

## BREATHING SYSTEM FILTERS AND HMEs

### 2. BREATHING SYSTEM FILTERS AND HMEs

#### ELECTROSTATIC FILTER AND HME

The **Filter/HME TwinStar® Plus** 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



<b>A</b>	<b>Filter + HME TwinStar® 90 Plus, disposable, ~90 ml dead space, 100 pcs.</b>	<b>MP05800</b>
<b>B</b>	<b>Filter + HME TwinStar® 60A Plus, disposable, ~60 ml dead space, angled, 100 pcs.</b>	<b>MP05810</b>
<b>C</b>	<b>Filter + HME TwinStar® 55 Plus, disposable, ~55 ml dead space, 100 pcs.</b>	<b>MP05805</b>
<b>D</b>	<b>Filter + HME TwinStar® 25 Plus, disposable, ~25 ml dead space, 100 pcs.</b>	<b>MP05815</b>
<b>E</b>	<b>Filter + HME TwinStar® 9 Plus, disposable, ~9 ml dead space, 100 pcs.</b>	<b>MP05820</b>

#### MECHANICAL FILTER AND HME

<b>F</b>	<b>Mechanical filter + HME TwinStar® HEPA Plus, disposable, ~90 ml dead space, 100 pcs.</b>	<b>MP05801</b>
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## BREATHING SYSTEM FILTERS AND HMEs

### SPECIFICATIONS

	<b>TwinStar® 90 Plus</b>	<b>TwinStar® 60A Plus</b>	<b>TwinStar® 55 Plus</b>
Part number	MP05800	MP05810	MP05805
Dead space	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

	<b>TwinStar® 25 Plus</b>	<b>TwinStar® 9 Plus</b>	<b>TwinStar® HEPA Plus</b>
Part number	MP05815	MP05820	MP05801
Dead space	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.

## BREATHING SYSTEM FILTERS

### MECHANICAL FILTER

The **SafeStar® Plus** mechanical high performance breathing system filter shows excellent retention rates, thereby significantly contributing to infection prophylaxis in anesthesia and ventilation treatment.

- High-performance mechanical HEPA filter
- High hydrophobicity
- Patient-side or device-side use
- Sampling connector with tethered cap
- Transparent housing for visual control
- Standardized connectors for safe connection to other components
- Clear labeling and red color coding for quick identification

**A**

D-36895-2021

**B**

D-36894-2021

**C**

D-36893-2021



<b>A</b>	<b>Mechanical filter SafeStar® 90 Plus, disposable, ~90 ml dead space, 100 pcs.</b>	<b>MP05785</b>
<b>B</b>	<b>Mechanical filter SafeStar® 60A Plus, disposable, ~60 ml dead space, angled, 100 pcs.</b>	<b>MP05795</b>
<b>C</b>	<b>Mechanical filter SafeStar® 55 Plus, disposable, ~55 ml dead space, 100 pcs.</b>	<b>MP05790</b>

## BREATHING SYSTEM FILTERS

### SPECIFICATIONS

	CareStar® 35 Plus	CareStar® 20 Plus
Part number	MP05755	MP05770
Dead space	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
Dead space	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.

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

To whom it may concern

### Manufacturer's Authorization

May 25, 2023

We, Drägerwerk AG & Co. KGaA, Moislinger Allee 53-55, 23558 Lübeck, Germany, who is an established and reputable manufacturer of medical equipment, having factories at Lübeck (Germany), Telford (United States), Andover (United States) and Shanghai (China), do hereby declare that

**"Echipamed-Plus" SRL Valea Trandafirilor 24 "B", of. 2-7 MD-2001, Chisinau Republic of Moldova**

is our official 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 31.12.2024.

Martin Koch  
Managing Director Sub Region East Europe



Drägerwerk AG & Co. KGaA  
Moislinger Allee 53-55  
23558 Lübeck, Germany  
Postal address:  
23542 Lübeck, Germany  
Tel. +49 451 882-0  
Fax +49 451 882-2080  
info@draeger.com  
www.draeger.com  
UID-Nr. DE135082211

Bank details:  
Commerzbank AG, Lübeck  
IBAN: DE95 2304 0022 0014 6795 00  
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

Chairman of the Supervisory Board  
for Drägerwerk AG & Co. KGaA  
and Drägerwerk Verwaltungs AG:  
Stefan Lauer  
Executive Board:  
Stefan Dräger (chairman)  
Rainer Klug  
Gert-Hartwig Lescow  
Dr. Reiner Piske  
Anton Schrofner



# CERTIFICATE

Management system as per  
**ISO 9001 : 2015**

The Certification Body TÜV NORD CERT GmbH hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2015, that the organization

**Drägerwerk AG & Co. KGaA**  
**Moislinger Allee 53-55**  
**23542 Lübeck**  
**Germany**

**with the sites according to the annex**


operates a management system in accordance with the requirements of ISO 9001 : 2015 and will be assessed for conformity within the 3 year term of validity of the certificate.

