

# EU Quality Management System Certificate

Certificate no.  
0930GB448230125

Final Assessment Report no.  
0930AU27F

Effective date  
2023-01-25

Expiry date  
2027-06-10

This is to certify that the quality system of

## Fritz Stephan GmbH

Kirchstraße 19, 56412, Gackenbach, Germany

SRN: DE-MF-000007591

For design, production, and final product inspection/testing of  
**Medical devices/groups of medical devices listed on the following pages**

Has been assessed and found to comply with respect to

### The conformity assessment procedure described in Annex IX Chapter I of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date  
Hamburg, 2023-01-25

For the issuing office  
DNV MEDCERT GmbH – Notified Body 0482  
Pilatuspool 2, 20355 Hamburg, Germany



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-096

  
Markus Bianchi  
Director Certification Body

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



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### Sites covered by this certificate

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

Fritz Stephan GmbH, Kirchstraße 5, 56412, Gackebach, Germany

### Products covered by this certificate

#### Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1201	R020101	BREATHING CIRCUITS, STANDARD
MDN 1201	R030101	VENTILATION MASKS

