documentation and record-keeping obligations (Art. 6 (1) lit. f) GDPR).

  Medical inquiries containing information on adverse events are processed in accordance with the requirements of pharmacovigilance, cosmetovigilance, and medical device vigilance;
- for the purposes of conducting clinical trials, the processing of your data is based on consent pursuant to Art. 6 (1) lit. a) in conjunction with Art. 7 and Art. 9 (2) lit. a) GDPR. The consent is voluntary and can be revoked at any time with effect for the future in accordance with Art. 7 (3) GDPR.

10. Your rights (data subject rights)

You have the right

- to request information about your data processed by Biofrontera (Art. 15 GDPR);
- to request the rectification of your data if it is incorrect or incomplete (Art. 16 GDPR);

- to restriction of processing, e.g. if the accuracy of data is disputed or the processing is unlawful (Art. 18 GDPR);
- to request the transfer of your data to you or another person in a commonly used format (Art. 20 GDPR);
- to lodge a complaint with a data protection supervisory authority (Art. 77 GDPR);
- to object to the processing of your data, provided that the processing is based exclusively on a legitimate interest of Biofrontera (Art. 21 GDPR);
- to request the deletion of your data if the processing is no longer necessary for the purpose of the processing or if there is no legal basis for further processing (Art. 17 GDPR);
- to withdraw consent to the processing of data that may have been given (Art. 7 (3) GDPR). The withdrawal of consent does not affect the lawfulness of processing of your data prior to the withdrawal of consent.

Please note, however, that these rights may be restricted to fulfil our legal pharmacovigilance, cosmetovigilance, and medical device vigilance obligations. Your rights are not fully applicable if there is a legal basis for processing your data. For example, we cannot delete information collected as part of an adverse event report unless it is incorrect. We may ask you to provide reasonable proof of your identity before complying with a request for access to or correction of your data.

11. Contact details

If you have any questions about this privacy policy or the processing of your data, please contact the data protection officer of Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH or Biofrontera AG.

You can contact the data protection officer of both companies at the following address:

- Hemmelrather Weg 201, 51377 Leverkusen, Germany with the addition “data protection”’or
- by e-mail datenschutz@biofrontera.com.