

Certificate

The certification body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

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

with locations listed in the appendix

has introduced, applies and maintains a quality management system in the area of:

Design and development, purchase, manufacture, final inspection and distribution of products as listed in the appendix

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date:

2020-06-12

Expiry date:

2022-06-05

Report No.:

1320PS26F QS – 1320

Procedure No.: Certificate No.:

1320GB445200612

Hamburg, 2020-06-12

MEDCERT Certification Body (Markus Bianchi)

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

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Appendix of certificate

Procedure No.:

QS - 1320

Certificate No.:

1320GB445200612

List of locations included in the scope of certificate

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

Andreas Fahl Medizintechnik-Vertrieb GmbH Aurbacherstraße 2 81541 München Germany

- End of list -

This appendix is integral part of the above-referenced certificate. The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de.

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Appendix of certificate

Procedure No.:

QS - 1320

Certificate No.:

1320GB445200612

List of activities and products included in the scope of certificate

Design and development, purchase, manufacture, 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
- Pulsoxymeters
- 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, training, maintenance and repair service

Processing of suction units

- End of list -

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