

EU Quality Management System Certificate

Certificate no.
1320GB448240228

Final Assessment Report no.
1320AU30F

Effective date
2024-02-28

Expiry date
2028-06-05

This is to certify that the quality system of

Andreas Fahl Medizintechnik-Vertrieb GmbH

August-Horch-Straße 4a, 51149 Köln, Germany

SRN: DE-MF-000006665

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 and III 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, 2024-02-28

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

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

Markus Bianchi
Director Certification



Certificate no.: 1320GB448240228
Place and date: Hamburg, 2024-02-28

Sites covered by this certificate

Andreas Fahl Medizintechnik-Vertrieb GmbH, August-Horch-Straße 4a, 51149 Köln, Germany

Andreas Fahl Medizintechnik-Vertrieb GmbH, Am Borsigturm 62, 13507 Berlin, Germany



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Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN1214	R0402	NATURAL BREATHING FILTERS

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN1201	R010501	TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, UNCUFFED
MDN1201	R010502	TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, CUFFED
MDN1201	R010503	TRACHEOSTOMY INNER CANNULAS

Intended purpose

Tracheostomy tubes are intended to stabilise the tracheostomy following laryngectomy or tracheotomy.

The tracheostomy tube is designed to keep the tracheostomy open. Tracheostomy tubes with cuff can be used for mechanical ventilation, including under anaesthesia. Percutec variants are designed for additional use in percutaneous dilatation tracheostomy.