

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.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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

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 –

This appendix is integral part of the above-referenced certificate.
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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 –

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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:

- 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
- ~~Pulseoxymeters~~
- Coniotomy-sets
- Voice prostheses 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

MEDCERT Form No. F 16 01 00 11e / Rev. 0 / 2009.10.05 / F16010011e.doc

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

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

Date: 2025-02-26
Our reference: QS-1320

Confirmation letter correcting and complementing information on an existing certificate in accordance with Article 120 (3) of Regulation (EU) 2017/745

Directive and annex	Directive 93/42/EEC, Annex II/V/VI
Organisation	Andreas Fahl Medizintechnik-Vertrieb GmbH
Registered place of business	August-Horch-Straße 4A 51149 Köln Germany
Certificate number	1320GB410200612
Certificate expiry date	2024-05-27
Scope of certification	<ul style="list-style-type: none">• 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 prostheses and accessories
Description of change(s)	addition of two facilities to the scope of certification
Effective date of change(s)	2025-02-26

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To whom it may concern,

DNV MEDCERT GmbH (previously: MEDCERT Prüfungs- und Zertifizierungsgesellschaft für die Medizin GmbH), a Notified Body according to Regulation (EU) 2017/745 on medical devices (MDR)¹ (NB 0482), herewith declares that, pursuant to Article 120 (1) of MDR, since 26 May 2021, no certificate under the Directive 93/42/EEC (Medical Device Directive, or MDD)² is allowed to be issued any more.

Consequently, pursuant to guidance MDCG 2020-3³, this Confirmation Letter is valid together with and complements the above-referenced certificate. We as a Notified Body are continuing to perform the surveillance activities for MDD certificates issued by DNV MEDCERT which are still valid, as laid out in the Article 120 (3) of MDR.

We hereby confirm that the above-referenced certificate has been issued to the above-referenced manufacturer and is still valid with the change(s) described in this letter.

Hamburg, 2025-02-26



Marius Bianchi
Certification Body Operations

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (<http://data.europa.eu/eli/reg/2017/745/2020-04-24>).

² Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (<http://data.europa.eu/eli/dir/1993/42/2007-10-11>).

³ MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (available on https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en).