## Scope

- Sales and service of medical devices, products, systems and services for
- Anesthesia, patient ventilation and inhalation incl. accessories, pediatrics, medical supply units, medical lights incl. OR lights, patient monitoring incl. software
- Medical Gas Management Systems
- Multivendor services and medical device management for hospitals (incl. contract management and service of medical devices with documentation, planning, testing and repair as well as incl. accessories for anesthesia, intensive care units and operating rooms)
- Medical device training for clinical and technical user
- Sales and service including customization and assembly of products, systems and services for
- Gas detection, analysis and measurement, personal protection, diving technology, breath alcohol and drug detection, system technology solutions, hydrostatic testing and filling of compressed air cylinders, fire extinguishing, evacuation and fire detection systems
- Training, shutdown and rental management

Certificate Registration No. 44 100 150221  
Audit Report No. 3529 8883

Valid from 2021-12-02  
Valid until 2024-12-01  
Initial certification 2015-12-02

  
Certification Body  
at TÜV NORD CERT GmbH

Essen, 2021-11-08

Validity can be verified at <https://www.tuev-nord.de/de/unternehmen/zertifizierung/zertifikatsdatenbank>.

TÜV NORD CERT GmbH

Am TÜV 1

45307 Essen

[www.tuev-nord-cert.com](http://www.tuev-nord-cert.com)



Deutsche  
Akkreditierungsstelle  
D-ZM-12007-01-00





# CERTIFICATE

Management system as per  
**ISO 14001 : 2015**

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**Drägerwerk AG & Co. KGaA**  
Moislinger Allee 53-55  
23542 Lübeck  
Germany

**with the sites according to the annex**

operates a management system in accordance with the requirements of ISO 14001 : 2015 and will be assessed for conformity within the 3 year term of validity of the certificate.

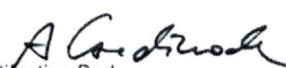
## Scope

**Sales and service of medical devices, products, systems and services for**

- Anesthesia, patient ventilation and inhalation incl. accessories, pediatrics, medical supply units, medical lights incl. OR lights, patient monitoring incl. software
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- Multivendor services and medical device management for hospitals (incl. contract management and service of medical devices with documentation, planning, testing and repair as well as incl. accessories for anesthesia, intensive care units and operating rooms)
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- Gas detection, analysis and measurement, personal protection, diving technology, breath alcohol and drug detection, system technology solutions, hydrostatic testing and filling of compressed air cylinders, fire extinguishing, evacuation and fire detection systems
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TÜV NORD CERT GmbH

Am TÜV 1

45307 Essen

[www.tuev-nord-cert.com](https://www.tuev-nord-cert.com)



**DAkKS**

Deutsche  
Akkreditierungsstelle  
D-2M-12007-01-00







Benannt durch/Designated by:  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zfz.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**

Moisliger 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](http://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

**Issue date:** 2023-03-14

*C. Dicks*

Christoph Dicks

Head of Certification/Notified  
Body







## 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**

<b>Classification:</b>	Class IIa
<b>Device Group:</b>	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
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z12040192 - GENERAL MEDICINE DIAGNOSIS AND MONITORING INSTRUMENTS - MEDICAL DEVICE SOFTWARE
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	A060304 - INTRA-OPERATION FLUID COLLECTION DEVICES
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	Z12040192 - GENERAL MEDICINE DIAGNOSIS AND MONITORING INSTRUMENTS - MEDICAL DEVICE SOFTWARE
<b>Intended Purpose:</b>	Software intended to provide clinical information for the purpose of supporting patient management and the decision making process
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	Z120804 - NEONATOLOGY INSTRUMENTS





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

### 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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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



TUV®





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für Gesundheitsschutz  
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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**

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

