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en/de

EU Declaration of Conformity
EU-Konformitätserklärung

CE 0123

Document No. / Dokument Nr. **MDR108-043-2302-003-0**
Date / Datum **2023-02-22**
Place / Ort **Germany – Lübeck**
Page / Seite **1 / 5**

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

Authorised representative / Europäischer Bevollmächtigter: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Digitally signed by Iurchevici Valeriu
Date: 2023.05.29 09:41:42 EEST
Reason: MoldSign Signature
Location: Moldova

Single registration number (SRN)/ einmalige Registrierungsnummer: DE-MF-000005329

hereby declares under its sole responsibility that the / erklärt hiermit in alleiniger Verantwortung, dass

Product Name / Produktbezeichnung	Device Category / Produktkategorie	Device Class / Geräteklasse	UMDNS Code / GMDN Code / EMDN Code
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

meets the following provisions:
mit den folgenden Bestimmungen übereinstimmt:

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European regulation (EU) 2017/745 on medical devices. An examination of the quality management System has been carried out following Annex IX (Chapters I and III and section 4) of the regulation by the Notified Body:/

Verordnung (EU) 2017/745 über Medizinprodukte. Eine Überprüfung des Qualitätsmanagementsystems, nach den Regeln wie in Anhang IX (Kapitel I and III und Abschnitt 4) der Verordnung beschrieben, wurde durch die Benannte Stelle vorgenommen:
TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123

The quality management system also complies to EN ISO 9001 and EN ISO 13485./

Das Qualitätsmanagementsystem erfüllt weiterhin die Anforderungen gemäß EN ISO 9001 und EN ISO 13485.

This declaration is effective for products placed on the market as of the date of issue. Any modifications of the device not authorized by Dräger will invalidate this declaration./
Diese Erklärung ist gültig für ab dem Ausstellungsdatum in Verkehr gebrachte Produkte. Jede nicht durch Dräger autorisierte Modifikation an dem Produkt führt zur Ungültigkeit dieser Erklärung.

For the signature on behalf of Dräger see upper left corner of page 1./
Für die Unterschrift im Namen von Dräger siehe linke obere Ecke der Seite 1.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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www.draeger.com
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Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

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Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
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Executive Board:
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Anton Schrofner

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

Product Name / Produktbezeichnung	**Device Category / Produktkategorie**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Applied Standards in full or in part / Vollständig oder teilweise angewendete Normen:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
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EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
EN ISO 23328-1:2008 *(ISO 23328-1:2003)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 1: Salt Test Method to assess Filtration Performance
EN ISO 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
EN ISO 9360-2:2009 *(ISO 9360-2:2001)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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

Extend of conformity assessment / Umfang der Konformitätsbewertung		
Part Number / Sachnummer	Product Name / Produktbezeichnung	Basic UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

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ЕС декларация за съответствие

Документ №	**MDR108-043-2302-003-0**
Дата	**2023-02-22**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Упълномощен представител: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Еднократен регистрационен номер (SRN): DE-MF-000005329

с настоящото декларира на своя отговорност, че

Име на продукта	Категория на уреда	Клас на уреда	Код UMDNS / Код GMDN / Код EMDN
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

отговаря на следните разпоредби:

ЕВРОПЕЙСКИ РЕГЛАМЕНТ (ЕС) 2017/745 относно медицински изделия. Извършено е проучване на системата за управление на качеството в съответствие с анекс IX (глави I и III и раздел 4) на регламента от нотифицирания орган: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Системата за управление на качеството също отговаря на EN ISO 9001 и EN ISO 13485.

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ЕС декларация за съответствие

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За продукти, пуснати на пазара, тази декларация е в сила от датата на издаване. Всяка модификация на уреда, която не е разрешена от Dräger, обезсилва тази декларация.

Това е превод на оригиналния документ (en/de) и затова не е подписан.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

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Dr. Reiner Piske
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Име на продукта	**Категория на уреда**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Напълно или частично приложени стандарти:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
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ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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

Обхват на оценката на съответствие		
Номер на частта	Име на продукта	Основен идентификатор UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
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MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

Declaración UE de conformidad

CE 0123

N.º de documento	**MDR108-043-2302-003-0**
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Lugar	**Germany – Lübeck**
Página	**1 / 5**

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

Representante autorizado: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Número de registro único (SRN): DE-MF-000005329

por la presente declara bajo su exclusiva responsabilidad que

Nombre del producto	Categoría del dispositivo	Clase del dispositivo	Código UMDNS / Código GMDN / Código EMDN
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
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HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

cumple las siguientes disposiciones:

REGLAMENTO EUROPEO (UE) 2017/745 sobre los productos sanitarios. Se ha efectuado un examen del sistema de gestión de la calidad siguiendo el anexo IX (capítulos I y III y sección 4) del reglamento del organismo notificado: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
El sistema de gestión de la calidad también cumple con EN ISO 9001 y EN ISO 13485.

CE 0123

Declaración UE de conformidad

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Esta declaración será efectiva para los productos puestos en el mercado a partir de la fecha de publicación. Cualquier modificación del dispositivo no autorizada por Dräger invalidará esta declaración.

