Privacy Notice
for support requests, complaints and reports of adverse effects

Dear Reporter,

You have contacted us or another party 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 designated as EU authorised representative. In this context, you have provided and/or will provide personal data to us directly, or we will receive your personal data from the party you contacted. In fulfilment of our obligations under the General Data Protection Regulation (GDPR), we inform you below about the processing of your personal data that we carry out.

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

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

NEXTEC medical GmbH
Zöllinplatz 4
D-79410 Badenweiler

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

Phone: +49 7632 8226-70
Fax: +49 7632 8226-555
Email: info@nextec-medical.com
Website: https://nextec-medical.com

You can reach our Data Protection Officer as follows:

Kivanc Semen

DataCo GmbH

Sandstraße 33, 80335 Munich, Germany

datenschutz@dataguard.de

Phone: +49 89 740045840

When handling complaints and reports of adverse effects as manufacturer of the product concerned, we work together with the distributors of that product and pass your personal data on to them. The distributor concerned then processes your data under its own responsibility.

In these cases, we conclude a corresponding joint controller arrangement pursuant to Art. 26(1), first sentence, of the GDPR. In particular, we then mutually undertake to forward your data protection requests to the joint controller. Both we and the distributor inform you about our

respective processing activities and their purposes. You may exercise your rights under the GDPR against us or against the distributor. We will support each other in handling your requests. We have mutually undertaken to comply with the applicable technical and organizational standards for data protection.

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

As a medical device manufacturer or as EU authorised representative for medical devices, we are subject to certain legal obligations to monitor products after they have been made available on the market. In addition, there are obligations relating to the detection, assessment, understanding and prevention of adverse effects or other problems related to a medical device, also known as vigilance obligations. These obligations require us to process information that enables us to identify a person directly or indirectly, i.e. the patient and/or the person reporting the adverse event (personal data).

Contact information for reporting persons is needed so that we can obtain further information on the reported complaints and/or adverse effects where necessary.

3. What information do we collect and process?

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

- Contact information of the reporting person: name, address, phone/email/fax;
- Occupation of the reporting person (e.g. physician or pharmacist).

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

- Identity information: name and/or initials;
- Demographic data: date of birth, age, sex, weight or height;
- Medical information about the event: 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 the manufacturer of the product concerned: with the responsible distributor of the product;
- If we are the EU authorised representative: the manufacturer of the product concerned;
- In all cases: IT service providers and processors who support us in fulfilling our obligations;
- In the case of serious incidents: the competent authority, where reporting is required by law;
- Insurers and other service providers in the event of legal disputes.

5.What legal bases apply to the use of your data?

Personal data related to the handling and documentation of complaints, including reports of health-related incidents, is processed for reasons of public interest in the area of public health on the basis of Art. 6(1)(c) and Art. 9(2)(i) GDPR in conjunction with Art. 10(9) (manufacturer) and Art. 11(3) (EU authorised representative) of the EU Medical Device Regulation and the EU In Vitro Diagnostic Medical Device Regulation.

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

If we are designated as EU authorised representative and the manufacturer is based outside the EU, or if we work with a subcontractor based outside the EU, your data may be transferred to a third country. This takes place under the conditions set out in Art. 44 et seq. GDPR: a) transfer on the basis of an adequacy decision of the European Commission pursuant to Art. 45 GDPR, by which the country is recognized as a safe third country; b) on the basis of standard contractual clauses of the European Commission together with supplementary safeguards to protect transfers.

7.How long is your data stored?

We are legally required to archive the documentation relating to all complaints and incident reports, including your personal data, for the period during which the version of our product concerned is placed on the market and for at least a further ten (10) years (or fifteen (15) years for implantable medical devices) after the last placing on the market of the version of the product concerned. In exceptional cases, longer retention rights also apply where the processing of your data is necessary for the establishment, exercise or defence of legal claims. Otherwise, we will delete your data once the purpose of use no longer applies.

8.What rights do you have?

You have the right:

- under Art. 15 GDPR, to request information about your personal data processed by us. In particular, you may request information about the purposes of processing, the categories 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 source of your data if it was not collected by us, and the existence of automated decision-making including profiling and, where applicable, meaningful information about its details;
- under Art. 16 GDPR, to request without undue delay the rectification of inaccurate personal data or the completion of your personal data stored by us;
- under Art. 17 GDPR, to request 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;

- under Art. 18 GDPR, to request the restriction of processing of your personal data where you contest the accuracy of the data, the processing is unlawful but you oppose its erasure, we no longer need the data but you require it for the establishment, exercise or defence of legal claims, or you have objected to the processing pursuant to Art. 21 GDPR;
- under Art. 20 GDPR, to receive the personal data you have provided to us in a structured, commonly used and machine-readable format or to request its transmission to another controller;
- under Art. 77 GDPR, to lodge a complaint with a supervisory authority. As a rule, you can contact the supervisory authority of your habitual residence, your place of work or the place of the alleged infringement.

9.Changes to this Privacy Notice

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