



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
1320GB452250226

Final assessment report no.
1320AU31F

Effective date
2025-02-26

Expiry date
2026-06-05

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 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, 2025-02-26

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




Markus Bianchi
Certification Body

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

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820115MS EN Rev 1 2024.10.18

ACCREDITED UNIT: DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.dnv.com



DNV

Certificate no.: 1320GB452250226
Place and date: Hamburg, 2025-02-26

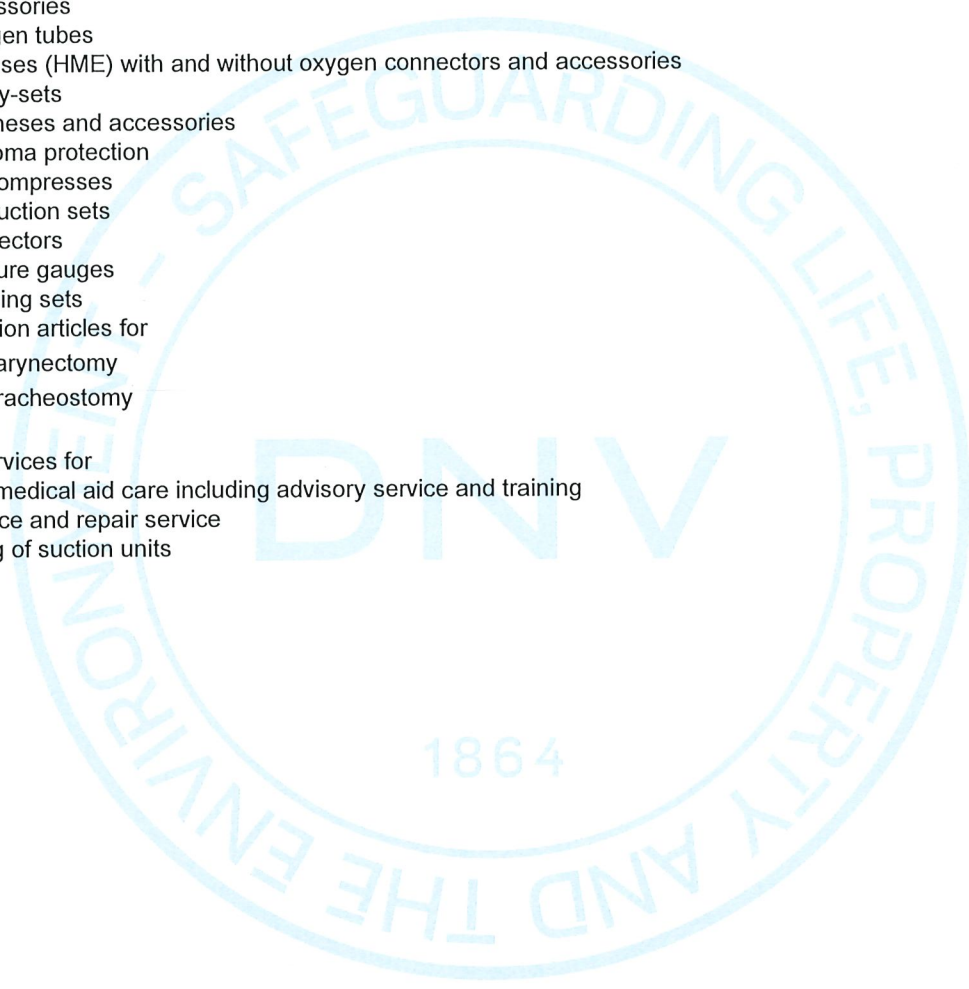
Activities and products/services covered by this certificate

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
- Coniostomy-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

