Document Release Sign-Off Page

Additional Information
The release contains a system generated 'Document Release Sign-Off Page' and the content of the 'Record'. The page numbers of the 'Document Release Sign-Off Page' are indicated in roman numerals and of the 'Record' in numeric numbers.

Affected Document Items			
Number	**Revision**	**Title**	**State**
11339270	00	MDR108-048-2406-012-0 VentStar Resus	Released

Document Review Signature Information				
Meaning of e-Signature	**Name (First- and Last Name)**	**User ID**	**Date/ Time (UTC, 24h)**	**Function**
Author	Jan Upmeier	upmeierj	2024-06-18 12:57:48	/
Reviewer	Kalle Jens Heckmann	heckmaka	2024-06-18 13:46:51	/
Reviewer	Holger Wagner	wagnehol	2024-06-18 14:01:12	/

EU Declaration of Conformity
EU-Konformitätserklärung

CE 0123

Document No. / Dokument Nr.	**MDR108-048-2406-012-0**
Date / Datum	**2024-06-18**
Place / Ort	**Germany - Lübeck**
Page / Seite	**1 / 4**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

meets the following provisions:
mit den folgenden Bestimmungen übereinstimmt:

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

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

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

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

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment/

Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten

EU Declaration of Conformity
EU-Konformitätserklärung

CE 0123

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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 the Document Release Sign-Off Page on page 1./
Für die Unterschrift im Namen von Dräger siehe "Document Release Sign-Off Page" auf Seite 1.

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

Holger Wagner

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

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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Sparkasse zu Lübeck
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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

EU Declaration of Conformity
EU-Konformitätserklärung

CE 0123

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

Product Name / Produktbezeichnung	**Device Category / Produktkategorie**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Applied Standards in full or in part / Vollständig oder teilweise angewendete Normen:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process

CE 0123

EU Declaration of Conformity
EU-Konformitätserklärung

Document No. / Dokument Nr.	**MDR108-048-2406-012-0**
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Product Name / Produktbezeichnung	**Device Category / Produktkategorie**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

CE 0123

ЕС декларация за съответствие

Документ №	**MDR108-048-2406-012-0**
Дата	**2024-06-18**
Място	**Germany - Lübeck**
Страница	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

отговаря на следните разпоредби:

ЕВРОПЕЙСКИ РЕГЛАМЕНТ (ЕС) 2017/745 относно медицински изделия. Извършено е проучване на системата за управление на качеството в съответствие с анекс IX (глави I и III и раздел 4) на регламента от нотифицирания орган: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Системата за управление на качеството също отговаря на EN ISO 9001 и EN ISO 13485.
ДИРЕКТИВА 2011/65/ЕС НА ЕВРОПЕЙСКИЯ ПАРЛАМЕНТ И НА СЪВЕТА от 8 юни 2011 година относно ограничението за употребата на определени опасни вещества в електрическото и електронното оборудване

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

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

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

Holger Wagner

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

Kalle Heckmann

CE 0123

ЕС декларация за съответствие

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

Име на продукта	**Категория на уреда**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Напълно или частично приложени стандарти:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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ЕС декларация за съответствие

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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
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

CE 0123

Declaración UE de conformidad

N.º de documento	**MDR108-048-2406-012-0**
Fecha	**2024-06-18**
Lugar	**Germany - Lübeck**
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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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

cumple las siguientes disposiciones:

REGLAMENTO EUROPEO (UE) 2017/745 sobre los productos sanitarios. Se ha efectuado un examen del sistema de gestión de la calidad siguiendo el anexo IX (capítulos I y III y sección 4) del reglamento del organismo notificado: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
El sistema de gestión de la calidad también cumple con EN ISO 9001 y EN ISO 13485.
DIRECTIVA 2011/65/UE DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos

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

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

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

Holger Wagner

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

Kalle Heckmann

CE 0123

Declaración UE de conformidad

N.º de documento	**MDR108-048-2406-012-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Nombre del producto	**Categoría del dispositivo**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Normas aplicadas total o parcialmente:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

CE 0123

Declaración UE de conformidad

N.º de documento	**MDR108-048-2406-012-0**
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Lugar	**Germany - Lübeck**
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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
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

CE 0123

EU prohlášení o shodě

Č. dokumentu	**MDR108-048-2406-012-0**
Datum	**2024-06-18**
Místo	**Germany - Lübeck**
Strana	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

splňuje následující ustanovení:

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY (EU) 2017/745 o zdravotnických prostředcích. Kontrola systému managementu kvality byla provedena oznámeným subjektem podle přílohy IX (kapitol I a III a oddílu 4) nařízení: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Systém managementu kvality splňuje rovněž požadavky norem EN ISO 9001 a EN ISO 13485.
SMĚRNICE EVROPSKÉHO PARLAMENTU A RADY 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních

Toto prohlášení nabývá platnosti pro produkty uvedené na trh ke dni vydání. Jakákoli úprava prostředku, která není schválena společností Dräger, toto prohlášení zneplatní.

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

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

Holger Wagner

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

Kalle Heckmann

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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

EU prohlášení o shodě

Č. dokumentu	**MDR108-048-2406-012-0**
Datum	**2024-06-18**
Místo	**Germany - Lübeck**
Strana	**2 / 3**

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

Název produktu	**Kategorie prostředku**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Použité normy, v celku nebo z části:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
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EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

CE 0123

EU prohlášení o shodě

Č. dokumentu	**MDR108-048-2406-012-0**
Datum	**2024-06-18**
Místo	**Germany - Lübeck**
Strana	**3 / 3**

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

Rozsah posuzování shody		
Číslo dílu	Název produktu	Základní UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

da

EU-overensstemmelseserklæring

CE 0123

Dokumentnr.	**MDR108-048-2406-012-0**
Dato	**2024-06-18**
Sted	**Germany - Lübeck**
Side	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

opfylder følgende bestemmelser:

EUROPÆISK FORORDNING (EU) 2017/745 om medicinsk udstyr. En undersøgelse af kvalitetsstyringssystemet er blevet foretaget i overensstemmelse med bilag IX (kapitel I og III og afsnit 4) til forordningen af det bemyndigede organ: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitetsstyringssystemet overholder ligeledes EN ISO 9001 og EN ISO 13485.
EUROPA-PARLAMENTETS OG RÅDETS DIREKTIV 2011/65/EU af 8. juni 2011 om begrænsning af anvendelsen af visse farlige stoffer i elektrisk og elektronisk udstyr

Denne erklæring gælder for produkter, der markedsføres efter udstedelsesdatoen. Ved enhver ændring af udstyret, der ikke er godkendt af Dräger, mister denne erklæring sin gyldighed.

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

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

Holger Wagner

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

Kalle Heckmann

CE 0123

EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-048-2406-012-0**
Dato	**2024-06-18**
Sted	**Germany - Lübeck**
Side	**2 / 3**

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

Produktnavn	**Apparatkategori**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Standarder, der anvendes helt eller delvist:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-048-2406-012-0**
Dato	**2024-06-18**
Sted	**Germany - Lübeck**
Side	**3 / 3**

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

Overensstemmelsesvurderingens omfang		
Varenummer	Produktnavn	Basic UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

et

CE 0123

ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-048-2406-012-0**
Kuupäev	**2024-06-18**
Koht	**Germany - Lübeck**
Lk	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

vastab järgmistele nõuetele:

EUROOPA MÄÄRUS (EL) 2017/745 meditsiiniseadmete kohta. Kvaliteedijuhtimise süsteemi on hinnatud teavitatud asutuses määruse IX lisa (peatükid I ja III ning jaotis 4) alusel: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvaliteedikontrolli süsteem vastab ka standarditele EN ISO 9001 ja EN ISO 13485.
EUROOPA PARLAMENDI JA NÕUKOGU DIREKTIIV 2011/65/EL, 8. juuni 2011, teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes

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

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

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

Holger Wagner

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

Kalle Heckmann

CE 0123

ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-048-2406-012-0**
Kuupäev	**2024-06-18**
Koht	**Germany - Lübeck**
Lk	**2 / 3**

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

Toote nimi	**Seadme kategooria**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Osaliselt või täielikult kohaldatud standardid:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
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EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
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EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-048-2406-012-0**
Kuupäev	**2024-06-18**
Koht	**Germany - Lübeck**
Lk	**3 / 3**

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

Vastavushinnangu ulatus		
Osa number	Toote nimi	Peamine UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-048-2406-012-0**
Ημερομηνία	**2024-06-18**
Τοποθεσία	**Germany - Lübeck**
Σελίδα	**1 / 4**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

συμμορφώνεται με τις ακόλουθες διατάξεις:

Ευρωπαϊκός κανονισμός (ΕΕ) 2017/745 περί ιατροτεχνολογικών προϊόντων. Πραγματοποιήθηκε έλεγχος του συστήματος διαχείρισης ποιότητας σύμφωνα με το παράρτημα IX (κεφάλαια I και III και ενότητα 4) του κανονισμού από τον κοινοποιημένο οργανισμό: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Το σύστημα διαχείρισης ποιότητας συμμορφώνεται επίσης με τα πρότυπα EN ISO 9001 και EN ISO 13485.
ΟΔΗΓΙΑ 2011/65/ΕΕ ΤΟΥ ΕΥΡΩΠΑΪΚΟΥ ΚΟΙΝΟΒΟΥΛΙΟΥ ΚΑΙ ΤΟΥ ΣΥΜΒΟΥΛΙΟΥ της 8ης Ιουνίου 2011 για τον περιορισμό της χρήσης ορισμένων επικίνδυνων ουσιών σε ηλεκτρικό και ηλεκτρονικό εξοπλισμό

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.

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-048-2406-012-0**
Ημερομηνία	**2024-06-18**
Τοποθεσία	**Germany - Lübeck**
Σελίδα	**2 / 4**

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

Holger Wagner

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

Kalle Heckmann

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
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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

Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου **MDR108-048-2406-012-0**
Ημερομηνία **2024-06-18**
Τοποθεσία **Germany - Lübeck**
Σελίδα **3 / 4**

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

Όνομα προϊόντος	**Κατηγορία συσκευής**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Πρότυπα που εφαρμόζονται πλήρως ή εν μέρει:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

CE 0123

Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-048-2406-012-0**
Ημερομηνία	**2024-06-18**
Τοποθεσία	**Germany - Lübeck**
Σελίδα	**4 / 4**

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

Επέκταση αξιολόγησης της συμμόρφωσης		
Αριθμός εξαρτήματος	Όνομα προϊόντος	Βασικό UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

CE 0123

Déclaration de conformité UE

N° du document	**MDR108-048-2406-012-0**
Date	**2024-06-18**
Ville	**Germany - Lübeck**
Page	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

satisfait aux dispositions suivantes :

RÉGLEMENTATION EUROPÉENNE (UE) 2017/745 sur les dispositifs médicaux. Une vérification du système de gestion de la qualité a été réalisée conformément à l'annexe IX (chapitres I et III, ainsi que section 4) de la réglementation suivante par l'organisme notifié : **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Le système de gestion de la qualité satisfait également aux normes EN ISO 9001 et EN ISO 13485.
DIRECTIVE 2011/65/UE DU PARLEMENT EUROPÉEN ET DU CONSEIL du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques

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

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

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

Holger Wagner

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

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
Tel +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
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IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

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

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Déclaration de conformité UE

