Data protection information
for support requests, complaints and reports of side effects

Dear reporter,

You have contacted us or another body to report your experience or the experience of another person with a medical device or in vitro diagnostic medical device of which we are the manufacturer or for which we have been appointed as the EU authorized representative. In this context, you have and/or will provide us with personal data directly or we will receive your personal data from another person you have contacted. In order to fulfilment our obligations under the General Data Protection Regulation (GDPR), we inform you below about the processing of your personal data carried out by us.

1. Who is responsible for data processing and who can you contact?

The controller within the meaning of the data protection regulations for the processing of personal data is

NEXTEC medical GmbH
Zöllinplatz 4
D-79410 Badenweiler

Managing Director: Dr.Katrin Wiemann, Dr.Johann Zanker

Tel.: +49 7632 8226-70 Fax: +49 7632 8226-555 E-Mail: info@nextec-medical.comWebseite: https://nextec-medical.com

You can reach our data protection officer as follows:

NEXTEC medical GmbH Data Protection Officer
Zöllinplatz 4
D-79410 Badenweiler

Tel.: +49 7632 8226-514 Fax: +49 7632 8226-555 E-Mail: data-protection@nextec-medical.com

When processing complaints and reports of side effects as an EU authorized representative, we work together with the manufacturer of the respective product and forward your personal data to them. The respective manufacturer then processes your data under its own responsibility.

In this case, we will enter into a corresponding agreement on joint data processing in accordance with Art.26 para.1 sentence 1 of the EU General Data Protection Regulation ("GDPR"). In particular, we then mutually undertake to forward your data protection inquiries to the co-responsible party.

2. How and for what purposes do we use your data?

As a medical device manufacturer or as an EU authorized representative for medical devices, we are subject to certain legal obligations to monitor products after they have been placed on the market. In addition, there are obligations relating to the detection, assessment, understanding and prevention of adverse effects or other problems associated with a medical device, also known as vigilance obligations. The aforementioned obligations require us to process information that enables us to identify a person, e.g. a patient and/or the person reporting the adverse event (personal data).

Contact information on the reporting persons is required in order to be able toto obtain further information on the reported complaints and/or side effects.

3. What information do we collect and process?

For the above purposes, we may process the following personal data about the person contacting us:

- Contact information of the reporting person: name, address, telephone/email/fax;
- Profession of the reporting person (e.g. doctor or pharmacist).

The following information may be required about the person affected by the notification:

- Identity-related information: Name and/or initials;
- Demographic data: Date of birth, age, gender, weight or height.
- Health related information: our product used, concomitant medication, reasons for use, state of health, course and outcome of the incident.

4.With whom do we share your data?

- If we are an EU authorized representative: Manufacturer of the product concerned;
- In all cases: Service providers and subcontractors who assist us in fulfilling our obligations;
- In the event of serious incidents: Supervisory authority, if notification is required by law,
- Insurers and other service providers in the event of contentious proceedings.

5.What is the legal basis for the use of your data?

The processing of personal data in connection with the processing and documentation of complaints, including reports of health-related incidents, is carried out for reasons of public interest in the area of public health on the basis of Art. 6 (1) (c, e) and Art.9 (2) (i) GDPR in conjunction with Art.10 Section 9 (manufacturer), Article 11 Section 3 (EU Authorized Representative) of the EU Medical Devices Regulation and the EU Regulation on In-Vitro Diagnostic Medical Devices.

6.Is data transferred to a third country or to an international organization?

If we are appointed as an EU authorized representative and the manufacturer is based abroad or if we work with a subcontractor based abroad, your data may be transferred to a third country. This is done under the conditions set out in Art.44 et seq. GDPR: a) Transfer on the basis of an adequacy decision of the EU Commission pursuant to Art.Art.45 GDPR, whereby it is recognized as a safe third country; b) on the basis of model clauses of the EU Commission and additional safeguards to protect transfers.

7.How long will your data be stored?

We are required by law to keep the documentation related to all complaints and incident reports, including your personal data, for the period of time the affected version of our product was on the market until at least another ten (10) years or fifteen (15) years for implantable medical devices after the affected version of the device was last placed on the market. In addition, in exceptional cases there are longer retention rights if the processing of your data is necessary for the assertion, exercise or defence of legal claims. Otherwise, we will delete your data once the purpose for which it was collected no longer applies.

8.What rights do you have?

You have the right:

- according to Art.15 GDPR to request information about your personal data processed by us. In particular, you can obtain information about the purposes of processing, the category of personal data, the categories of recipients to whom your data has been or will be disclosed, the planned storage period, the existence of a right to rectification, erasure, restriction of processing or objection, the existence of a right to lodge a complaint, the origin of your data if it was not collected by us, and the existence of automated decision-making including profiling and, if applicable, request meaningful information about their details;
- according to Art.16 GDPR to immediately demand the correction of incorrect or incomplete personal data stored by us;
- according to Art.17 GDPR to demand the erasure of your personal data stored by us, unless the processing is necessary for exercising the right of freedom of expression and information, for compliance with a legal obligation, for reasons of public interest or for the establishment, exercise or defence of legal claims;
- according to Art.18 GDPR to demand the restriction of the processing of your personal data, insofar as the accuracy of the data is disputed by you, the processing is unlawful, but you refuse to delete it and we no longer need the data, but you need it for the assertion, exercise or defence of legal claims or you have objected to processing in accordance with Art.21 GDPR have lodged an objection to the processing;
- according to Art.20 GDPR to receive your personal data that you have provided to us in a structured, commonly used and machine-readable format or to request that it be transmitted to another controller;

- according to Art.77 GDPR to lodge a complaint with a supervisory authority. As a rule, you can contact the supervisory authority of your usual place of residence or workplace or the place of the alleged infringement.

9.Amendment of the data protection information

We may update this privacy notice from time to time. Updates will be published on our website. Any changes will take effect upon publication. We therefore recommend that you visit this page regularly to check for any updates.