Digitally signed by Iurchevici Valeriu
Date: 2025.05.02 17:14:31 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Dräger

Technology for Life

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

To whom it may concern

Our reference
739/22 // ew-de

Phone
+49 451 882-2471

E-mail
Erika.Wagner@draeger.com

November 11, 2024

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 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 31.12.2025.

Drägerwerk AG & Co. KGaA

Fiesser Caroline
Digital unterschrieben von Fiesser Caroline
Datum: 2024.11.11 17:17:54 +01'00'

Dr. Caroline Fiesser
Authorized Representative

ppa. T. Engel
Digitally signed by Tatjana Engel
Date: 2024.11.12 12:42:04 +01'00'

Tatjana Engel
Authorized Representative

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

IAF

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14143-01-00

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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
Drägerwerk AG & Co. KGaA 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
Drägerwerk AG & Co. KGaA 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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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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:

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

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

Report No.: 713308726

Valid from: 2024-01-14
Valid until: 2027-01-13

Date, 2023-12-28

Christoph Dicks
Head of Certification/Notified Body

"TECHIPAMED-PLUS" SOCIETATEA CU RASPUNDERE LIMITATA IDNO 1003600077677 REPUBLICA MOLDOVA mun. CHIŞINĂU

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Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

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

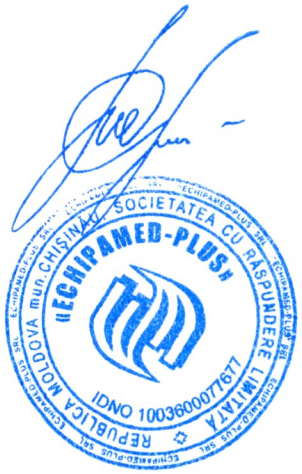
Facility(ies):

Drägerwerk AG & Co. KGaA
Moislinger 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



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TÜV SÜD 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 010578 0039 Rev. 14

Manufacturer:

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

SRN Manufacturer - DE-MF-000005329

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 010578 0039 Rev. 14

Report No.:	713336654
Preceding Certificate No.:	G10 010578 0039 Rev. 13
Valid from:	2025-03-18
Valid until:	2030-03-17
Date of Initial Issuance:	2020-03-18

Issue date: 2025-02-03

Christoph Dicks
Head of Certification/Notified Body

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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 010578 0039 Rev. 14

Classification:	Class IIa
Device Group:	R02 - BREATHING CIRCUITS AND CATHETER MOUNTS R0301 - RESPIRATORY MASKS R030201 - VENTILATION BALLOONS R0401 - VENTILATION FILTERS R0402 - NATURAL BREATHING FILTERS Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS Z120309 - MEDICAL/MEDICINAL GAS PIPELINE SYSTEMS AND RELATED ACCESSORIES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z12040192 - GENERAL MEDICINE DIAGNOSIS AND MONITORING INSTRUMENTS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	A060304 - INTRA-OPERATION FLUID COLLECTION DEVICES
Intended Purpose:	-
Classification:	Class IIb
Device Group:	Z12040192 - GENERAL MEDICINE DIAGNOSIS AND MONITORING INSTRUMENTS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	Software intended to provide clinical information for the purpose of supporting patient management and the decision making process
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 IIb
Device Group:	Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS
Intended Purpose:	Devices for the purpose of ventilation and/or anesthesia

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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 010578 0039 Rev. 14

Classification:	Class IIb
Device Group:	Z120309 - MEDICAL/MEDICINAL GAS PIPELINE SYSTEMS AND RELATED ACCESSORIES
Intended Purpose:	Devices intended to distribute or supply gases, vacuum, electricity or data to equipment in diagnostic, therapy or surgery
Classification:	Class IIb
Device Group:	R020107 - THERMOREGULATED BREATHING CIRCUITS
Intended Purpose:	Inspiratory (and expiratory) heated disposable breathing circuit for conducting humidified breathing gas from humidifier to patient
Classification:	Class IIb
Device Group:	R020101 - STANDARD BREATHING CIRCUITS
Intended Purpose:	Devices intended to administer gases for the purpose of ventilation
Classification:	Class IIb
Device Group:	Z120401 - GENERAL MEDICINE DIAGNOSIS AND MONITORING INSTRUMENTS
Intended Purpose:	Devices intended to provide clinical data on the network to support diagnosis and therapy decisions
Classification:	Class IIb
Device Group:	Z1203019092 - VARIOUS INSTRUMENTS FOR ANAESTHESIA AND PULMONARY VENTILATION SUPPORT - MEDICAL DEVICE SOFTWARE
Intended Purpose:	Software intended to support the decision making process in anesthesia and/or intensive care
Classification:	Class IIa
Device Group:	Z121590 - VARIOUS PNEUMOLOGY AND RESPIRATORY PHYSIOPATHOLOGY INSTRUMENTS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z120390 - VARIOUS INSTRUMENTS TO SUPPORT AND MONITOR VITAL SIGNS
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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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 010578 0039 Rev. 14

Revision History:

Rev.	Dated	Report	Description
00	2020-03-18	713169482	-
01	2021-07-02	713184148	-
02	2021-09-30	713215188	-
03	2021-10-01	713215832	-
04	2021-10-04	713215842	-
05	2021-10-04	713219421	-
06	2021-11-22	713229134	-
07	2022-02-21	713213004	-
08	2022-10-06	713225304_CN	-
09	2023-03-14	713253108_CN	Supplemented: Device(s)/group of device(s) added
10	2024-01-09	713298423	Supplemented: Device(s)/group of device(s) added
11	2024-02-12	713298535	Supplemented: Device(s)/group of device(s) added
12	2024-04-26	713312303	Supplemented: Device(s)/group of device(s) added
13	2024-09-20	713334366	Supplemented: Device(s)/group of device(s) added
14	2025-03-18	713336654	Renewal of certificate

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