N° du document	**MDR108-048-2406-012-0**
Date	**2024-06-18**
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**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Normes appliquées en totalité ou en partie :	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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Déclaration de conformité UE

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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
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

CE 0123

EU izjava o sukladnosti

Br. dokumenta	**MDR108-048-2406-012-0**
Datum	**2024-06-18**
Mjesto	**Germany - Lübeck**
Stranica	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

sukladan sa sljedećim odredbama:

UREDBA (EU) 2017/745 o medicinskim proizvodima. Ocjena sustava upravljanja kvalitetom provedena je prema Prilogu IX. (poglavlju I. i III. i stavku 4.) uredbe od strane prijavljenog tijela: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sustav upravljanja kvalitetom također je sukladan normama EN ISO 9001 i EN ISO 13485.
DIREKTIVA 2011/65/EU EUROPSKOG PARLAMENTA I VIJEĆA od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi

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

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

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

Holger Wagner

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

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EU izjava o sukladnosti

Br. dokumenta	**MDR108-048-2406-012-0**
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Mjesto	**Germany - Lübeck**
Stranica	**2 / 3**

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

Naziv proizvoda	**Kategorija proizvoda**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Norme primijenjene u cijelosti ili djelomično:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

CE 0123

EU izjava o sukladnosti

Br. dokumenta	**MDR108-048-2406-012-0**
Datum	**2024-06-18**
Mjesto	**Germany - Lübeck**
Stranica	**3 / 3**

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

Opseg ocjene sukladnosti		
Broj dijela	Naziv proizvoda	Osnovni UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

CE 0123

Dichiarazione di conformità UE

N. documento	**MDR108-048-2406-012-0**
Data	**2024-06-18**
Luogo	**Germany - Lübeck**
Pagina	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

è conforme alle seguenti disposizioni:

REGOLAMENTO EUROPEO (UE) 2017/745 relativo ai dispositivi medici. È stata effettuata una verifica del sistema di gestione della qualità ai sensi dell'allegato IX (capitoli I e III e sezione 4) del regolamento dell'organismo notificato: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Il sistema di gestione della qualità è altresì conforme alle norme EN ISO 9001 e EN ISO 13485.
DIRETTIVA 2011/65/UE DEL PARLAMENTO EUROPEO E DEL CONSIGLIO dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche

La presente dichiarazione è valevole per i prodotti lanciati sul mercato a partire dalla data di pubblicazione. Qualsiasi modifica del dispositivo non autorizzata da Dräger invalida la presente dichiarazione.

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

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

Holger Wagner

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

Kalle Heckmann

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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Dichiarazione di conformità UE

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

Nome prodotto	**Categoria dispositivo**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Standard applicati integralmente o parzialmente:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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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
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

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ES atbilstības deklarācija

Dokumenta Nr. **MDR108-048-2406-012-0**
Datums **2024-06-18**
Vieta **Germany - Lübeck**
Lappuse **1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

atbilst šādiem noteikumiem:

EIROPAS REGULA (ES) 2017/745 par medicīnas ierīcēm. Kvalitātes vadības sistēmas pārbaudi veikusi pilnvarotā iestāde saskaņā ar regulas IX. pielikumu (nodaļas I un III, 4. sadaļa): **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitātes vadības sistēma atbilst arī EN ISO 9001 un EN ISO 13485.
EIROPAS PARLAMENTA UN PADOMES DIREKTĪVA 2011/65/ES (2011. gada 8. jūnijs) par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās

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

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

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

Holger Wagner

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Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

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Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
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Stefan Lauer
Executive Board:
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ES atbilstības deklarācija

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

Izstrādājuma nosaukums	**Ierīces kategorija**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Pilnībā vai daļēji piemērotie standarti:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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ES atbilstības deklarācija

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

Atbilstības novērtēšanas pagarinājums		
Daļas numurs	Izstrādājuma nosaukums	Pamata UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