Esta es una traducción del documento original (en/de) y, por lo tanto, no lleva firma.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

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

Nombre del producto	**Categoría del dispositivo**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Normas aplicadas total o parcialmente:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
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Declaración UE de conformidad

N.º de documento	**MDR108-043-2302-003-0**
Fecha	**2023-02-22**
Lugar	**Germany – Lübeck**
Página	**5 / 5**

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

Alcance de la evaluación de conformidad		
Número de referencia	Nombre del producto	UDI-DI básico
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

CE 0123

EU prohlášení o shodě

Č. dokumentu	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
Místo	**Germany – Lübeck**
Strana	**1 / 5**

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

Zplnomocněným zástupcem: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Jednorázové registračních číslo (SRN): DE-MF-000005329

tímto prohlašuje na svou výhradní zodpovědnost, že

Název produktu	Kategorie prostředku	Třída prostředku	Kód UMDNS / Kód GMDN / Kód EMDN
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

splňuje následující ustanovení:

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY (EU) 2017/745 o zdravotnických prostředcích. Kontrola systému managementu kvality byla provedena oznámeným subjektem podle přílohy IX (kapitol I a III a oddílu 4) nařízení: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Systém managementu kvality splňuje rovněž požadavky norem EN ISO 9001 a EN ISO 13485.

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
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Tel +49 451 882-0
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info@draeger.com
www.draeger.com
VAT no. 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

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EU prohlášení o shodě

Č. dokumentu	**MDR108-043-2302-003-0**
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Místo	**Germany – Lübeck**
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Toto prohlášení nabývá platnosti pro produkty uvedené na trh ke dni vydání. Jakákoli úprava prostředku, která není schválena společností Dräger, toto prohlášení zneplatní.

Toto je překlad původního dokumentu (en/de), a proto nenese podpis.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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EU prohlášení o shodě

Č. dokumentu	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
Místo	**Germany – Lübeck**
Strana	**3 / 5**

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

Název produktu	**Kategorie prostředku**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Použité normy, v celku nebo z části:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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EU prohlášení o shodě

Č. dokumentu	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
Místo	**Germany – Lübeck**
Strana	**4 / 5**

ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets
EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
EN ISO 23328-1:2008 *(ISO 23328-1:2003)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 1: Salt Test Method to assess Filtration Performance
EN ISO 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
EN ISO 9360-2:2009 *(ISO 9360-2:2001)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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EU prohlášení o shodě

Č. dokumentu	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
Místo	**Germany – Lübeck**
Strana	**5 / 5**

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

Rozsah posuzování shody		
Číslo dílu	Název produktu	Základní UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

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EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-043-2302-003-0**
Dato	**2023-02-22**
Sted	**Germany – Lübeck**
Side	**1 / 5**

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

Autoriseret repræsentant: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Individuelt registreringsnummer (SRN): DE-MF-000005329

erklærer hermed på eget ansvar, at

Produktnavn	Apparatkategori	Apparatklasse	UMDNS-kode / GMDN-kode / EMDN-kode
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

opfylder følgende bestemmelser:

EUROPÆISK FORORDNING (EU) 2017/745 om medicinsk udstyr. En undersøgelse af kvalitetsstyringssystemet er blevet foretaget i overensstemmelse med bilag IX (kapitel I og III og afsnit 4) til forordningen af det bemyndigede organ: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitetsstyringssystemet overholder ligeledes EN ISO 9001 og EN ISO 13485.

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EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-043-2302-003-0**
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Denne erklæring gælder for produkter, der markedsføres efter udstedelsesdatoen. Ved enhver ændring af udstyret, der ikke er godkendt af Dräger, mister denne erklæring sin gyldighed.

Dette er en oversættelse af det originale dokument (en/de) og er derfor ikke forsynet med en underskrift.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
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Kalle Heckmann

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Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
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EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-043-2302-003-0**
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Sted	**Germany – Lübeck**
Side	**3 / 5**

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

Produktnavn	**Apparatkategori**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Standarder, der anvendes helt eller delvist:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-043-2302-003-0**
Dato	**2023-02-22**
Sted	**Germany – Lübeck**
Side	**4 / 5**

ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets
EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
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EN ISO 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
EN ISO 9360-2:2009 *(ISO 9360-2:2001)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-043-2302-003-0**
Dato	**2023-02-22**
Sted	**Germany – Lübeck**
Side	**5 / 5**

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

Overensstemmelsesvurderingens omfang		
Varenummer	Produktnavn	Basic UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

CE 0123

ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-043-2302-003-0**
Kuupäev	**2023-02-22**
Koht	**Germany – Lübeck**
Lk	**1 / 5**

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

Volitatud esindaja: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Kordumatu registreerimisnumber (SRN): DE-MF-000005329

kinnitab käesolevaga oma ainuvastutusel, et

Toote nimi	Seadme kategooria	Seadme klass	UMDNS-kood / GMDN-kood / EMDN-kood
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

vastab järgmistele nõuetele:

EUROOPA MÄÄRUS (EL) 2017/745 meditsiiniseadmete kohta. Kvaliteedijuhtimise süsteemi on hinnatud teavitatud asutuses määruse IX lisa (peatükid I ja III ning jaotis 4) alusel: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvaliteedikontrolli süsteem vastab ka standarditele EN ISO 9001 ja EN ISO 13485.

