

# MANAGEMENT SYSTEM CERTIFICATE

Certificate No:  
164429-2014-AQ-GER-DAkKS

Initial certification date:  
20 January 2019

Valid:  
20 January 2019 - 19 January 2022

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, construction, manufacture, final inspection, distribution, planning, installation and service of central gas supply systems, outlets, medical gas devices and accessories, autogenous welding and cutting equipment, compressed gas technology**

Place and date:  
**Essen, 17 July 2019**



Deutsche  
Akkreditierungsstelle  
D-ZM-18453-01-00

For the issuing office:  
**DNV GL - Business Assurance**  
**Schnieringshof 14, 45329 Essen, Germany**

**Thomas Beck**  
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:

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

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

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:** 2020-06-03  
**Expiry date:** 2021-12-18

Report No.: 0874PS25F  
Procedure No.: QS – 0874  
Certificate No.: 0874GB445200603

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](mailto:info@medcert.de).

MEDCERT is a DAkkS accredited management systems  
certification body

# 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](mailto:info@medcert.de).

MEDCERT Identification Number: 0482





**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.  
The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto: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](http://www.zlg.de)  
ZLG-BS-237.10.15



## 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

CE 0482

EC Certificate of Conformity No.: 0874GB410190712



Benannte Stelle:  
notified body:

MedCert GmbH  
Pilatuspool 2  
20355 Hamburg  
Germany