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en/de

EU Declaration of Conformity
EU-Konformitätserklärung

CE 0123

Document No. / Dokument Nr.	**MDR108-043-2206-009-0**
Date / Datum	**2022-06-03**
Place / Ort	**Germany - Lübeck**
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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

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

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meets the following provisions:
mit den folgenden Bestimmungen übereinstimmt:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices/ Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rates vom 5. April 2017 über Medizinprodukte
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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

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

Kalle Heckmann

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Bank details:
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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
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Executive Board:
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Drägerwerk AG & Co. KGaA
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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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012)*	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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

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ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
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

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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 №	**MDR108-043-2206-009-0**
Дата	**2022-06-03**
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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:

РЕГЛАМЕНТ (ЕС) 2017/745 НА ЕВРОПЕЙСКИЯ ПАРЛАМЕНТ И НА СЪВЕТА от 5 април 2017 година за медицинските изделия

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ЕС декларация за съответствие

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Системата за управление на качеството също отговаря на EN ISO 9001 и EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

Director
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Business Unit Hospital Consumables & Accessories
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Kalle Heckmann

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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
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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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012*)	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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ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
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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
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
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MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

CE 0123

Declaración UE de conformidad

N.º de documento	**MDR108-043-2206-009-0**
Fecha	**2022-06-03**
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 (UE) 2017/745 DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 5 de abril de 2017 sobre los productos sanitarios

CE 0123

Declaración UE de conformidad

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Página	**2 / 5**

El sistema de gestión de la calidad también cumple con EN ISO 9001 y EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
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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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012)*	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
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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
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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
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

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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

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EU prohlášení o shodě

Č. dokumentu	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
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 ze dne 5. dubna 2017 o zdravotnických prostředcích

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EU prohlášení o shodě

Č. dokumentu	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
Místo	**Germany - Lübeck**
Strana	**2 / 5**

Systém managementu kvality splňuje rovněž požadavky norem EN ISO 9001 a EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

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

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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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:
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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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EU prohlášení o shodě

Č. dokumentu	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012*)	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
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

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EU prohlášení o shodě

Č. dokumentu	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
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

da

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EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-043-2206-009-0**
Dato	**2022-06-03**
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:

EUROPA-PARLAMENTETS OG RÅDETS FORORDNING (EU) 2017/745 af 5. april 2017 om medicinsk udstyr

da

EU-overensstemmelseserklæring

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Dokumentnr.	**MDR108-043-2206-009-0**
Dato	**2022-06-03**
Sted	**Germany - Lübeck**
Side	**2 / 5**

Kvalitetsstyringssystemet overholder ligeledes EN ISO 9001 og EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

Director
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Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

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Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
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Executive Board:
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Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-043-2206-009-0**
Dato	**2022-06-03**
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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012)*	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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.	**MDR108-043-2206-009-0**
Dato	**2022-06-03**
Sted	**Germany - Lübeck**
Side	**4 / 5**

ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
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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
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EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-043-2206-009-0**
Dato	**2022-06-03**
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

et

CE 0123

ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-043-2206-009-0**
Kuupäev	**2022-06-03**
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 PARLAMENDI JA NÕUKOGU MÄÄRUS (EL) 2017/745 5. aprill 2017, milles käsitletakse meditsiiniseadmeid

Drägerwerk AG & Co. KGaA
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Anton Schrofner

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-043-2206-009-0**
Kuupäev	**2022-06-03**
Koht	**Germany - Lübeck**
Lk	**2 / 5**

Kvaliteedikontrolli süsteem vastab ka standarditele EN ISO 9001 ja EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
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Medical Division

Timo Harms

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-043-2206-009-0**
Kuupäev	**2022-06-03**
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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012)*	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-043-2206-009-0**
Kuupäev	**2022-06-03**
Koht	**Germany - Lübeck**
Lk	**4 / 5**

ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
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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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et

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-043-2206-009-0**
Kuupäev	**2022-06-03**
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

Δήλωση συμμόρφωσης ΕΕ

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Αρ. εγγράφου **MDR108-043-2206-009-0**
Ημερομηνία **2022-06-03**
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:

ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2017/745 ΤΟΥ ΕΥΡΩΠΑΪΚΟΥ ΚΟΙΝΟΒΟΥΛΙΟΥ ΚΑΙ ΤΟΥ ΣΥΜΒΟΥΛΙΟΥ της 5ης Απριλίου 2017 για τα ιατροτεχνολογικά προϊόντα

