Dräger

Technology for Life

Digitally signed by Iurchevici Valeriu
Date: 2024.07.15 16:29:33 EEST
Reason: MoldSign Signature
Location: Moldova

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

To whom it may concern

Manufacturer's Authorization

May 25, 2023

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. 2-7 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 only above mentioned Company is authorized to do registration, quote, seil, 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 31.12.2024.

Martin Koch
Managing Director Sub Region East Europe

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

CERTIFICATE

Management system as per
ISO 9001 : 2015

The Certification Body TÜV NORD CERT GmbH hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2015, that the organization

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

with the sites according to the annex

operates a management system in accordance with the requirements of ISO 9001 : 2015 and will be assessed for conformity within the 3 year term of validity of the certificate.

Scope

- **Sales and service of medical devices, products, systems and services for**
  - **Anesthesia, patient ventilation and inhalation incl. accessories, pediatrics, medical supply units, medical lights incl. OR lights, patient monitoring incl. software**
  - **Medical Gas Management Systems**
  - **Multivendor services and medical device management for hospitals (incl. contract management and service of medical devices with documentation, planning, testing and repair as well as incl. accessories for anesthesia, intensive care units and operating rooms)**
  - **Medical device training for clinical and technical user**
- **Sales and service including customization and assembly of products, systems and services for**
  - **Gas detection, analysis and measurement, personal protection, diving technology, breath alcohol and drug detection, system technology solutions, hydrostatic testing and filling of compressed air cylinders, fire extinguishing, evacuation and fire detection systems**
- **Training, shutdown and rental management**

Certificate Registration No. 44 100 150221
Audit Report No. 3529 8883

Valid from 2021-12-02
Valid until 2024-12-01
Initial certification 2015-12-02

Certification Body
at TÜV NORD CERT GmbH

Essen, 2021-11-08

Validity can be verified at https://www.tuev-nord.de/de/unternehmen/zertifizierung/zertifikatsdatenbank.

TÜV NORD CERT GmbH Am TÜV 1 45307 Essen www.tuev-nord-cert.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-12007-01-00

CERTIFICATE

Management system as per
ISO 14001 : 2015

The Certification Body TÜV NORD CERT GmbH hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2015, that the organization

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TÜV NORD CERT GmbH Am TÜV 1 45307 Essen www.tuev-nord-cert.com

Deutsche Akkreditierungsstelle D-ZM-12007-01-00

CERTIFICATE

Management system as per
ISO 45001 : 2018

The Certification Body TÜV NORD CERT GmbH hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2015, that the organization

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany
with the sites according to the annex

operates a management system in accordance with the requirements of ISO 45001 : 2018 and will be assessed for conformity within the 3 year term of validity of the certificate.

Scope

Sales and service of medical devices, products, systems and services for
- Anesthesia, patient ventilation and inhalation incl. accessories, pediatrics, medical supply units, medical lights incl. OR lights, patient monitoring incl. software
- Medical Gas Management Systems
- Multivendor services and medical device management for hospitals (incl. contract management and service of medical devices with documentation, planning, testing and repair as well as incl. accessories for anesthesia, intensive care units and operating rooms)
- Medical device training for clinical and technical user
Sales and service including customization and assembly of products, systems and services for
- Gas detection, analysis and measurement, personal protection, diving technology, breath alcohol and drug detection, system technology solutions, hydrostatic testing and filling of compressed air cylinders, fire extinguishing, evacuation and fire detection systems
Training, shutdown and rental management

Certificate Registration No. 44 126 150221
Audit Report No. 3529 8885

Valid from 2021-12-02
Valid until 2024-12-01
Initial certification 2015 (BS OHSAS 18001)

S. Vetter
Certification Body
at TÜV NORD CERT GmbH

Essen, 2021-11-08

Validity can be verified at https://www.tuev-nord.de/de/unternehmen/zertifizierung/zertifikatsdatenbank.

TÜV NORD CERT GmbH Am TÜV 1 45307 Essen www.tuev-nord-cert.com

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-12007-01-00

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.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 010578 0039 Rev. 09

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 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:G10 010578 0039 Rev. 09

Report No.: 713253108_CN

Preceding Certificate No.: G10 010578 0039 Rev. 08

Valid from: 2023-03-14
Valid until: 2025-03-17

Date of Initial Issuance: 2020-03-18

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-03-14

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

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

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(Class IIa and Class IIb Devices)

No. G10 010578 0039 Rev. 09

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

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(Class IIa and Class IIb Devices)

No. G10 010578 0039 Rev. 09

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

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	-

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No. G10 010578 0039 Rev. 09

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

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