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ES atitikties deklaracija

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Dokumento Nr.	**MDR108-048-2406-012-0**
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Vieta	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
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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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

atitinka šias nuostatas:

EUROPOS PARLAMENTO IR TARYBOS REGLAMENTA (ES) 2017/745 dėl medicinos prietaisų. Notifikuotoji įstaiga, atlikusi kokybės valdymo sistemos patikrinimą pagal reglamento IX priedą (I ir III skyrius bei 4 skirsnį): **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kokybės valdymo sistema taip pat atitinka EN ISO 9001 ir EN ISO 13485 standartus.
EUROPOS PARLAMENTO IR TARYBOS DIREKTYVA 2011/65/ES 2011 m. birželio 8 d. dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo

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

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

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

Holger Wagner

Director
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Business Unit Hospital Consumables & Accessories
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Kalle Heckmann

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ES atitikties deklaracija

Dokumento Nr.	**MDR108-048-2406-012-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Prietaiso pavadinimas	**Prietaiso kategorija**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Iš dalies ar visa apimtimi taikyti standartai:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

CE 0123

ES atitikties deklaracija

Dokumento Nr.	**MDR108-048-2406-012-0**
Data	**2024-06-18**
Vieta	**Germany - Lübeck**
Psl.	**3 / 3**

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

Išsami informacija apie atitikties vertinimą		
Prekės kodas	Prietaiso pavadinimas	Pagrindinis UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

CE 0123

EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-048-2406-012-0**
Dátum	**2024-06-18**
Hely	**Germany - Lübeck**
Oldal	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

megfelel a következő rendelkezéseknek:

AZ EURÓPAI PARLAMENT ÉS A TANÁCS (EU) 2017/745 RENDELETE az orvostechnikai eszközökről. A minőségirányítási rendszer vizsgálatát a bejelentett szervezet az irányelv IX. melléklete (az I. és III. fejezet és a 4. szakasz) szerint végezte: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
A minőségirányítási rendszer megfelel továbbá az EN ISO 9001 és az EN ISO 13485 szabványoknak is.
AZ EURÓPAI PARLAMENT ÉS A TANÁCS 2011/65/EU IRÁNYELVE (2011. június 8.) egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról

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

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

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

Holger Wagner

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

Kalle Heckmann

CE 0123

EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-048-2406-012-0**
Dátum	**2024-06-18**
Hely	**Germany - Lübeck**
Oldal	**2 / 3**

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

Termék neve	**Készülékkategória**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Teljesen vagy részben alkalmazott szabványok:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
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EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
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EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

CE 0123

EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-048-2406-012-0**
Dátum	**2024-06-18**
Hely	**Germany - Lübeck**
Oldal	**3 / 3**

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

A megfelelőségértékelés meghosszabbítása		
Cikkszám	Termék neve	Alapvető UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

EU-verklaring van overeenstemming

CE 0123

Documentnr.	**MDR108-048-2406-012-0**
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Plaats	**Germany - Lübeck**
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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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

voldoet aan de volgende bepalingen:

EUROPESE VERORDENING (EU) 2017/745 voor medische hulpmiddelen. De aangemelde instantie heeft het kwaliteitsborgingssysteem onderzocht overeenkomstig Bijlage IX (hoofdstukken I en III en deel 4) van de verordening: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Het kwaliteitsmanagementsysteem voldoet ook aan EN ISO 9001 en EN ISO 13485.
RICHTLIJN 2011/65/EU VAN HET EUROPEES PARLEMENT EN DE RAAD van 8 juni 2011 betreffende beperking van het gebruik van bepaalde gevaarlijke stoffen in elektrische en elektronische apparatuur.

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.