CE 0123

ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-043-2302-003-0**
Kuupäev	**2023-02-22**
Koht	**Germany – Lübeck**
Lk	**2 / 5**

Käesolev deklaratsioon kehtib toodete kohta, mis on turule toodud alates deklaratsiooni väljaandmise kuupäevast. Deklaratsioon kaotab kehtivuse, kui tootel tehakse muudatusi, mille kohta ei ole Drägerilt nõusolekut saadud.

Tegu on originaaldokumendi (en/de) tõlkega ja seetõttu ei ole sellel allkirja.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-043-2302-003-0**
Kuupäev	**2023-02-22**
Koht	**Germany – Lübeck**
Lk	**3 / 5**

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

Toote nimi	**Seadme kategooria**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Osaliselt või täielikult kohaldatud standardid:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
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EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
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ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-043-2302-003-0**
Kuupäev	**2023-02-22**
Koht	**Germany – Lübeck**
Lk	**4 / 5**

ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets
EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
EN ISO 23328-1:2008 *(ISO 23328-1:2003)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 1: Salt Test Method to assess Filtration Performance
EN ISO 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
EN ISO 9360-2:2009 *(ISO 9360-2:2001)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

CE 0123

ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-043-2302-003-0**
Kuupäev	**2023-02-22**
Koht	**Germany – Lübeck**
Lk	**5 / 5**

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

Vastavushinnangu ulatus		
Osa number	Toote nimi	Peamine UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-043-2302-003-0**
Ημερομηνία	**2023-02-22**
Τοποθεσία	**Germany – Lübeck**
Σελίδα	**1 / 5**

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

Εξουσιοδοτημένος αντιπρόσωπος: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Μεμονωμένος αριθμός εγγραφής (SRN): DE-MF-000005329

δηλώνει με αποκλειστική ευθύνη ότι

Όνομα προϊόντος	Κατηγορία συσκευής	Κλάση συσκευής	Κωδικός UMDNS / Κωδικός GMDN / Κωδικός EMDN
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

συμμορφώνεται με τις ακόλουθες διατάξεις:

Ευρωπαϊκός κανονισμός (ΕΕ) 2017/745 περί ιατροτεχνολογικών προϊόντων. Πραγματοποιήθηκε έλεγχος του συστήματος διαχείρισης ποιότητας σύμφωνα με το παράρτημα IX (κεφάλαια I και III και ενότητα 4) του κανονισμού από τον κοινοποιημένο οργανισμό: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Το σύστημα διαχείρισης ποιότητας συμμορφώνεται επίσης με τα πρότυπα EN ISO 9001 και EN ISO 13485.

CE 0123

Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-043-2302-003-0**
Ημερομηνία	**2023-02-22**
Τοποθεσία	**Germany – Lübeck**
Σελίδα	**2 / 5**

Η παρούσα δήλωση ισχύει για προϊόντα που τίθενται στην αγορά από την ημερομηνία έκδοσης. Οποιαδήποτε τροποποίηση στη συσκευή χωρίς την έγκριση της Dräger θα ακυρώσει την παρούσα δήλωση.

Το παρόν αποτελεί μετάφραση του πρωτότυπου εγγράφου (από τα αγγλικά/γερμανικά) και γι' αυτό το λόγο δεν φέρει σφραγίδα.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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Fax +49 451 882-2080
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www.draeger.com
VAT no. DE135082211

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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

CE 0123

Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου **MDR108-043-2302-003-0**
Ημερομηνία **2023-02-22**
Τοποθεσία **Germany – Lübeck**
Σελίδα **3 / 5**

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

Όνομα προϊόντος	**Κατηγορία συσκευής**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Πρότυπα που εφαρμόζονται πλήρως ή εν μέρει:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-043-2302-003-0**
Ημερομηνία	**2023-02-22**
Τοποθεσία	**Germany – Lübeck**
Σελίδα	**4 / 5**

ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
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ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου **MDR108-043-2302-003-0**
Ημερομηνία **2023-02-22**
Τοποθεσία **Germany – Lübeck**

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

Επέκταση αξιολόγησης της συμμόρφωσης		
Αριθμός εξαρτήματος	Όνομα προϊόντος	Βασικό UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
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MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

Déclaration de conformité UE

CE 0123

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Date	**2023-02-22**
Ville	**Germany – Lübeck**
Page	**1 / 5**

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

Mandataire: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Numéro d'enregistrement unique (SRN): DE-MF-000005329

déclare par la présente et sous sa seule responsabilité que le

Nom du produit	Catégorie de l'appareil	Classe de l'appareil	Code UMDNS / Code GMDN / Code EMDN
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

satisfait aux dispositions suivantes :

RÉGLEMENTATION EUROPÉENNE (UE) 2017/745 sur les dispositifs médicaux. Une vérification du système de gestion de la qualité a été réalisée conformément à l'annexe IX (chapitres I et III, ainsi que section 4) de la réglementation suivante par l'organisme notifié : **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Le système de gestion de la qualité satisfait également aux normes EN ISO 9001 et EN ISO 13485.

Drägerwerk AG & Co. KGaA
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Déclaration de conformité UE

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La déclaration s’applique aux produits mis sur le marché à partir de la date de publication. Toute modification non autorisée par Dräger apportée sur l’appareil rend cette déclaration caduque.

