

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To whom it may concern

Our reference

DW-legal / 119/13

Phone

+49 451 882-2471

E-mail

Erika.Wagner@draeger.com

## Manufacturer's Authorization

09.02.2021

We, **Drägerwerk AG & Co. KGaA**, Moislinger Allee 53-55, 23558 Lübeck, Germany, who is an established and reputable manufacturer of medical equipment, having factories at Lübeck (Germany), Telford (United States), Andover (United States) and Shanghai (China), do hereby declare that

**“Echipamed-Plus” SRL  
Valea Trandafirilor 24 “B”, of. 80  
MD-2001, Chisinau  
Republic of Moldova**

is our official distributor and local representative for Anesthesia Devices, Incubators, Ventilation Machines, Monitoring, Pendant and Operating Lights of Drägerwerk AG & Co. KGaA in the territory of the Republic of Moldova.

We declare that the above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, as well as to perform installation and after sales service of Anesthesia Devices, Incubators, Ventilation Machines, Monitoring, Pendant and Operating Lights manufactured by us in their own name and on their own account.

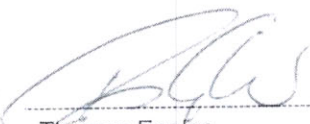
This authorization letter will remain valid until 31.12.2021.

Duly authorized to sign this Authorization on behalf of

**Drägerwerk AG & Co. KGaA**

  
Claus Martin Baumann

Authorized representative

  
Thomas Engler

Authorized representative



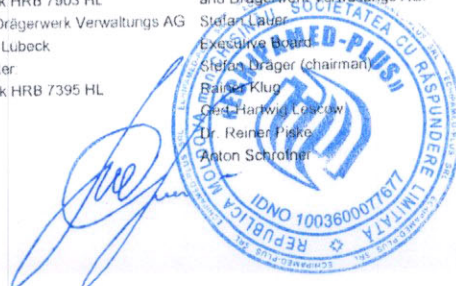
Drägerwerk AG & Co. KGaA  
Moislinger Allee 53-55  
23558 Lübeck, Germany  
Postal address:  
23542 Lübeck, Germany  
Tel +49 451 882-0  
Fax +49 451 882-2080  
info@draeger.com  
www.draeger.com  
VAT no. DE135082211

Bank details:  
Commerzbank AG, Lübeck  
IBAN: DE95 2304 0022 0014 6795 00  
Swift-Code: COBA DE FF 230  
Sparkasse zu Lübeck  
IBAN: DE15 2305 0101 0001 0711 17  
Swift-Code: NOLADE21SPL

Registered office: Lübeck  
Commercial register:  
Local court Lübeck HRB 7903 HL  
General partner: Drägerwerk Verwaltungs AG  
Registered office: Lübeck  
Commercial register:  
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board  
for Drägerwerk AG & Co. KGaA  
and Drägerwerk Verwaltungs AG:

Stefan Lührer  
Executive Board:  
Stefan Dräger (chairman)  
Rainer Klug  
Gerd Harwig, Lötscow  
Dr. Reiner Piske  
Anton Schröter



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Management Service

# CERTIFICATE

The Certification Body  
of TÜV SÜD Management Service GmbH  
certifies that

## Dräger

**Drägerwerk AG & Co. KGaA**  
Moislinger Allee 53-55, 23542 Lübeck  
Germany

for the Scope of application

Design and development, production and distribution of  
diagnostic and therapeutic medical devices and installations  
as well as consulting and services  
in the field of medical technology

**Revalstraße 1, 23560 Lübeck**  
Germany

for the Scope of application

**Production and distribution of diagnostic  
and therapeutic medical devices and installations**

has established and applies  
a Quality Management System.

An audit was performed, Order No. **707037695**.

Proof has been furnished that the requirements according to

### ISO 9001:2015

are fulfilled.

The certificate is valid from **2021-01-15** until **2024-01-14**.

Certificate Registration No.: **12 100 49423 TMS**.

Head of Certification Body  
Munich, 2021-01-13



TUV®



Product Service

# Certificate

No. Q5 010578 0031 Rev. 01

**Holder of Certificate:** **Drägerwerk AG & Co. KGaA**  
 Moislinger Allee 53-55  
 23542 Lübeck  
 GERMANY

**Certification Mark:**



**Scope of Certificate:** **Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 010578 0031 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 010578 0031 Rev. 01)

**Report No.:** 713193628  
**Valid from:** 2021-01-18  
**Valid until:** 2024-01-13

**Date,** 2021-01-18

Christoph Dicks  
 Head of Certification/Notified Body





Product Service

# Certificate

No. Q5 010578 0031 Rev. 01

**Applied Standard(s):** EN ISO 13485:2016  
 Medical devices - Quality management systems -  
 Requirements for regulatory purposes  
 (ISO 13485:2016)  
 DIN EN ISO 13485:2016

**Facility(ies):** Drägerwerk AG & Co. KGaA  
 Moislinger Allee 53-55, 23542 Lübeck, GERMANY

Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights

Drägerwerk AG & Co. KGaA  
 Revalstraße 1, 23560 Lübeck, GERMANY

Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights

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Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 010578 0037 Rev. 01**

**Manufacturer:** **Drägerwerk AG & Co. KGaA**  
Moislinger Allee 53-55  
23542 Lübeck  
GERMANY

**Facility(ies):** Drägerwerk AG & Co. KGaA  
Revalstraße 1, 23560 Lübeck, GERMANY  
  
Drägerwerk AG & Co. KGaA  
Moislinger Allee 53-55, 23542 Lübeck, GERMANY

**Product Category(ies):** Anaesthetic equipment with standard accessories,  
Infusion equipment with standard accessories,  
Pediatric equipment with standard accessories,  
Lung ventilator equipment with standard accessories,  
Monitoring equipment with standard accessories,  
Equipment for suction, breathing-, inhalation-, oxygen-  
and aerosol-therapy with standard accessories,  
Medical supply units and terminal units for pressurized  
medical gases and vacuum,  
Pipelines for compressed medical gases and vacuum,  
Anaesthetic gas scavenging systems, Components for  
medical gas management systems, Software for diagnosis based on clinical  
data Incl. patient data, monitoring and device parameter, Visualization,  
diagnostic and therapeutic software for anesthesia and respiratory devices

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 713162398

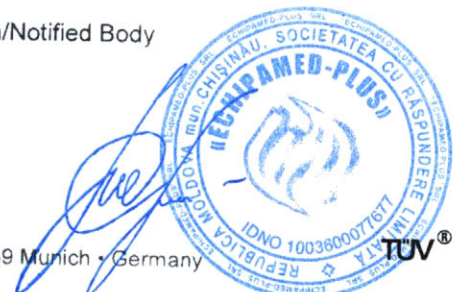
**Valid from:** 2020-01-15  
**Valid until:** 2024-05-26

**Date,** 2019-12-09

Christoph Dicks  
Head of Certification/Notified Body

Page 1 of 1  
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



TÜV SÜD  
 ZERTIFIKAT ♦ CERTIFICATE ♦ 認證書 ♦ CERTIFICADO ♦ CERTIFICAT ♦ CERTIFICAT