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EU-verklaring van overeenstemming

Documentnr.	**MDR108-048-2406-012-0**
Datum	**2024-06-18**
Plaats	**Germany - Lübeck**
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Registered office: Lübeck
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General partner: Drägerwerk
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Chairman of the Supervisory Board for
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Anton Schrofner

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EU-verklaring van overeenstemming

Documentnr.	**MDR108-048-2406-012-0**
Datum	**2024-06-18**
Plaats	**Germany - Lübeck**
Pagina	**3 / 4**

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

Productnaam	**Apparaatcategorie**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Volledig of gedeeltelijk toegepaste normen:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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EU-verklaring van overeenstemming

Documentnr.	**MDR108-048-2406-012-0**
Datum	**2024-06-18**
Plaats	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Reikwijdte van conformiteitsbeoordeling		
Onderdeelnummer	Productnaam	Basis UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

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CE 0123

Deklaracja zgodności UE

Nr dokumentu	**MDR108-048-2406-012-0**
Data	**2024-06-18**
Miejsce	**Germany - Lübeck**
Strona	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

spełnia wymogi następujących przepisów:

ROZPORZĄDZENIE PARLAMENTU EUROPEJSKIEGO I RADY (EU) 2017/745 w sprawie wyrobów medycznych. Zostało przeprowadzone badanie systemu zarządzania jakością zgodnie z Załącznikiem IX (rozdziały I i III, sekcja 4) Rozporządzenia przez jednostkę notyfikowaną: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
System zarządzania jakością spełnia też normy EN ISO 9001 i EN ISO 13485.
DYREKTYWA PARLAMENTU EUROPEJSKIEGO I RADY 2011/65/UE z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym

Niniejsza deklaracja dotyczy produktów wprowadzonych na rynek wg daty wydania. Wszelkie modyfikacje urządzenia niezatwierdzone przez Dräger spowodują utratę ważności niniejszej deklaracji.

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

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

Holger Wagner

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

Kalle Heckmann

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Deklaracja zgodności UE

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Miejsce	**Germany - Lübeck**
Strona	**2 / 3**

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

Nazwa produktu	**Kategoria urządzenia**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Zastosowane normy (w całości lub w części):	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
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EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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Deklaracja zgodności UE

Nr dokumentu	**MDR108-048-2406-012-0**
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Miejsce	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Zakres oceny zgodności		
Numer części	Nazwa produktu	Basic UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

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Declaração de conformidade da UE

Nº. do documento	**MDR108-048-2406-012-0**
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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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

está em conformidade com as seguintes disposições:

REGULAMENTO (UE) 2017/745 relativo aos dispositivos médicos. Um exame do sistema de gerenciamento de qualidade foi realizado seguindo o Anexo IX (Capítulos I e III e a seção 4) do regulamento pelo Órgão notificado: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
O sistema de gerenciamento de qualidade também está em conformidade com a EN ISO 9001 e a EN ISO 13485.
DIRETIVA 2011/65/UE DO PARLAMENTO EUROPEU E DO CONSELHO de 8 de junho de 2011 relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrônicos

Esta declaração é válida para produtos colocados no mercado a partir da data de emissão. Quaisquer modificações no equipamento não autorizadas pela Dräger invalidarão esta declaração.

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

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

Holger Wagner

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Declaração de conformidade da UE

Nº. do documento	**MDR108-048-2406-012-0**
Data	**2024-06-18**
Local	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Nome do produto	**Categoria do equipamento**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Normas aplicadas total ou parcialmente:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
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EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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Declaração de conformidade da UE

Nº. do documento	**MDR108-048-2406-012-0**
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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
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

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Declaraţie de conformitate UE

CE 0123

Nr. document	**MDR108-048-2406-012-0**
Data	**2024-06-18**
Localitatea	**Germany - Lübeck**
Pagina	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

îndeplinește următoarele cerințe:

REGULAMENTUL (UE) 2017/745 privind dispozitivele medicale. O analiză a sistemului de management al calităţii a fost efectuată conform Anexei IX (capitolele I şi III şi secţiunea 4) a reglementării Organismului notificat: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sistemul de management al calităţii îndeplineşte de asemenea cerinţele standardelor EN ISO 9001 şi EN ISO 13485.
DIRECTIVA 2011/65/UE A PARLAMENTULUI EUROPEAN ȘI A CONSILIULUI din 8 iunie 2011 privind restricțiile de utilizare a anumitor substanțe periculoase în echipamentele electrice și electronice

Această declaraţie are efect pentru produsele puse pe piaţă începând cu data emiterii. Orice modificare a dispozitivului neautorizată de Dräger va anula această declaraţie.