Il s'agit d'une traduction du document original (en/de) et ne porte donc pas de signature.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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Déclaration de conformité UE

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

Nom du produit	**Catégorie de l'appareil**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Normes appliquées en totalité ou en partie :	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
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Déclaration de conformité UE

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ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
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ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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Déclaration de conformité UE

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Date	**2023-02-22**
Ville	**Germany – Lübeck**
Page	**5 / 5**

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

Étendue de l'évaluation de la conformité		
Référence de pièce	Nom du produit	IUD-ID de base
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
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MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
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MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

hr

EU izjava o sukladnosti

CE 0123

Br. dokumenta	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
Mjesto	**Germany – Lübeck**
Stranica	**1 / 5**

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

Ovlašteni zastupnik: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Jedinstveni registracijski broj (SRN): DE-MF-000005329

ovime izjavljuje pod vlastitom odgovornošću da je

Naziv proizvoda	Kategorija proizvoda	Razred proizvoda	UMDNS kod / GMDN kod / EMDN kod
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

sukladan sa sljedećim odredbama:

UREDBA (EU) 2017/745 o medicinskim proizvodima. Ocjena sustava upravljanja kvalitetom provedena je prema Prilogu IX. (poglavlju I. i III. i stavku 4.) uredbe od strane prijavljenog tijela: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sustav upravljanja kvalitetom također je sukladan normama EN ISO 9001 i EN ISO 13485.

Drägerwerk AG & Co. KGaA
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CE 0123

EU izjava o sukladnosti

Br. dokumenta	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
Mjesto	**Germany – Lübeck**
Stranica	**2 / 5**

Ova izjava za proizvode stavljene na tržište stupa na snagu od datuma izdavanja. U slučaju bilo kakvih izmjena proizvoda koje nisu odobrene od strane tvrtke Dräger ova izjava gubi svoju valjanost.

Ovo je prijevod izvornog dokumenta (engl./njem.) i stoga ne sadrži potpis.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

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
VAT no. 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

CE 0123

EU izjava o sukladnosti

Br. dokumenta	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
Mjesto	**Germany – Lübeck**
Stranica	**3 / 5**

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

Naziv proizvoda	**Kategorija proizvoda**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Norme primijenjene u cijelosti ili djelomično:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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EU izjava o sukladnosti

Br. dokumenta	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
Mjesto	**Germany – Lübeck**
Stranica	**4 / 5**

ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets
EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
EN ISO 23328-1:2008 *(ISO 23328-1:2003)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 1: Salt Test Method to assess Filtration Performance
EN ISO 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
EN ISO 9360-2:2009 *(ISO 9360-2:2001)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

CE 0123

EU izjava o sukladnosti

Br. dokumenta MDR108-043-2302-003-0
Datum 2023-02-22
Mjesto Germany – Lübeck

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

Opseg ocjene sukladnosti		
Broj dijela	Naziv proizvoda	Osnovni UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

CE 0123

Dichiarazione di conformità UE

N. documento	**MDR108-043-2302-003-0**
Data	**2023-02-22**
Luogo	**Germany – Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Mandatario: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Numero di registrazione unico (SRN): DE-MF-000005329

dichiara con la presente sotto la propria responsabilità che

Nome prodotto	Categoria dispositivo	Classe dispositivo	Codice UMDNS / Codice GMDN / Codice EMDN
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

è conforme alle seguenti disposizioni:

REGOLAMENTO EUROPEO (UE) 2017/745 relativo ai dispositivi medici. È stata effettuata una verifica del sistema di gestione della qualità ai sensi dell'allegato IX (capitoli I e III e sezione 4) del regolamento dell'organismo notificato: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Il sistema di gestione della qualità è altresì conforme alle norme EN ISO 9001 e EN ISO 13485.

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Dichiarazione di conformità UE

N. documento	**MDR108-043-2302-003-0**
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La presente dichiarazione è valevole per i prodotti lanciati sul mercato a partire dalla data di pubblicazione. Qualsiasi modifica del dispositivo non autorizzata da Dräger invalida la presente dichiarazione.

Si tratta di una traduzione del documento originale (en/de) e non porta pertanto una firma.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

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IBAN: DE15 2305 0101 0001 0711 17
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Dichiarazione di conformità UE

N. documento	**MDR108-043-2302-003-0**
Data	**2023-02-22**
Luogo	**Germany – Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Nome prodotto	**Categoria dispositivo**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Standard applicati integralmente o parzialmente:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
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EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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Dichiarazione di conformità UE

N. documento	**MDR108-043-2302-003-0**
Data	**2023-02-22**
Luogo	**Germany – Lübeck**
Pagina	**4 / 5**

ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
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ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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Dichiarazione di conformità UE

N. documento	**MDR108-043-2302-003-0**
Data	**2023-02-22**
Luogo	**Germany – Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Estensione della valutazione di conformità		
Numero d'ordine	Nome prodotto	UDI-DI di base
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
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MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

CE 0123

ES atbilstības deklarācija

Dokumenta Nr. **MDR108-043-2302-003-0**
Datums **2023-02-22**
Vieta **Germany – Lübeck**
Lappuse **1 / 5**

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

Pilnvarotais pārstāvis: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Vienotais reģistrācijas numurs (VRN): DE-MF-000005329

pilnībā atbildot par to, apliecina, ka

Izstrādājuma nosaukums	Ierīces kategorija	Ierīces klase	UMDNS kods / GMDN kods / EMDN kods
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

atbilst šādiem noteikumiem:

EIROPAS REGULA (ES) 2017/745 par medicīnas ierīcēm. Kvalitātes vadības sistēmas pārbaudi veikusi pilnvarotā iestāde saskaņā ar regulas IX. pielikumu (nodaļas I un III, 4. sadaļa): **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitātes vadības sistēma atbilst arī EN ISO 9001 un EN ISO 13485.

