

Certificate

The Certification Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company

**Fritz Stephan GmbH
Kirchstraße 19
56412 Gackebach
Germany**

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard has been verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2022-06-11
Expiry date: 2025-06-10

Report No.: 0930FS27F
Procedure No.: QS – 0930
Certificate No.: 0930GB445220610

Hamburg, 2022-06-10



MEDCERT Certification Body
Lorenz Runge

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a management systems certification body
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Appendix of certificate

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Activities and products/services in the scope of certification

Design and development, manufacture, inspection, distribution, and servicing of

- Inhalation anesthesia devices
- Breathing circuits for anesthesia gas inhalation
- Ventilators
- Breathing circuits for ventilation
- Pneumotachographs
- Respiratory masks and prongs
- Oxygen concentrators
- Central gas supplies

Distribution of

- Anesthesia gas monitor devices
- Aerosol / bubble humidifiers
- Medical air injectors
- Flowmeters

Locations in the scope of certification

Fritz Stephan GmbH
Kirchstraße 19
56412 Gackebach
Germany

This appendix is integral part of the above-referenced certificate.
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