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

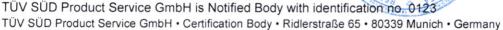| Report No.:	713253108_CN
Preceding Certificate No.:	G10 010578 0039 Rev. 08
Valid from:	2023-03-14
Valid until:	2025-03-17
Date of Initial Issuance:	2020-03-18

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2023-03-14

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BS-MDR-099

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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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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

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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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICAT ◆ CERTIFICADO ◆ CERTIFICAT

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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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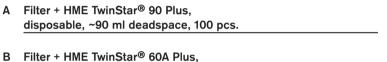
BREATHING SYSTEM FILTERS AND HMEs

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

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NEONATAL CARE
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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

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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.

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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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BREATHING SYSTEM FILTERS AND HMEs

2. BREATHING SYSTEM FILTERS AND HMEs

The TwinStar® 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 heat and moisture
– Reduced condensation in the breathing circuit
– Minimal workload and low cost
– Sampling connector with tethered cap
– Sampling port in convenient 45° angle
– Transparent housing for visual control
– Standardized connectors for safe connection to other components
– Clear labeling and blue color coding for quick identification

A   Electrostatic filter and HME TwinStar® 90, disposable, 90 mL deadspace, 50 pcs.   **MP01800**

B   Electrostatic filter and HME TwinStar® 65A, disposable, 65 mL deadspace, angled, 50 pcs.   **MP01810**

C   Electrostatic filter and HME TwinStar® 55, disposable, 55 mL deadspace, 50 pcs.   **MP01805**

D   Electrostatic filter and HME TwinStar® 25, disposable, 25 mL deadspace, 50 pcs.   **MP01815**

E   Electrostatic filter and HME TwinStar® 10A, disposable, 10 mL deadspace, angled, 50 pcs.   **MP01825**

F   Electrostatic filter and HME TwinStar® 8, disposable, 8 mL deadspace, 50 pcs.   **MP01820**

G   Mechanical filter and HME TwinStar® HEPA, disposable, 55 mL deadspace, 50 pcs.   **MP01801**

A
MT-4385-2007

B
MT-4745-2007

C
MT-11164-2006

D
MT-0105-2008

E
MT-4397-2007

F
MT-4396-2007

G
MT-4388-2007

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BREATHING SYSTEM FILTERS

The CareStar® 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
– Sampling port in convenient 45° angle
– Transparent housing for visual control
– Standardized connectors for safe connection
  to other components
– Clear labeling and red color coding
  for quick identification

A

MT-4387-2007

B

MT-4747-2007

C

MT-0011-2007

A	Electrostatic filter CareStar® 45, disposable, 45 mL deadspace, 50 pcs.	MP01755
B	Electrostatic filter CareStar® 40A, disposable, 40 mL deadspace, angled, 50 pcs.	MP01765
C	Electrostatic filter CareStar® 30, disposable, 30 mL deadspace, 50 pcs.	MP01770

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BREATHING SYSTEM FILTERS AND HMEs

SPECIFICATIONS

	Filter/HME TwinStar® 90	Filter/HME TwinStar® 65A	Filter/HME TwinStar® 55	Filter/HME TwinStar® 25
Deadspace (mL)			55	
Recommended tidal volume (mL)			300 to 1,500	
Bacterial retention (%)**			99.999	
Viral retention (%)**			99.99	
Filtration method			Electrostatic	
Moisture loss* (mg H_2O/l air)			7.2@Vt 500 mL	
Moisture output (mg H_2O/l air)			36.8	
Resistance (mbar)			0.9 at 30 L/min	
Weight (g)			28	
ISO connectors			22M/15F – 22F/15M	
Sampling port			Luer Lock with tethered cap	
Housing			Polypropylene	
Maximum duration of use			24 hours	
Shelf life in undamaged packaging			3 years	
Product			PVC-free/ Latex free	

SPECIFICATIONS

	Filter/HME TwinStar® 10A	Filter/HME TwinStar® 8	Filter/HME TwinStar® HEPA
Deadspace (mL)			
Recommended tidal volume (mL)			
Bacterial retention (%)**			
Viral retention (%)**			
Filtration method			
Moisture loss* (mg H_2O/l air)			
Moisture output (mg H_2O/l air)			
Resistance (mbar)			
Weight (g)			
ISO connectors			
Sampling port			
Housing			
Maximum duration of use			
Shelf life in undamaged packaging			
Product			

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

*According to ISO EN 9360-1:2009.
**Test has been performed by Nelson Lab, USA, before 2010

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BREATHING SYSTEM FILTERS

SPECIFICATIONS

	Filter CareStar® 45	Filter CareStar® 40A	Filter CareStar® 30
Deadspace (mL)			30
Recommended tidal volume (mL)			100 to 1,500
Bacterial retention (%)**			99.999
Viral retention (%)**			99.99
Filtration method			Electrostatic
Moisture loss* (mg H_2O/l air)			–
Moisture output (mg H_2O/l air)			–
Resistance (mbar)			0.6 at 30 L/min
Weight (g)			23
ISO connectors			22M/15F – 22F/15M
Sampling port			Luer Lock with tethered cap
Housing			Polypropylene
Maximum duration of use			24 hours
Shelf life in undamaged packaging			3 years
Product			PVC-free/ Latex free

SPECIFICATIONS

	Filter SafeStar® 80	Filter SafeStar® 60A	Filter SafeStar® 55
Deadspace (mL)			
Recommended tidal volume (mL)			
Bacterial retention (%)**			
Viral retention (%)**			
Filtration method			
Moisture loss* (mg H_2O/l air)			
Moisture output (mg H_2O/l air)			
Resistance (mbar)			
Weight (g)			
ISO connectors			
Sampling port			
Housing			
Maximum duration of use			
Shelf life in undamaged packaging			
Product			

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