



ECHIPAMED P L U S

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Nr. F/N
din 22.05.2025

*Către Grupul de lucru al
Centrului Pentru Achiziții Publice Centralizate în Sănătate*

DECLARAȚIE

Prin prezenta, compania „ECHIPAMED-PLUS” SRL, în conformitate cu condițiile expuse în documentele aferente invitației de participare la Licitația Deschisă nr. **ocds-b3wdp1-MD- ocds-b3wdp1-MD-1777453151767 / 21603065 din 22.05.2026** cu privire la **«Achiziționarea centralizată a Consumabilelor, accesoriilor și pieselor de schimb pentru Dispozitive medicale conform necesităților instituțiilor medico-sanitare publice- IMSP- pentru anul 2026 – PARTEA I (Bază) - Repetat»**, declară pe propria răspundere că, toate produsele propuse în oferta noastră pentru loturile 53 și 57, în condițiile legislației în vigoare și practicilor instanțelor responsabile, sunt piese de schimb pentru dispozitive medicale, pentru care producătorii nu eliberează certificate CE separate și care nu dețin calitatea de dispozitive medicale, respectiv, nu cad sub incidența Legii nr.102 din 09-06-2017 ”Cu privire la dispozitivele medicale” și, respectiv, nu necesită înregistrarea lor în Registrul de Stat al Dispozitivelor medicale.

Produsele propuse în oferta noastră pentru loturile 9 și 10 sunt prezente în Registrul de Stat al Dispozitivelor Medicale a AMDM, după cum urmează:

Lot 9 – DM000653565, în baza ordinului nr.Rg04-000259 din 09.11.2023;

Lot 10 – DM000570311, în baza ordinului nr.Rg04-000179 din 27.07.2023.

Totodată, confirmăm că toate produsele și piesele, oferite de către compania noastră în cadrul ofertei noastre, sunt originale, de la producătorul dispozitivelor medicale Dragerwerk AG & Co. KgaA (Germania).

Cu stimă,

Valeriu Iurchevici
Director
“ECHIPAMED-PLUS” SRL



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Zentralstelle der Länder
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bei Arzneimitteln und
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www.bfarm.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. 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](http://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

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-02-03





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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. 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 anaesthesia





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(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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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

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





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

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



Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

Our reference
739/22 // ew-de

To whom it may concern

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'



Digitally signed by Tatjana
Engel
Date: 2024.11.12
12:42:04 +01'00'

Dr. Caroline Fiesser
Authorized Representative

Tatjana Engel
Authorized Representative



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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
UID-Nr. DE135082211

Chairman of the Supervisory Board
for Drägerwerk AG & Co. KGaA
and Drägerwerk Verwaltungs AG:

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