CE 0123

ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-043-2302-003-0**
Datums	**2023-02-22**
Vieta	**Germany – Lübeck**
Lappuse	**2 / 5**

Šī deklarācija ir spēkā izstrādājumiem, kas laisti tirgū no izdošanas datuma. Jebkādi ierīces pārveidojumi, kurus nav atļāvis Dräger, padarīs šo deklarāciju par spēkā neesošu.

Šis ir oriģinālā dokumenta (en/de) tulkojums, tādēļ uz tā nav paraksta.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

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ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-043-2302-003-0**
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Lappuse	**3 / 5**

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

Izstrādājuma nosaukums	**Ierīces kategorija**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Pilnībā vai daļēji piemērotie standarti:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
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EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
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ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-043-2302-003-0**
Datums	**2023-02-22**
Vieta	**Germany – Lübeck**
Lappuse	**4 / 5**

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EN ISO 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
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EN ISO 9360-2:2009 *(ISO 9360-2:2001)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-043-2302-003-0**
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Vieta	**Germany – Lübeck**
Lappuse	**5 / 5**

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

Atbilstības novērtēšanas pagarinājums		
Daļas numurs	Izstrādājuma nosaukums	Pamata UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
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MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
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MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
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ES atitikties deklaracija

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Psl.	**1 / 5**

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

Įgaliotasis atstovas: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Bendrasis registracijos numeris (BRN): DE-MF-000005329

prisiimdami visą atsakomybę pareiškia, kad:

Prietaiso pavadinimas	Prietaiso kategorija	Prietaiso klasė	UMDNS kodas / GMDN kodas / EMDN kodas
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

atitinka šias nuostatas:

EUROPOS PARLAMENTO IR TARYBOS REGLAMENTA (ES) 2017/745 dėl medicinos prietaisų. Notifikuotoji įstaiga, atlikusi kokybės valdymo sistemos patikrinimą pagal reglamento IX priedą (I ir III skyrius bei 4 skirsnį): **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kokybės valdymo sistema taip pat atitinka EN ISO 9001 ir EN ISO 13485 standartus.

CE 0123

ES atitikties deklaracija

Dokumento Nr.	**MDR108-043-2302-003-0**
Data	**2023-02-22**
Vieta	**Germany – Lübeck**
Psl.	**2 / 5**

Ši deklaracija taikoma prietaisams, pateiktiems į rinką jų išleidimo dieną. Atlikus neleistinus „Dräger“ prietaiso keitimus, ši deklaracija taps negaliojanti.

Tai yra originalaus dokumento vertimas (iš anglų / vokiečių k.), todėl nereikia parašo.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

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
VAT no. 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
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Chairman of the Supervisory Board for
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Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
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Psl.	**3 / 5**

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

Prietaiso pavadinimas	**Prietaiso kategorija**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Iš dalies ar visa apimtimi taikyti standartai:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets
EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
EN ISO 23328-1:2008 *(ISO 23328-1:2003)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 1: Salt Test Method to assess Filtration Performance
EN ISO 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
EN ISO 9360-2:2009 *(ISO 9360-2:2001)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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ES atitikties deklaracija

Dokumento Nr.	**MDR108-043-2302-003-0**
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Psl.	**5 / 5**

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

Išsami informacija apie atitikties vertinimą		
Prekės kodas	Prietaiso pavadinimas	Pagrindinis UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

CE 0123

EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-043-2302-003-0**
Dátum	**2023-02-22**
Hely	**Germany – Lübeck**
Oldal	**1 / 5**

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

Meghatalmazott képviselő: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Egyedi regisztrációs szám (SRN): DE-MF-000005329

saját kizárólagos felelősségére kijelenti, hogy a

Termék neve	Készülékkategória	Készülékosztály	UMDNS-kód / GMDN-kód / EMDN-kód
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

megfelel a következő rendelkezéseknek:

AZ EURÓPAI PARLAMENT ÉS A TANÁCS (EU) 2017/745 RENDELETE az orvostechnikai eszközökről. A minőségirányítási rendszer vizsgálatát a bejelentett szervezet az irányelv IX. melléklete (az I. és III. fejezet és a 4. szakasz) szerint végezte: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
A minőségirányítási rendszer megfelel továbbá az EN ISO 9001 és az EN ISO 13485 szabványoknak is.

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EU megfelelőségi nyilatkozat

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Ez a nyilatkozat a kiállítását követően forgalomba hozott termékekre érvényes. A készüléken végzett bármilyen, a Dräger által nem engedélyezett módosítás érvényteleníti a nyilatkozatot.

