



EG-KONFORMITÄTSERKLÄRUNG

entsprechend Anhang II der Richtlinie 93/42/EWG über Medizinprodukte

EC DECLARATION OF CONFORMITY

according to annex II of the Council Directive 93/42/EEC concerning medical devices

Wir erklären in alleiniger Verantwortung, dass die unten bezeichneten Produkte den einschlägigen Bestimmungen der Richtlinie 93/42/EWG über Medizinprodukte entsprechen.

We declare under our sole responsibility that the products mentioned below meet the provisions of the Council Directive 93/42/EEC concerning medical devices.

Entnahmestelle Forano / Levante für medizinische Druckgase und Vakuum
Terminal Unit Forano / Levante for compressed medical gases and vacuum

DIN EN ISO 9170-1:2008

DIN 13260-2:2013

SVENSK STANDARD SS 8752430:2017

BRITISH STANDARD BS 5682:2015

NORME FRANÇAISE NF S 90-116:1988

Carbamed

Klasse/ Class: IIa

Revisionsstand/ revision stand: 2.0

Bei einer nicht bestimmungsgemäßen Verwendung des Produkts oder einer nicht mit uns abgestimmten Änderung verliert diese Erklärung ihre Gültigkeit. Diese Konformitätserklärung ist gültig für oben genannte Produkte, mit Herstellungsdatum bis 18.12.2023 oder bis zur Ausstellung einer revidierten Konformitätserklärung.

In the event of using this product not according with the regulations or modification without our approval this declaration will be rendered invalid. This Declaration of Conformity is valid for above products, with date of manufacture up to 18 December 2023 or a revised declaration is made.

Hamburg 2020-01-23/ T. Greggersen Geschäftsführer/director of company

Ort/Datum/Name
Place/Date/Name

Hersteller:
Manufacturer:

GREGGERSEN Gasetechnik, Germany
Bodestraße 27-29
21031 Hamburg
Germany



Benannte Stelle:
notified body:

MedCert GmbH
Pilatuspool 2
20355 Hamburg
Germany



EC Certificate of Conformity No.: 0874GB410190712

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Medizinisches Flowmeter Kolibri Medical Flowmeter Kolibri

DIN EN ISO 15002 ; DIN 13260-2 ; BS 5682 ; NF S 90-116 ; SS 87 524 30
Klasse/Class IIa
Revisionsstand/ revision status: 1.1

Bei einer nicht bestimmungsgemäßen Verwendung des Produkts oder einer nicht mit uns abgestimmten Änderung verliert diese Erklärung ihre Gültigkeit.

In the event of using this product not according with the regulations or modification without our approval this declaration will be rendered invalid.

Hamburg 2010-07-01/ T. Greggersen

Ort/Datum/Name
Place/Date/Name

Hersteller:
Manufacturer:

GREGGERSEN Gasetechnik, Germany
Bodestraße 27-29
21031 Hamburg
Germany

 0482

Benannte Stelle:
notified body:

MedCert GmbH
Pilatuspool 2
20355 Hamburg
Germany

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We declare under our sole responsibility that the products mentioned below meet the provisions of the Council Directive 93/42/EEC concerning medical devices.

Medizinisches Röhren Flowmeter
Medical Tube Flowmeter

DIN EN ISO 15002 ; DIN 13260-2 ; BS 5682 ; NF S 90-116 ; SS 87 524 30

Klasse/Class IIa

Revisionsstand/ revision status: 1.1

Bei einer nicht bestimmungsgemäßen Verwendung des Produkts oder einer nicht mit uns abgestimmten Änderung verliert diese Erklärung ihre Gültigkeit.

In the event of using this product not according with the regulations or modification without our approval this declaration will be rendered invalid.

Hamburg 2011-09-01/ T. Greggersen

Ort/Datum/Name
Place/Date/Name

Hersteller:
Manufacturer:

GREGGERSEN Gasetechnik, Germany
Bodestraße 27-29
21031 Hamburg
Germany

 0482

Benannte Stelle:
notified body:

MedCert GmbH
Pilatuspool 2
20355 Hamburg
Germany

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000500063-MSC-RvA-DEU

Initial certification date:
22 December 2021

Valid:
22 December 2021 – 21 December 2024

This is to certify that the management system of
Greggersen Gasetechnik GmbH
Bodestraße 27-29, 21031 Hamburg, Germany

has been found to conform to the Quality Management System standard:
ISO 9001:2015

This certificate is valid for the following scope:

Design and development, manufacture, final inspection, distribution, planning, installation and service of central gas supply systems, terminal units, medical gas devices and accessories, autogenous welding and cutting equipment, compressed gas technology

Place and date:
Barendrecht, 22 December 2021

For the issuing office:
DNV - Business Assurance
Zwolsseweg 1, 2994 LB Barendrecht,
Netherlands



Erie Koek
Management Representative

Certificate

The Certification Body

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

herewith certifies that the company

**Greggersen Gasetechnik GmbH
Bodestraße 27-29
21031 Hamburg
Germany**

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard has been verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2021-12-19
Expiry date: 2024-12-18

Report No.: 0874FS27F
Procedure No.: QS – 0874
Certificate No.: 0874GB445211208

Hamburg, 2021-12-08

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 is a management systems certification body
accredited by DAkkS.

Appendix of certificate

Procedure No.: QS – 0874
Certificate No.: 0874GB445211208

Activities and products/services in the scope of certification

Design and development, manufacture, final inspection, distribution, installation, and servicing of

- Central gas supply systems
- Terminal units
- Medical gas devices and accessories

Locations in the scope of certification

Greggersen Gasetechnik GmbH
Bodestraße 27-29
21031 Hamburg
Germany

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.

MEDCERT is a management systems certification body
accredited by DAkkS.

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:

Greggersen Gasetechnik GmbH
Bodestraße 27-29
21031 Hamburg
Germany

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: 2020-06-03

Expiry date: 2023-12-18

Report No.: 0874PS25F
Process No.: QS – 0874
Certificate No.: 0874GB410200603

Hamburg, 2020-06-03

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 – 0874

Certificate No.: 0874GB410200603

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

- **Central gas supply systems**
- **Terminal units**
- **Pressure reducers**
- **Flowmeters**
- **Compressed gas and vacuum regulators**
- **Low pressure hose assemblies**
- **Suction units**
- **Vaporizer and atomizer units**
- **Insufflation units**

– End of list –

This appendix is integral part of the above-referenced certificate.
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MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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ZLG-BS-237.10.15