MED CERT®

Certification. Medical Only.

EC Certificate of Conformity

The Notified 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 assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-06-12**
Expiry date: **2024-05-27**

Report No.: 1320PS26F
Process No.: QS – 1320
Certificate No.: 1320GB410200612

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.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

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Appendix of EC Certificate of Conformity

Process No.: QS – 1320
Certificate No.: 1320GB410200612

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 –

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Appendix of EC Certificate of Conformity

Process No.: QS – 1320
Certificate No.: 1320GB410200612

List of products / product categories included in the scope of certificate

- **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**
- **Coniotomy-sets**
- **Voice protheses and accessories**

– End of list –

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

Hamburg, 2022.03.16

CONFIRMATION

According to the Date of Application (DoA) of the MDR 2017/745 at the 2021.05.27 the Directive 93/42/EEC is no more an active regulation.
For this reason, certificates for Directive 93/42/EEC cannot be issued or changed any more.

As the applied change is not a significant change according to MDCG 2020-3 this change can be accepted, but a revised MDD certificate cannot be issued.

Applied change:

- Deletion of the facility

Andreas Fahl Medizintechnik-Vertrieb GmbH
Aurbacherstralie 2
81541 München
Germany

This confirmation is an attachment to the related certificates
1320DE410200612,
1320GB410200612,
1320DE416200612,
1320GB416200612,
1320DE415200612 and
1320GB415200612.

It confirms that they remain valid including the applied changes and are still applicable.

Best regards

Marcus Harder
Director Certification

MEDCERT
Zertifizierungs- und Prüfungsgesellschaft
für die Medizin GmbH
Pilatuspool 2
20355 Hamburg
e-mail: info@medcert.de · www.medcert.de

Tel.: +49 (0)40 - 226 3325 - 0
Fax: +49 (0)40 - 226 3325 - 15
Geschäftsführer: Klaus-Dieter Ziel, Dipl.-Ing.
Handelsregister: Hamburg HRB 55912
Steuernummer: 48/742/02822
Ust-Identnummer: DE164312394

Bankverbindungen:
Deutsche Bank · Konto Nr.: 277 80 90 · BLZ 200 700 00
IBAN: DE58 2007 0000 0277 8090 00 · BIC: DEUTDEHHXXX
Hamburger Sparkasse · Konto Nr.: 1382 120 788 · BLZ 200 505 50
IBAN: DE13 2005 0550 1382 1207 88 · BIC: HASPDEHHXXX

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Andreas Fahl Medizintechnik-Vertrieb GmbH
August-Horch-Straße 4a
51149 Köln
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Hamburg, 2022.03.16

CONFIRMATION

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For this reason, certificates for Directive 93/42/EEC cannot be issued or changed any more.

As the applied change is not a significant change according to MDCG 2020-3 this change can be accepted, but a revised MDD certificate cannot be issued.

Applied change:

- Limitation of the Scope to

- 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~~
- Coniotomy-sets
- Voice protheses and accessories

This confirmation is an attachment to the related certificates 1320DE410200612 and 1320GB410200612. It confirms that they remain valid including the applied changes and are still applicable.

Best regards

Marcus Harder
Director Certification

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IBAN: DE13 2005 0550 1382 1207 88 · BIC: HASPDEHHXXX