Ez az eredeti dokumentum (en/de) fordítása, és ezért nem szerepel rajta aláírás.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

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Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Termék neve	**Készülékkategória**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Teljesen vagy részben alkalmazott szabványok:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
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Oldal	**5 / 5**

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

A megfelelőségértékelés meghosszabbítása		
Cikkszám	Termék neve	Alapvető UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
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MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

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EU-verklaring van overeenstemming

Documentnr.	**MDR108-043-2302-003-0**
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Plaats	**Germany – Lübeck**
Pagina	**1 / 5**

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

Gemachtigde: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Enkelvoudig registratienummer (SRN): DE-MF-000005329

verklaart hierbij onder haar volledige eigen verantwoordelijkheid dat

Productnaam	Apparaatcategorie	Apparaatklasse	UMDNS-code / GMDN-code / EMDN-code
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

voldoet aan de volgende bepalingen:

EUROPESE VERORDENING (EU) 2017/745 voor medische hulpmiddelen. De aangemelde instantie heeft het kwaliteitsborgingssysteem onderzocht overeenkomstig Bijlage IX (hoofdstukken I en III en deel 4) van de verordening: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Het kwaliteitsmanagementsysteem voldoet ook aan EN ISO 9001 en EN ISO 13485.

Drägerwerk AG & Co. KGaA
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Deze verklaring geldt voor producten die op de markt zijn gebracht vanaf de datum van afgifte. Elke modificatie van het product waarvoor Dräger geen toestemming heeft gegeven, maakt deze verklaring ongeldig.

Dit is een vertaling van het originele document en benodigt derhalve geen ondertekening.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Productnaam	**Apparaatcategorie**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Volledig of gedeeltelijk toegepaste normen:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
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EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
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EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Reikwijdte van conformiteitsbeoordeling		
Onderdeelnummer	Productnaam	Basis UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

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Deklaracja zgodności UE

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23542 Lübeck
Germany

Upoważniony przedstawiciel: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Pojedynczy numer rejestracyjny (SRN): DE-MF-000005329

deklaruje niniejszym na swoją wyłączną odpowiedzialność, że

Nazwa produktu	Kategoria urządzenia	Klasa urządzenia	Kod UMDNS / Kod GMDN / Kod EMDN
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

spełnia wymogi następujących przepisów:

ROZPORZĄDZENIE PARLAMENTU EUROPEJSKIEGO I RADY (EU) 2017/745 w sprawie wyrobów medycznych. Zostało przeprowadzone badanie systemu zarządzania jakością zgodnie z Załącznikiem IX (rozdziały I i III, sekcja 4) Rozporządzenia przez jednostkę notyfikowaną: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
System zarządzania jakością spełnia też normy EN ISO 9001 i EN ISO 13485.

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
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info@draeger.com
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VAT no. DE135082211

Bank details:
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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
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Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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Deklaracja zgodności UE

Nr dokumentu	**MDR108-043-2302-003-0**
Data	**2023-02-22**
Miejsce	**Germany – Lübeck**
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Niniejsza deklaracja dotyczy produktów wprowadzonych na rynek wg daty wydania. Wszelkie modyfikacje urządzenia niezatwierdzone przez Dräger spowodują utratę ważności niniejszej deklaracji.

Jest to tłumaczenie oryginalnego dokumentu i dlatego nie jest opatrzone podpisem.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

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Nr dokumentu	**MDR108-043-2302-003-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Nazwa produktu	**Kategoria urządzenia**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Zastosowane normy (w całości lub w części):	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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Deklaracja zgodności UE

Nr dokumentu	**MDR108-043-2302-003-0**
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ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets
EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
EN ISO 23328-1:2008 *(ISO 23328-1:2003)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 1: Salt Test Method to assess Filtration Performance
EN ISO 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
EN ISO 9360-2:2009 *(ISO 9360-2:2001)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

CE 0123

Deklaracja zgodności UE

Nr dokumentu	**MDR108-043-2302-003-0**
Data	**2023-02-22**
Miejsce	**Germany – Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Zakres oceny zgodności		
Numer części	Nazwa produktu	Basic UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

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Declaração de conformidade da UE

Nº. do documento	**MDR108-043-2302-003-0**
Data	**2023-02-22**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Mandatário: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

O número de registro único (SRN): DE-MF-000005329

declara, sob exclusiva responsabilidade, que

Nome do produto	Categoria do equipamento	Classe do equipamento	Código UMDNS / Código GMDN / Código EMDN
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

está em conformidade com as seguintes disposições:

REGULAMENTO (UE) 2017/745 relativo aos dispositivos médicos. Um exame do sistema de gerenciamento de qualidade foi realizado seguindo o Anexo IX (Capítulos I e III e a seção 4) do regulamento pelo Órgão notificado: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
O sistema de gerenciamento de qualidade também está em conformidade com a EN ISO 9001 e a EN ISO 13485.

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Declaração de conformidade da UE

Nº. do documento	**MDR108-043-2302-003-0**
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Esta declaração é válida para produtos colocados no mercado a partir da data de emissão. Quaisquer modificações no equipamento não autorizadas pela Dräger invalidarão esta declaração.