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

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

Holger Wagner

Director
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Declaţie de conformitate UE

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

Numele produsului	**Categoria dispozitivului**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Standarde aplicate în totalitate sau parţial:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
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Declaraţie de conformitate UE

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Drägerwerk AG & Co. KGaA
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Evaluarea extinsă a conformităţii		
Cod articol	Numele produsului	UDI-DI de bază
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

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EÚ vyhlásenie o zhode

Dokument č.	**MDR108-048-2406-012-0**
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Strana	**1 / 3**

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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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

spĺňa nasledujúce nariadenia:

EURÓPSKE NARIADENIE (EÚ) 2017/745 o zdravotníckych pomôckach. Preskúmanie systému riadenia kvality bolo vykonané notifikovaným orgánom podľa prílohy IX (kapitoly I a III a oddielu 4) nariadenia: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Systém riadenia kvality tiež spĺňa normy STN EN ISO 9001 a STN EN ISO 13485.
SMERNICA EURÓPSKEHO PARLAMENTU A RADY 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach

Toto vyhlásenie pre výrobky uvedené na trh nadobúda platnosť dňom vydania. Akékoľvek zmeny zariadenia, ktoré neschválila spoločnosť Dräger, vedú k strate platnosti tohto vyhlásenia.

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

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

Holger Wagner

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EÚ vyhlásenie o zhode

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Strana	**2 / 3**

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

Názov výrobku	**Kategória zariadenia**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Použité normy v úplnom alebo v čiastočnom znení:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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EÚ vyhlásenie o zhode

Dokument č.	**MDR108-048-2406-012-0**
Dátum	**2024-06-18**
Miesto	**Germany - Lübeck**
Strana	**3 / 3**

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

Rozsah posúdenia zhody		
Objednávacie číslo	Názov výrobku	Základné UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

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Izjava EU o skladnosti

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Št. dokumenta	**MDR108-048-2406-012-0**
Datum	**2024-06-18**
Kraj	**Germany - Lübeck**
Stran	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

izpolnjuje naslednje določbe:

EVROPSKA UREDBA (EU) 2017/745 o medicinskih pripomočkih. Sistem upravljanja kakovosti je na podlagi Priloge IX (poglavji I in III in razdelek 4) uredbe preveril priglašeni organ: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sistem upravljanja kakovosti je skladen tudi z EN ISO 9001 in EN ISO 13485.
DIREKTIVA 2011/65/EU EVROPSKEGA PARLAMENTA IN SVETA z dne 8. junija 2011 o omejevanju uporabe nekaterih nevarnih snovi v električni in elektronski opremi

Ta izjava velja za izdelke, na trg dane z datumom izdaje. Vsaka sprememba naprave brez soglasja družbe Dräger razveljavi to izjavo.

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

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

Holger Wagner

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

Kalle Heckmann

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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:
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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Izjava EU o skladnosti

Št. dokumenta	**MDR108-048-2406-012-0**
Datum	**2024-06-18**
Kraj	**Germany - Lübeck**
Stran	**2 / 3**

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

Ime izdelka	**Kategorija naprave**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
V celoti ali deloma uporabljeni standardi:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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Izjava EU o skladnosti

