



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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





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





Benannt durch/Designated by
Zentralstelle der Länder
für Koordinationstätigkeiten
bei Arzneimitteln und
Medizinprodukten
www.zsl.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 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: ./.





Benannt durch/Designated by:
 Zentralstelle der Länder
 für Verbraucherschutz
 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. 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





ECHIPAMED P L U S

Moldova, MD-2001, str. Valea Trandafirilor, 24 «B», of. 2-7
tel. +373 (22) 234-349, 234-225; fax +373 (22) 234-225
office@echipamed.com, info@echipamed.com

F/N din 12.06.2026

*Către Grupul de lucru al
IMSP SCMC „V. Ignatenco”*

DECLARAȚIE

Prin prezenta compania „ECHIPAMED-PLUS” SRL, în conformitate cu condițiile expuse în documentele aferente invitației de participare la COP nr. 21627922 / ocds-b3wdp1-MD-1780551275805 din 13.06.2026 cu privire la achiziționarea “Necesarul de piese de schimb, accesorii și consumabile pentru dispozitive medicale pentru anul 2026 REPETAT”, cu respect Vă comunicăm, că în conformitate cu standardele de serviciu ale companiei germane Dragerwerk AG & Co. KGaA, informațiile despre piesele de schimb și seturile de mentenanță nu se află și nu sunt reflectate în cataloage/broșuri separate sau documentație tehnică de acces public liber.

Respectuos amintim, că în calitate de unic distribuitor oficial în Republica Moldova pentru tot spectrul de producție medicală (inclusiv dispozitive propriu-zise, soluții arhitecturale, accesorii, consumabile, piese de schimb, reparații și mentenanță) al companiei germane Dragerwerk AG & Co. KgaA, dispunând de centru tehnic propriu cu ingineri certificați (actele confirmative se anexează), compania „ECHIPAMED-PLUS” SRL operează doar cu produse originale Draeger, de producție proprie sau terță, acceptată oficial de producător.

Cu stimă,

Director
“ECHIPAMED-PLUS” SRL
Iurchevici Valeriu