

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
0930GB452250702

Final assessment report no.
0930AU30F

Effective date
2025-07-02

Expiry date
2028-06-10

This is to certify that

Fritz Stephan GmbH

Kirchstraße 19, 56412 Gackebach, Germany

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

This management system has been audited and found to conform to the quality management systems standard

EN ISO 13485:2016 + AC:2018 + A11:2021

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2025-07-02

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany



DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00



Marcus Harder
Certification Body Operations

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com

Activities and products/services covered by this certificate

Design and development, manufacturing, 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

Sites covered by this certificate and associated (partial) scopes

Fritz Stephan GmbH, Kirchstraße 19, 56412 Gackebach, Germany

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