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

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. 13

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. 13

Report No.:	713334366
Preceding Certificate No.:	G10 010578 0039 Rev. 12
Valid from:	2024-09-20
Valid until:	2025-03-17
Date of Initial Issuance:	2020-03-18

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-09-20

Digitally signed by Iurchevici Valeriu
Date: 2025.04.14 16:58:50 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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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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No. G10 010578 0039 Rev. 13

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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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

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Dräger

Technology for Life

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

To whom it may concern

Our reference
739/22 // ew-de

Phone
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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

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IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner:
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Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL
UID-Nr. DE135082211