





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

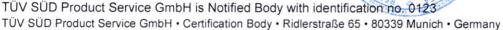
Body

Issue date:

2023-03-14









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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

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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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2022-02-21 713213004

08 2022-10-06 713225304 CN

2023-03-14 713253108_CN

Supplemented: Device(s)/group of

device(s) added

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