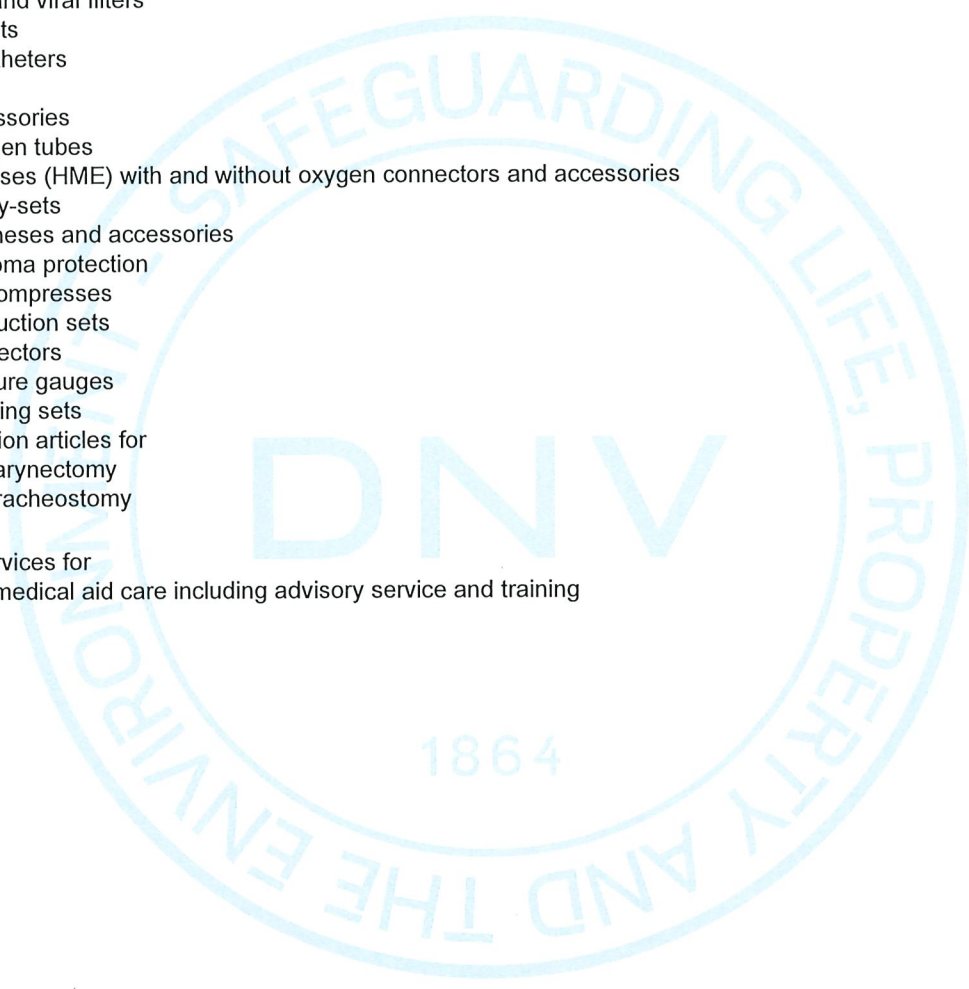
Andreas Fahl Medizintechnik-Vertrieb GmbH, August-Horch-Straße 4a, 51149 Köln, Germany

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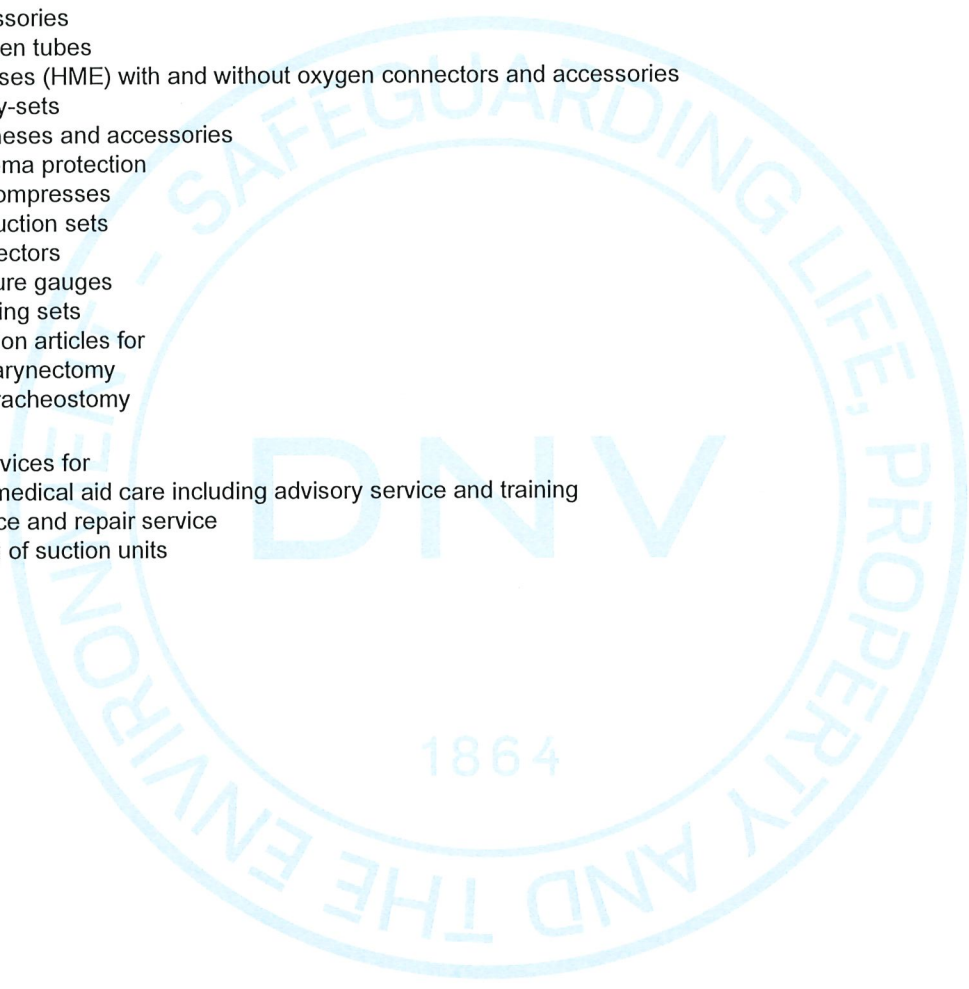
Andreas Fahl Medizintechnik-Vertrieb GmbH, August-Horch-Straße 6, 51149 Köln, Germany

Manufacturing of

- Inhalation devices
- Tracheostomy tubes with and without speaking valve
- Cleaning and care accessories for tracheostomy tubes
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- Bacterial- and viral filters
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DNV

Certificate no.: [1320GB452250226](#)
Place and date: [Hamburg, 2025-02-26](#)

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

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
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 - Tracheostomy

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

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