CE 0123

Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-043-2206-009-0**
Ημερομηνία	**2022-06-03**
Τοποθεσία	**Germany - Lübeck**
Σελίδα	**2 / 5**

Το σύστημα διαχείρισης ποιότητας συμμορφώνεται επίσης με τα πρότυπα EN ISO 9001 και EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

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

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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info@draeger.com
www.draeger.com
VAT no. DE135082211

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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	**MDR108-043-2206-009-0**
Ημερομηνία	**2022-06-03**
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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012)*	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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 **MDR108-043-2206-009-0**
Ημερομηνία **2022-06-03**
Τοποθεσία **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

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου **MDR108-043-2206-009-0**
Ημερομηνία **2022-06-03**
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
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
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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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Déclaration de conformité UE

N° du document	**MDR108-043-2206-009-0**
Date	**2022-06-03**
Ville	**Germany - Lübeck**
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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 :

RÈGLEMENT (UE) 2017/745 DU PARLEMENT EUROPÉEN ET DU CONSEIL du 5 avril 2017 relatif aux dispositifs médicaux

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Déclaration de conformité UE

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Le système de gestion de la qualité satisfait également aux normes EN ISO 9001 et EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

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

Kalle Heckmann

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Dr. Reiner Piske
Anton Schrofner

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Déclaration de conformité UE

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Ville	**Germany - Lübeck**
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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 :	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012*)	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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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Déclaration de conformité UE

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Date	**2022-06-03**
Ville	**Germany - Lübeck**
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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
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Déclaration de conformité UE

N° du document	**MDR108-043-2206-009-0**
Date	**2022-06-03**
Ville	**Germany - Lübeck**
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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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MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

hr

CE 0123

EU izjava o sukladnosti

Br. dokumenta	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
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 EUROPSKOG PARLAMENTA I VIJEĆA od 5. travnja 2017. o medicinskim proizvodima

CE 0123

EU izjava o sukladnosti

Br. dokumenta	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
Mjesto	**Germany - Lübeck**
Stranica	**2 / 5**

Sustav upravljanja kvalitetom također je sukladan normama EN ISO 9001 i EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

Director
Research & Development
Business Unit Hospital Consumables & Accessories
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EU izjava o sukladnosti

Br. dokumenta	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012*)	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 80601-2-12:2020 *(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
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ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

CE 0123

EU izjava o sukladnosti

Br. dokumenta	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
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
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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

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EU izjava o sukladnosti

Br. dokumenta	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
Mjesto	**Germany - Lübeck**
Stranica	**5 / 5**

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

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Dichiarazione di conformità UE

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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 (UE) 2017/745 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO del 5 aprile 2017 relativo ai dispositivi medici

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Dichiarazione di conformità UE

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Il sistema di gestione della qualità è altresì conforme alle norme EN ISO 9001 e EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

Director
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Kalle Heckmann

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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

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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Dichiarazione di conformità UE

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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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012)*	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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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Dichiarazione di conformità UE

N. documento	**MDR108-043-2206-009-0**
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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 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
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Dichiarazione di conformità UE

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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
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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ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-043-2206-009-0**
Datums	**2022-06-03**
Vieta	**Germany - Lübeck**
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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 PARLAMENTA UN PADOMES REGULA (ES) 2017/745 (2017. gada 5. aprīlis), kas attiecas uz medicīniskām ierīcēm

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ES atbilstības deklarācija

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Kvalitātes vadības sistēma atbilst arī EN ISO 9001 un EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
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Timo Harms

Director
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Kalle Heckmann

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Executive Board:
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Anton Schrofner

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ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-043-2206-009-0**
Datums	**2022-06-03**
Vieta	**Germany - Lübeck**
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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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012*)	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
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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
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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ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-043-2206-009-0**
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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
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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
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

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ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-043-2206-009-0**
Datums	**2022-06-03**
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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MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

CE 0123

ES atitikties deklaracija

Dokumento Nr.	**MDR108-043-2206-009-0**
Data	**2022-06-03**
Vieta	**Germany - Lübeck**
Psl.	**1 / 5**

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
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 REGLAMENTAS (ES) 2017/745 2017 m. balandžio 5 d. dėl medicinos priemonių

CE 0123

ES atitikties deklaracija

Dokumento Nr.	**MDR108-043-2206-009-0**
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Vieta	**Germany - Lübeck**
Psl.	**2 / 5**

Kokybės valdymo sistema taip pat atitinka EN ISO 9001 ir EN ISO 13485 standartus.

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.