Št. dokumenta	**MDR108-048-2406-012-0**
Datum	**2024-06-18**
Kraj	**Germany - Lübeck**
Stran	**3 / 3**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Obseg ugotavljanja skladnosti		
Kataloška številka	Ime izdelka	Basic UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-048-2406-012-0**
Päivämäärä	**2024-06-18**
Paikka	**Germany - Lübeck**
Sivu	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

täyttää seuraavat vaatimukset:

EUROOPAN PARLAMENTIN JA NEUVOSTON ASETUS (EU) 2017/745 lääkinnällisistä laitteista. Laatujärjestelmän on tarkastanut asetuksen liitettä IX (I ja III luvun 4 kohtaa) noudattaen seuraava ilmoitettu laitos: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Laatujärjestelmä täyttää lisäksi standardien EN ISO 9001 ja EN ISO 13485 vaatimukset.
EUROOPAN PARLAMENTIN JA NEUVOSTON DIREKTIIVI 2011/65/EU, annettu 8 päivänä kesäkuuta 2011, tiettyjen vaarallisten aineiden käytön rajoittamisesta sähkö- ja elektroniikkalaitteissa

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

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

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

Holger Wagner

Director
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Kalle Heckmann

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VAT no. DE135082211

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
Registered office: Lübeck
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Dr. Reiner Piske
Anton Schrofner

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-048-2406-012-0**
Päivämäärä	**2024-06-18**
Paikka	**Germany - Lübeck**
Sivu	**2 / 3**

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

Tuotenimi	**Laitteen luokitus**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Kokonaan tai osittain sovellettavat standardit:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010 AMD 1 2013 A2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices -Application of risk management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices -Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-1:2020 (ISO 18562-1:2017-03)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -Part 1: Evaluation and testing within a risk management Process
EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-048-2406-012-0**
Päivämäärä	**2024-06-18**
Paikka	**Germany - Lübeck**
Sivu	**3 / 3**

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

Vaatimustenmukaisuuden arvioinnin laajuus		
Osanumero	Tuotenimi	Yksilöllinen UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**

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EU-försäkran om överensstämmelse

Dokument nr.	**MDR108-048-2406-012-0**
Datum	**2024-06-18**
Plats	**Germany - Lübeck**
Sida	**1 / 3**

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
VentStar breathing circuits for resuscitation	Ventilator breathing circuit, single-use	IIb	UMDNS 14-238/ GMDN 37706/ EMDN R020107

uppfyller följande bestämmelser:

EUROPEISKA FÖRORDNINGEN (EU) 2017/745 om medicintekniska produkter. En undersökning av kvalitetshanteringssystemet har utförts enligt bilaga IX (kapitel I och III och avsnitt 4) till förordningen av det anmälda organet: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitetshanteringssystemet uppfyller även EN ISO 9001 och EN ISO 13485.
EUROPAPARLAMENTETS OCH RÅDETS DIREKTIV 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning

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

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

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

Holger Wagner

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

Kalle Heckmann

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Commerzbank AG, Lübeck
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EU-försäkran om överensstämmelse

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Plats	**Germany - Lübeck**
Sida	**2 / 3**

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

Produktnamn	**Enhetskategori**
VentStar breathing circuits for resuscitation	**Ventilator breathing circuit, single-use**
Helt eller delvis tillämpade standarder:	
EN ISO 13485:2016+AC 2018+A11:2021 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1: 2006+A1:2013+A12:2014 +A2:2021 (IEC 60601-1:2005+A1:2012+COR1 2014 +A2:2020)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 (IEC 60601-1-1:2014+A1:2020)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
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EN ISO 80601-2-74:2021 (ISO 80601-2-74:2021)	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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EU-försäkran om överensstämmelse

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Sida	**3 / 3**

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

Omfattning bedömning av överensstämmelse		
Artikelnummer	Produktnamn	Bas UDI-DI
MP17030	**VentStar Resus heated (N)**	**040486751308048XK19Z000L7**
MP17031	**VentStar AutoBreath heated (N)**	**040486751308048XK19X010KU**