

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

Our reference  
739/22 // ew-de

To whom it may concern

Phone  
+49 451 882-2471

E-mail  
Erika.Wagner@draeger.com

November 24, 2025

### Manufacturer's Authorization

We, Drägerwerk AG & Co. KGaA, Moislinger Allee 53-55, 23558 Lübeck, Germany, an established and reputable manufacturer of medical equipment, with manufacturing facilities located in Germany, Moislinger Allee 53-55, 23558 Lübeck, Germany and in the United States of America through Draeger Medical Systems, Inc, 3135 Quarry Road, Telford, PA 18969, USA, and 6 Tech Drive, Andover, MA 01810, USA, and in China through Shanghai Dräger Medical Instrument Co. Ltd., Building 3, No. 229 Hu Po Rd, Shanghai International Medical Zone, Pudong District, Shanghai, China, 201321, do hereby declare that

### **"Echipamed-Plus" SRL, Valea Trandafirilor 24 "B", of. 2-7 MD-2001, Chisinau Republic of Moldova**

is our 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 at present only above-mentioned company is authorized to do registration, 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 31.12.2026.

Drägerwerk AG & Co. KGaA



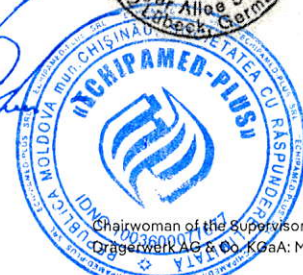
Digital unterschrieben von  
Claus Martin Baumann  
Datum: 2025.11.24  
12:50:46 +01'00'

Claus Martin Baumann  
Authorized Representative



Digitally signed by Tatjana  
Engel  
Date: 2025.11.25  
12:25:29 +01'00'

Tatjana Engel  
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

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: NOLADE2ISPL

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  
UID-Nr. DE135082211

Chairwoman of the Supervisory Board for  
Drägerwerk AG & Co. KGaA: Maria Dietz  
Chairman of the Supervisory Board for  
Drägerwerk Verwaltungs AG: Stefan Lauer

Executive Board:  
Stefan Dräger (chairman)  
Stefanie Hirsch  
Rainer Klug  
Gert-Hartwig Lescow  
Dr. Reiner Piske  
Anton Schrofner

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT ◆ 認 證 證 書 ◆ CERTIFICATE ◆ ZERTIFIKAT



Management Service

# CERTIFICATE

Certificate Registration No.: 12 100 49423 TMS / Order No.: 707037695

The Certification Body  
of TÜV SÜD Management Service GmbH  
certifies that the organization

## Dräger

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

for the scope

**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;  
Design, development and distribution of products and services to  
support healthcare workflows**

*including the sites see enclosure*

has established and applies a Quality Management System.

An audit was performed and has furnished proof  
that the requirements according to

**DIN EN ISO 9001:2015**

are fulfilled.

The certificate is valid from **2024-01-15** until **2027-01-14**.

Fred Wenke  
Head of Certification Body  
Munich, 2023-12-14

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Management Service

# ENCLOSURE OF CERTIFICATE

Certificate Registration No.: 12 100 49423 TMS / Order No.: 707037695

certificate holder:

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

at the sites	scope
<b>Drägerwerk AG &amp; Co. KGaA</b> Moislinger Allee 53-55 23542 Lübeck Germany	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; Design, development and distribution of products and services to support healthcare workflows
<b>Drägerwerk AG &amp; Co. KGaA</b> Revalstraße 1 23560 Lübeck Germany	Production and distribution of diagnostic and therapeutic medical devices and installations

Fred Wenke  
 Head of Certification Body  
 Munich, 2023-12-14

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Product Service

# Certificate

No. Q5 010578 0031 Rev. 02

**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 as well as Installations 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 and sterile Equipment for 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.\\_02](http://www.tuvsud.com/ps-cert?q=cert:Q5_010578_0031_Rev._02)

**Report No.:** 713308726

**Valid from:** 2024-01-14

**Valid until:** 2027-01-13

**Date,** 2023-12-28

*C. Dicks*

Christoph Dicks

Head of Certification/Notified Body



# Certificate

No. Q5 010578 0031 Rev. 02

**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

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

Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices as well as Installations 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 and sterile Equipment for Medical Lights

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

Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices as well as Installations 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 and sterile Equipment for Medical Lights





Benannt durch/Designated by  
Zentralsstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zgl.de  
BS-MDR-099



Product Service

## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 061092 0079 Rev. 02**

**Manufacturer:** **Draeger Medical Systems, Inc.**  
3135 Quarry Road  
Telford PA 18969-1042  
USA

SRN Manufacturer - US-MF-000020721

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10\\_061092\\_0079\\_Rev\\_02](http://www.tuvsud.com/ps-cert?q=cert:G10_061092_0079_Rev_02)

**Report No.:** 72197021  
**Preceding Certificate No.:** G10 061092 0079 Rev. 01  
**Valid from:** 2025-03-21  
**Valid until:** 2027-08-01  
**Date of Initial Issuance:** 2022-08-02

**Issue date:** 2025-03-21

*C. Dicks*

Christoph Dicks  
Head of Certification/Notified Body





Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 www.zflg.de  
 BS-MDR-099



Product Service

## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
 (Class IIa and Class IIb Devices)

**No. G10 061092 0079 Rev. 02**

**Classification:** Class IIb  
**Device Group:** Z120804 - NEONATOLOGY INSTRUMENTS  
**Intended Purpose:** Warming therapy devices intended to provide controlled ambient conditions for premature babies and neonates in closed and open care therapy

**Classification:** Class IIa  
**Device Group:** Z120302 - VITAL SIGNS MONITORING INSTRUMENTS  
**Intended Purpose:** -

**Classification:** Class IIb  
**Device Group:** Z120302 - VITAL SIGNS MONITORING INSTRUMENTS  
**Intended Purpose:** Devices intended for the purpose of physiological parameter monitoring.

**Classification:** Class IIa  
**Device Group:** Z12039092 - VARIOUS INSTRUMENTS TO SUPPORT AND MONITOR VITAL SIGNS - MEDICAL DEVICE SOFTWARE  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** R02010101 - BREATHING CIRCUITS, W/O WATER TRAP  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** Z120804 - NEONATOLOGY INSTRUMENTS  
**Intended Purpose:** -

**The validity of this certificate depends on conditions and/or is limited to the following:** -

### Revision History:

Rev.	Dated	Report	Description
00	2022-08-02	72180021	-
01	2023-10-31	72189568-1	Supplemented: Device(s)/group of device(s) added
02	2025-03-21	72197021	Supplemented: Device(s)/group of device(s) added