Este documento é uma tradução do documento original (en/de) e, portanto, não precisa ser assinado.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

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Nº. do documento	**MDR108-043-2302-003-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Nome do produto	**Categoria do equipamento**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Normas aplicadas total ou parcialmente:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
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EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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Declaração de conformidade da UE

Nº. do documento	**MDR108-043-2302-003-0**
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ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets
EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
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EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
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ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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Declaração de conformidade da UE

Nº. do documento	**MDR108-043-2302-003-0**
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Local	**Germany – Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Extensão da avaliação de conformidade		
Número da peça	Nome do produto	UDI-DI básico
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

Declaraţie de conformitate UE

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

Reprezentant autorizat: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Număr unic de înregistrare (SRN): DE-MF-000005329

declară prin prezenta pe proprie răspundere că

Numele produsului	Categoria dispozitivului	Clasa dispozitivului	Codul UMDNS / Codul GMDN / Codul EMDN
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

îndeplinește următoarele cerințe:

REGULAMENTUL (UE) 2017/745 privind dispozitivele medicale. O analiză a sistemului de management al calităţii a fost efectuată conform Anexei IX (capitolele I şi III şi secţiunea 4) a reglementării Organismului notificat: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sistemul de management al calităţii îndeplineşte de asemenea cerinţele standardelor EN ISO 9001 şi EN ISO 13485.

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Nr. document	**MDR108-043-2302-003-0**
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Această declaraţie are efect pentru produsele puse pe piaţă începând cu data emiterii. Orice modificare a dispozitivului neautorizată de Dräger va anula această declaraţie.

Aceasta este o traducere a documentului original (en/de) şi din această cauză nu necesită o semnătură.

Head of Regulatory Affairs Business Unit Hospital Consumables & Accessories Medical Division	Director Research & Development Business Unit Hospital Consumables & Accessories Medical Division
Holger Wagner	Kalle Heckmann

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

Numele produsului	**Categoria dispozitivului**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Standarde aplicate în totalitate sau parţial:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
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Declaraţie de conformitate UE

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Pagina	**4 / 5**

ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets
EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
EN ISO 23328-1:2008 *(ISO 23328-1:2003)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 1: Salt Test Method to assess Filtration Performance
EN ISO 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
EN ISO 9360-2:2009 *(ISO 9360-2:2001)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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Declaraţie de conformitate UE

Nr. document	**MDR108-043-2302-003-0**
Data	**2023-02-22**
Localitatea	**Germany – Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Evaluarea extinsă a conformităţii		
Cod articol	Numele produsului	UDI-DI de bază
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

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EÚ vyhlásenie o zhode

Dokument č.	**MDR108-043-2302-003-0**
Dátum	**2023-02-22**
Miesto	**Germany – Lübeck**
Strana	**1 / 5**

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

Splnomocnený zástupca: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Jedinečné registračné číslo (SRN): DE-MF-000005329

týmto na vlastnú zodpovednosť vyhlasuje, že

Názov výrobku	Kategória zariadenia	Trieda zariadenia	Kód UMDNS / Kód GMDN / Kód EMDN
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

spĺňa nasledujúce nariadenia:

EURÓPSKE NARIADENIE (EÚ) 2017/745 o zdravotníckych pomôckach. Preskúmanie systému riadenia kvality bolo vykonané notifikovaným orgánom podľa prílohy IX (kapitoly I a III a oddielu 4) nariadenia: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Systém riadenia kvality tiež spĺňa normy STN EN ISO 9001 a STN EN ISO 13485.

CE 0123

EÚ vyhlásenie o zhode

Dokument č.	**MDR108-043-2302-003-0**
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Miesto	**Germany – Lübeck**
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Toto vyhlásenie pre výrobky uvedené na trh nadobúda platnosť dňom vydania. Akékoľvek zmeny zariadenia, ktoré neschválila spoločnosť Dräger, vedú k strate platnosti tohto vyhlásenia.

Toto je preklad pôvodného dokumentu (en/de) a preto na ňom nie je uvedený podpis.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

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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:
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Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
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EÚ vyhlásenie o zhode

Dokument č.	**MDR108-043-2302-003-0**
Dátum	**2023-02-22**
Miesto	**Germany – Lübeck**
Strana	**3 / 5**

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

Názov výrobku	**Kategória zariadenia**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Použité normy v úplnom alebo v čiastočnom znení:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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Dokument č.	**MDR108-043-2302-003-0**
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ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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EÚ vyhlásenie o zhode

Dokument č.	**MDR108-043-2302-003-0**
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Miesto	**Germany – Lübeck**
Strana	**5 / 5**

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

Rozsah posúdenia zhody		
Objednávacie číslo	Názov výrobku	Základné UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
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MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

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Izjava EU o skladnosti

Št. dokumenta	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
Kraj	**Germany – Lübeck**
Stran	**1 / 5**

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

Pooblaščeni predstavnik: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Enotna registrska številka (SRN): DE-MF-000005329

izjavlja z vso odgovornostjo, da

Ime izdelka	Kategorija naprave	Razred naprave	Koda UMDNS / Koda GMDN / Koda EMDN
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

izpolnjuje naslednje določbe:

EVROPSKA UREDBA (EU) 2017/745 o medicinskih pripomočkih. Sistem upravljanja kakovosti je na podlagi Priloge IX (poglavji I in III in razdelek 4) uredbe preveril priglašeni organ: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sistem upravljanja kakovosti je skladen tudi z EN ISO 9001 in EN ISO 13485.

