



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





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

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

Date, 2021-01-18

C. Dicks

Christoph Dicks
Head of Certification/Notified Body



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
Mölsinger 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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CERTIFICATE

Management system as per
ISO 14001 : 2015

In accordance with TÜV NORD CERT procedures, it is hereby certified that

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

with the site Revalstraße 1, 23560 Lübeck, Germany

applies a management system in line with the above standard for the following scope

Design and development, manufacturing, sales and servicing of diagnostic and therapeutic medical devices and installations as well as consulting and services in the field of medical technology

Certificate Registration No. 07 104 980284-050
Audit Report No. 3522 3922

Valid from 2018-12-16
Valid until 2021-12-15
Initial certification 2009-12-16

A Goodrich

Certification Body
at TÜV NORD CERT GmbH

Essen, 2018-11-08

This certification was conducted in accordance with the TÜV NORD CERT auditing and certification procedures and is subject to regular surveillance audits. This certificate is valid in conjunction with the main certificate.

TÜV NORD CERT GmbH

Langemarckstraße 20

45141 Essen



Deutsche
Akkreditierungsstelle
D-ZM-12007-01-01



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



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.

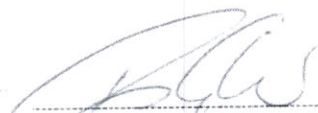
We declare that the above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, as well as to perform installation and after sales service of Anesthesia Devices, Incubators, Ventilation Machines, Monitoring, Pendant and Operating Lights manufactured by us in their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



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Moislinger Allee 53-55
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www.draeger.com
VAT no. DE135082211

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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 Lohr
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gerd Harwig, Lothar
Dr. Reiner Piske
Anton Schröder