Director
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Medical Division

Timo Harms

Director
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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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012*)	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 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
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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

CE 0123

ES atitikties deklaracija

Dokumento Nr.	**MDR108-043-2206-009-0**
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Vieta	**Germany - Lübeck**
Psl.	**4 / 5**

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
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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
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

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ES atitikties deklaracija

Dokumento Nr.	**MDR108-043-2206-009-0**
Data	**2022-06-03**
Vieta	**Germany - Lübeck**
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

hu

EU megfelelőségi nyilatkozat

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Dokumentum száma	**MDR108-043-2206-009-0**
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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 (2017. április 5.) az orvostechnikai eszközökről

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A minőségirányítási rendszer megfelel továbbá az EN ISO 9001 és az EN ISO 13485 szabványoknak is.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

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
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 megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-043-2206-009-0**
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Hely	**Germany - Lübeck**
Oldal	**3 / 5**

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012)*	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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 megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-043-2206-009-0**
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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

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EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-043-2206-009-0**
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Hely	**Germany - Lübeck**
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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
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-verklaring van overeenstemming

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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:

VERORDENING (EU) 2017/745 VAN HET EUROPEES PARLEMENT EN DE RAAD van 5 april 2017 betreffende medische hulpmiddelen

EU-verklaring van overeenstemming

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Het kwaliteitsmanagementsysteem voldoet ook aan EN ISO 9001 en EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
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Timo Harms

Director
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Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

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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:
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Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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EU-verklaring van overeenstemming

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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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012)*	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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-verklaring van overeenstemming

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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

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EU-verklaring van overeenstemming

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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

pl

Deklaracja zgodności UE

CE 0123

Nr dokumentu	**MDR108-043-2206-009-0**
Data	**2022-06-03**
Miejsce	**Germany - Lübeck**
Strona	**1 / 5**

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
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 (UE) 2017/745 z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych

CE 0123

Deklaracja zgodności UE

Nr dokumentu	**MDR108-043-2206-009-0**
Data	**2022-06-03**
Miejsce	**Germany - Lübeck**
Strona	**2 / 5**

System zarządzania jakością spełnia też normy EN ISO 9001 i EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

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

Kalle Heckmann

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Sparkasse zu Lübeck
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Local court Lübeck HRB 7903 HL
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Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
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Nr dokumentu	**MDR108-043-2206-009-0**
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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):	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012*)	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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

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Miejsce	**Germany - Lübeck**
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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

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Deklaracja zgodności UE

Nr dokumentu	**MDR108-043-2206-009-0**
Data	**2022-06-03**
Miejsce	**Germany - Lübeck**
Strona	**5 / 5**

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	**MDR108-043-2206-009-0**
Data	**2022-06-03**
Local	**Germany - Lübeck**
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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 DO PARLAMENTO EUROPEU E DO CONSELHO de 5 de abril de 2017 relativo aos dispositivos médicos

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Declaração de conformidade da UE

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O sistema de gerenciamento de qualidade também está em conformidade com a EN ISO 9001 e a EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

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

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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www.draeger.com
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
Commercial register:
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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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Declaração de conformidade da UE

Nº. do documento	**MDR108-043-2206-009-0**
Data	**2022-06-03**
Local	**Germany - Lübeck**
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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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012)*	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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	**MDR108-043-2206-009-0**
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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

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Declaração de conformidade da UE

Nº. do documento	**MDR108-043-2206-009-0**
Data	**2022-06-03**
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

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Declaraţie de conformitate UE

CE 0123

Nr. document	**MDR108-043-2206-009-0**
Data	**2022-06-03**
Localitatea	**Germany - Lübeck**
Pagina	**1 / 5**

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 AL PARLAMENTULUI EUROPEAN ȘI AL CONSILIULUI din 5 aprilie 2017 privind dispozitivele medicale

Drägerwerk AG & Co. KGaA
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Executive Board:
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Declaraţie de conformitate UE

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Sistemul de management al calităţii îndeplineşte de asemenea cerinţele standardelor EN ISO 9001 şi EN ISO 13485.

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.

