

MANAGEMENT SYSTEM CERTIFICATE

Certificate no
1320GB452260527A

Final assessment report no.
1320AU33F

Effective date
2026-06-06

Expiry date
2029-06-05

This is to certify that

Andreas Fahl Medizintechnik-Vertrieb GmbH

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

has introduced, applies and maintains a management system at the sites listed on the following page(s).

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, 2026-05-27

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



DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

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


Annika Chill
Certification Body Operations

Activities and products/services covered by this certificate

Design and development, manufacturing, and distribution of

- Inhalation devices
- Tracheostomy tubes with and without speaking valve
- Cleaning and care accessories for tracheostomy tubes
- Disinfectants
- Bacterial- and viral filters
- Suction units
- Suction catheters
- Nebulizers
- Tube accessories
- Nasal oxygen tubes
- Artificial noses (HME) with and without oxygen connectors and accessories
- Percutaneous tracheostomy sets
- Voice prostheses and accessories
- Tracheostoma protection
- Tracheal compresses
- Tracheal suction sets
- Tube connectors
- Cuff-pressure gauges
- PEG dressing sets
- Rehabilitation articles for
 - Larynectomy
 - Tracheostomy

Provision of services for

- Individual medical aid care including advisory service and training
- Maintenance and repair service
- Processing of suction units

Sites covered by this certificate and associated (partial) scopes

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

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 - Tracheostomy

Provision of services for

- Individual medical aid care including advisory service and training

Andreas Fahl Medizintechnik-Vertrieb GmbH, August-Horch-Straße 6, 51149 Köln, Germany

Manufacturing of

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Provision of services for

- Individual medical aid care including advisory service and training
- Maintenance and repair service
- Processing of suction units

Andreas Fahl Medizintechnik-Vertrieb GmbH, August-Horch-Straße 6b, 51149 Köln, Germany

Distribution of

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

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