

MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 1320GB445240228

Final assessment report no.

Effective date 2024-02-28

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

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

Place and date Hamburg, 2024-02-28



For the issuing office

DNV MEDCERT GmbH

Pilatuspdol 2, 20355 Hamburg, Germany

Markus Bianchi
Director Certification

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



Certificate no.: 1320GB445240228 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

Activities and products/services covered by this certificate

Design and development, purchase, manufacturing, final inspection 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 protheses and accessories
- Tracheostoma protection
- Tracheal compresses
- Tracheal suction sets
- Tube connectors
- Cuff-pressure gauges
- PEG dressing sets
- Rehabilitation articles for
 - Larynectomy
 - Tracheostomy

Individual medical aid care including advisory service and training

Maintenance and repair service

Processing of suction units