Director Quality & Regulatory Affairs Business Unit Hospital Consumables & Accessories Medical Division	Director Research & Development Business Unit Hospital Consumables & Accessories Medical Division
Timo Harms	Kalle Heckmann

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Declaraţie de conformitate UE

Nr. document	**MDR108-043-2206-009-0**
Data	**2022-06-03**
Localitatea	**Germany - Lübeck**
Pagina	**3 / 5**

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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012)*	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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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Declaraţie de conformitate UE

Nr. document	**MDR108-043-2206-009-0**
Data	**2022-06-03**
Localitatea	**Germany - Lübeck**
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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
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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
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

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Declaraţie de conformitate UE

Nr. document	**MDR108-043-2206-009-0**
Data	**2022-06-03**
Localitatea	**Germany - Lübeck**
Pagina	**5 / 5**

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
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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

CE 0123

Dokument č.	**MDR108-043-2206-009-0**
Dátum	**2022-06-03**
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:

NARIADENIE EURÓPSKEHO PARLAMENTU A RADY (EÚ) 2017/745 z 5. apríla 2017 o zdravotníckych pomôckach

CE 0123

EÚ vyhlásenie o zhode

Dokument č.	**MDR108-043-2206-009-0**
Dátum	**2022-06-03**
Miesto	**Germany - Lübeck**
Strana	**2 / 5**

Systém riadenia kvality tiež spĺňa normy STN EN ISO 9001 a STN EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

Director
Research & Development
Business Unit Hospital Consumables & Accessories
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EÚ vyhlásenie o zhode

Dokument č.	**MDR108-043-2206-009-0**
Dátum	**2022-06-03**
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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012*)	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 1041:2008 + A1 2013	Information supplied by the manufacturer with 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

CE 0123

EÚ vyhlásenie o zhode

Dokument č. **MDR108-043-2206-009-0**
Dátum **2022-06-03**
Miesto **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

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EÚ vyhlásenie o zhode

Dokument č.	**MDR108-043-2206-009-0**
Dátum	**2022-06-03**
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
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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Izjava EU o skladnosti

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Št. dokumenta	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
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:

UREDBA (EU) 2017/745 EVROPSKEGA PARLAMENTA IN SVETA z dne 5. aprila 2017 o medicinskih pripomočkih

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Izjava EU o skladnosti

Št. dokumenta	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
Kraj	**Germany - Lübeck**
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Sistem upravljanja kakovosti je skladen tudi z EN ISO 9001 in EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

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

Kalle Heckmann

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
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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

Izjava EU o skladnosti

Št. dokumenta	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
Kraj	**Germany - Lübeck**
Stran	**3 / 5**

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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012*)	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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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Izjava EU o skladnosti

Št. dokumenta	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
Kraj	**Germany - Lübeck**
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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

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Izjava EU o skladnosti

Št. dokumenta	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
Kraj	**Germany - Lübeck**
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

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-043-2206-009-0**
Päivämäärä	**2022-06-03**
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, annettu 5 päivänä huhtikuuta 2017, lääkinnällisistä laitteista

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-043-2206-009-0**
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Sivu	**2 / 5**

Laatujärjestelmä täyttää lisäksi standardien EN ISO 9001 ja EN ISO 13485 vaatimukset.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

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

Kalle Heckmann

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Swift-Code: NOLADE21SPL

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Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
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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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Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-043-2206-009-0**
Päivämäärä	**2022-06-03**
Paikka	**Germany - Lübeck**
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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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012)*	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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	**MDR108-043-2206-009-0**
Päivämäärä	**2022-06-03**
Paikka	**Germany - Lübeck**
Sivu	**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

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-043-2206-009-0**
Päivämäärä	**2022-06-03**
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

EU-försäkran om överensstämmelse

CE 0123

Dokument nr.	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
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:

EUROPAPARLAMENTETS OCH RÅDETS FÖRORDNING (EU) 2017/745 av den 5 april 2017 om medicintekniska produkter

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EU-försäkran om överensstämmelse

Dokument nr.	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
Plats	**Germany - Lübeck**
Sida	**2 / 5**

Kvalitetshanteringssystemet uppfyller även EN ISO 9001 och EN ISO 13485.

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.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

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

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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Tel +49 451 882-0
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info@draeger.com
www.draeger.com
VAT no. DE135082211

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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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Commercial register:
Local court Lübeck HRB 7395 HL

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Executive Board:
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Dr. Reiner Piske
Anton Schrofner

CE 0123

EU-försäkran om överensstämmelse

Dokument nr.	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
Plats	**Germany - Lübeck**
Sida	**3 / 5**

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:	
EN 60601-1:2006/A1:2013 *(IEC 60601-1:2005 +A1:2012*)	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 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016+COR:2017 *(ISO 15223-1:2016 COR)*	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

CE 0123

EU-försäkran om överensstämmelse

Dokument nr.	**MDR108-043-2206-009-0**
Datum	**2022-06-03**
Plats	**Germany - Lübeck**
Sida	**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

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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