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Izjava EU o skladnosti

Št. dokumenta	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
Kraj	**Germany – Lübeck**
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Ta izjava velja za izdelke, na trg dane z datumom izdaje. Vsaka sprememba naprave brez soglasja družbe Dräger razveljavi to izjavo.

To je prevod originalnega dokumenta (en/de) in zato ni podpisan.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
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Št. dokumenta	**MDR108-043-2302-003-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Ime izdelka	**Kategorija naprave**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
V celoti ali deloma uporabljeni standardi:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
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EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
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Izjava EU o skladnosti

Št. dokumenta	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
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ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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Izjava EU o skladnosti

Št. dokumenta	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
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Stran	**5 / 5**

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

Obseg ugotavljanja skladnosti		
Kataloška številka	Ime izdelka	Basic UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

CE 0123

EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro **MDR108-043-2302-003-0**
Päivämäärä **2023-02-22**
Paikka **Germany – Lübeck**
Sivu **1 / 5**

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

Valtuutetulla edustajalla: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Rekisterinumero: DE-MF-000005329

vakuuttaa täten yksinomaisella vastuullaan, että

Tuotenimi	Laitteen luokitus	Laiteluokka	UMDNS-koodi / GMDN-koodi / EMDN-koodi
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

täyttää seuraavat vaatimukset:

EUROOPAN PARLAMENTIN JA NEUVOSTON ASETUS (EU) 2017/745 lääkinnällisistä laitteista. Laatujärjestelmän on tarkastanut asetuksen liitettä IX (I ja III luvun 4 kohtaa) noudattaen seuraava ilmoitettu laitos: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Laatujärjestelmä täyttää lisäksi standardien EN ISO 9001 ja EN ISO 13485 vaatimukset.

Drägerwerk AG & Co. KGaA
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Dr. Reiner Piske
Anton Schrofner

CE 0123

EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-043-2302-003-0**
Päivämäärä	**2023-02-22**
Paikka	**Germany – Lübeck**
Sivu	**2 / 5**

Tätä vakuutusta sovelletaan tuotteisiin, jotka on saatettu markkinoille antamispäivästä alkaen. Laitteeseen tehtävät muutokset, joita Dräger ei ole hyväksynyt, mitätöivät tämän vakuutuksen.

Tämä on alkuperäisen (saksan-/englanninkielisen) asiakirjan käännös, eikä siinä siksi ole allekirjoitusta.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
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Kalle Heckmann

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-043-2302-003-0**
Päivämäärä	**2023-02-22**
Paikka	**Germany – Lübeck**
Sivu	**3 / 5**

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

Tuotenimi	**Laitteen luokitus**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Kokonaan tai osittain sovellettavat standardit:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro **MDR108-043-2302-003-0**
Päivämäärä **2023-02-22**
Paikka **Germany – Lübeck**

ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets
EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
EN ISO 23328-1:2008 *(ISO 23328-1:2003)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 1: Salt Test Method to assess Filtration Performance
EN ISO 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
EN ISO 9360-2:2009 *(ISO 9360-2:2001)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-043-2302-003-0**
Päivämäärä	**2023-02-22**
Paikka	**Germany – Lübeck**
Sivu	**5 / 5**

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

Vaatimustenmukaisuuden arvioinnin laajuus		
Osanumero	Tuotenimi	Yksilöllinen UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

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EU-försäkran om överensstämmelse

Dokument nr.	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
Plats	**Germany – Lübeck**
Sida	**1 / 5**

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

Auktoriserad representant: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Enkelt registreringsnummer (SRN): DE-MF-000005329

förklarar härmed under sitt eget ansvar att

Produktnamn	Enhetskategori	Enhetsklass	UMDNS-kod / GMDN-kod / EMDN-kod
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

uppfyller följande bestämmelser:

EUROPEISKA FÖRORDNINGEN (EU) 2017/745 om medicintekniska produkter. En undersökning av kvalitetshanteringssystemet har utförts enligt bilaga IX (kapitel I och III och avsnitt 4) till förordningen av det anmälda organet: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitetshanteringssystemet uppfyller även EN ISO 9001 och EN ISO 13485.

Drägerwerk AG & Co. KGaA
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info@draeger.com
www.draeger.com
VAT no. 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

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EU-försäkran om överensstämmelse

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Denna försäkran gäller för produkter som släpps ut på marknaden från och med utgivningsdatum. Alla ändringar av enheten som inte godkänts av Dräger ogiltiggör denna försäkran.

Detta är en översättning av originaldokument (en/de) och därför har det inte någon signatur.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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EU-försäkran om överensstämmelse

Dokument nr.	**MDR108-043-2302-003-0**
Datum	**2023-02-22**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Produktnamn	**Enhetskategori**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Helt eller delvis tillämpade standarder:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
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ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
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Dokument nr.	**MDR108-043-2302-003-0**
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Plats	**Germany – Lübeck**
Sida	**5 / 5**

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

Omfattning bedömning av överensstämmelse		
Artikelnummer	Produktnamn	Bas UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF