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

Digitally signed by Iurchevici Valeriu
Date: 2023.09.17 16:01:18 EEST
Reason: MoldSign Signature
Location: Moldova

Date of Initial Issuance: 2020-03-18

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2023-03-14

«ECHIPAMED-PLUS» IDNO 1003600076777

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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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BREATHING SYSTEM FILTERS AND HMEs

2. BREATHING SYSTEM FILTERS AND HMES

ELECTROSTATIC FILTER AND HME

The TwinStar® Plus filter/HME from Dräger is a combination of an efficient HME and a high-performance breathing system filter, thereby significantly contributing to infection prophylaxis in ventilation treatment.

- Combination of efficient HME and high-performance breathing system filter
- High retention rates for bacteria and viruses
- High return of moisture
- Minimal workload and low cost
- Sampling connector with tethered cap
- Transparent housing for visual control
- Standardized connectors for safe connection to other components
- Clear labeling and blue color coding for quick identification

A	**Filter + HME TwinStar® 90 Plus, disposable, ~90 ml deadspace, 100 pcs.**	**MP05800**
B	**Filter + HME TwinStar® 60A Plus, disposable, ~60 ml deadspace, angled, 100 pcs.**	**MP05810**
C	**Filter + HME TwinStar® 55 Plus, disposable, ~55 ml deadspace, 100 pcs.**	**MP05805**
D	**Filter + HME TwinStar® 25 Plus, disposable, ~25 ml deadspace, 100 pcs.**	**MP05815**
E	**Filter + HME TwinStar® 9 Plus, disposable, ~9 ml deadspace, 100 pcs.**	**MP05820**

MECHANICAL FILTER AND HME

F	**Mechanical filter + HME TwinStar® HEPA Plus, disposable, ~90 ml deadspace, 100 pcs.**	**MP05801**

A

D-36901-2021

B

D-36900-2021

C

D-36899-2021

D

D-36898-2021

E

D-36897-2021

F

D-36896-2021

Not all articles are available worldwide.

BREATHING SYSTEM FILTERS

ELECTROSTATIC FILTER

The CareStar® Plus breathing system filter significantly contributes to infection prophylaxis in anesthesia and ventilation treatment through high retention rates.

- High-performance electrostatic filter
- Patient-side or device-side use
- Minimal workload and low cost
- Sampling connector with tethered cap
- Transparent housing for visual control
- Standardized connectors for safe connection to other components
- Clear labeling and yellow color coding for quick identification

A **Electrostatic filter CareStar® 35 Plus, disposable, ~35 ml deadspace, 100 pcs.** **MP05755**

B **Electrostatic filter CareStar® 20 Plus, disposable, ~20 ml deadspace, 100 pcs.** **MP05770**

A

D-36892-2021

B

D-36891-2021

Not all articles are available worldwide.

HMEs

HME

HumidStar® Plus moisture exchangers from Dräger partially take over the function of the upper airways and efficiently humidify the inspired air.

- High return of moisture
- Minimal workload and low cost
- Sampling connector with tethered cap
- Transparent housing for visual control
- Standardized connectors for safe connection to other components
- Clear labeling and green color coding for quick identification

A	**HME HumidStar® 55 Plus*, disposable, ~55 ml deadspace, 100 pcs.**	**MP05730**
B	**HME HumidStar® 25 Plus*, disposable, ~25 ml deadspace, 100 pcs.**	**MP05735**
C	**HME HumidStar® 2 Plus, disposable, 2 ml deadspace, 100 pcs.**	**MP05845**
D	**HME HumidStar® Trach Plus, disposable, 6 ml deadspace, 100 pcs.**	**MP05750**

A

D-36903-2021

B

D-36902-2021

C

D-1021-2020

D

D-4552-2019

Not all articles are available worldwide.

BREATHING SYSTEM FILTERS AND HMEs

SPECIFICATIONS

	TwinStar® 90 Plus	TwinStar® 60A Plus	TwinStar® 55 Plus
Part number	MP05800	MP05810	MP05805
Deadspace	90 ml	60 ml	55 ml
Recommended tidal volume	300 to 1500 ml	300 to 1500 ml	300 to 1500 ml
Bacterial retention**	≥ 99.99%	≥ 99.99%	≥ 99.99%
Viral retention**	≥ 99.9%	≥ 99.9%	≥ 99.9%
Filtration method	electrostatic	electrostatic	electrostatic
Moisture loss*	≤ 5.9 mg/l at VT = 500 ml	≤ 6.3 mg/l at VT = 500 ml	≤ 9.4 mg/l at VT = 500 ml
Moisture return	≥ 38.1 mg/l at VT = 500 ml	≥ 37.7 mg/l at VT = 500 ml	≥ 34.6 mg/l at VT = 500 ml
Resistance	≤ 1.0 mbar at 30 l/min	≤ 1.3 mbar at 30 l/min	≤ 1.3 mbar at 30 l/min
Maximum duration of use	24 hours	24 hours	24 hours
Product	PVC-free/ Latex free	PVC-free/ Latex free	PVC-free/ Latex free

	TwinStar® 25 Plus	TwinStar® 9 Plus	TwinStar® HEPA Plus
Part number	MP05815	MP05820	MP05801
Deadspace	25 ml	9 ml	90 ml
Recommended tidal volume	100 to 500 ml	30 to 150 ml	300 to 1500 ml
Bacterial retention**	≥ 99,98%	≥ 99.99%	≥ 99.9999%
Viral retention**	≥ 99.9%	≥ 99.9%	≥ 99.9999%
Filtration method	electrostatic	electrostatic	mechanical
Moisture loss*	≤ 11.8 mg/l at VT = 250 ml	≤ 10.30 mg/l at VT = 50 ml	≤ 10.9 mg/l at VT = 500 ml
Moisture return	≥ 32.2 mg/l at VT = 250 ml	≥ 33.7 mg/l at VT = 50 ml	≥ 33.1 mg/l at VT = 500 ml
Resistance	≤ 1.8 mbar at 30 l/min	≤ 1.5 mbar at 15 l/min	≤ 1.6 mbar at 30 l/min
Maximum duration of use	24 hours	24 hours	24 hours
Product	PVC-free/ Latex free	PVC-free/ Latex free	PVC-free/ Latex free

Cleanroom manufactured according to EN ISO 14644-1:2014.

*According to DIN EN ISO 9360-1 2009.
**Test has been performed by Nelson Lab, USA, in 2021.

Not all articles are available worldwide.

BREATHING SYSTEM FILTERS

SPECIFICATIONS

	CareStar® 35 Plus	CareStar® 20 Plus
Part number	MP05755	MP05770
Deadspace	35 ml	20 ml
Recommended tidal volume	300 to 1500 ml	100 to 500 ml
Bacterial retention**	≥ 99.99%	≥ 99.99%
Viral retention**	≥ 99.9%	≥ 99.9%
Filtration method	electrostatic	electrostatic
Moisture loss*	–	–
Moisture return	–	–
Resistance	≤ 0.9 mbar at 30 l/min	≤ 1.3 mbar at 30 l/min
Maximum duration of use	24 hours	24 hours
Product	PVC-free/ Latex free	PVC-free/ Latex free

	SafeStar® 90 Plus	Safe Star® 60A Plus	SafeStar® 55 Plus
Part number	MP05785	MP05795	MP05790
Deadspace	90 ml	60 ml	55 ml
Recommended tidal volume	300 to 1500 ml	300 to 1500 ml	300 to 1500 ml
Bacterial retention**	≥ 99.9999%	≥ 99.999%	≥ 99.999%
Viral retention**	≥ 99.999%	≥ 99.9999%	≥ 99.999%
Filtration method	mechanical	mechanical	mechanical
Moisture loss*	–	–	–
Moisture return	–	–	–
Resistance	≤ 1.3 mbar at 30 l/min	≤ 2.0 mbar at 30 l/min	≤ 2.0 mbar at 30 l/min
Maximum duration of use	24 hours	24 hours	24 hours
Product	PVC-free/ Latex free	PVC-free/ Latex free	PVC-free/ Latex free

Cleanroom manufactured according to EN ISO 14644-1:2014.

*According to DIN EN ISO 9360-1 2009.
**Test has been performed by Nelson Lab, USA, in 2021.

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HMEs

SPECIFICATIONS

	HumidStar® 55 Plus	HumidStar® 25 Plus	HME HumidStar® 2 Plus
Part number	MP05730	MP05735	MP05845
Deadspace	55 ml	25 ml	2 ml
Recommended tidal volume	300 to 1,500 ml	100 to 500 ml	10 to 50 ml
Bacterial retention	–	–	–
Viral retention	–	–	–
Filtration method	–	–	–
Moisture loss*	≤ 7.8 mg/l at VT = 500 ml	≤ 9.3 mg/l at VT = 250 ml	≤ 11.5 mg/l at VT = 45 ml
Moisture return	≥ 36.2 mg/l at VT = 500 ml	≥ 34.7 mg/l at VT = 250 ml	≥ 32.5 mg/l at VT = 45 ml
Resistance	≤ 0.6 mbar at 30 l/min	≤ 0.3 mbar at 30 l/min	≤ 1.2 mbar at 15 l/min
Maximum duration of use	24 hours	24 hours	24 hours
Product	PVC-free/ Latex free	PVC-free/ Latex free	PVC-free/ Latex free

	HME HumidStar® Trach Plus
Part number	MP05750
Deadspace	6 ml
Recommended tidal volume	100 to 1,500 ml
Bacterial retention	–
Viral retention	–
Filtration method	–
Moisture loss*	≤ 10.8 mg/l at Vt = 250 ml
Moisture return	≥ 33.2 mg/l at Vt = 250 ml
Resistance	≤ 0.3 mbar at 60 l/min
Maximum duration of use	24 hours
Product	PVC-free/ Latex free

Cleanroom manufactured according to EN ISO 14644-1:2014.

*According to DIN EN ISO 9360-1 2009.

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