en/de

EU Declaration of Conformity
EU-Konformitätserklärung

CE 0123

Document No. / Dokument Nr.	**MDR108-030-2212-028-0**
Date / Datum	**2022-12-01**
Place / Ort	**Germany - Lübeck**
Page / Seite	**1 / 5**

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

Authorised representative / Europäischer Bevollmächtigter: N/A

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

Single registration number (SRN)/ einmalige Registrierungsnummer: DE-MF-00005329

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
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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.

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

Timo Harms

Drägerwerk AG & Co. KGaA
Dräger
Regulatory Affairs
D-23542 Lübeck

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

Kalle Heckmann

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
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Fax +49 451 882-2080
info@draeger.com
www.draeger.com
VAT no. DE135082211

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IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

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

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

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

Product Name / Produktbezeichnung	**Device Category / Produktkategorie**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Applied Standards in full or in part / Vollständig oder teilweise angewendete Normen:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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EU Declaration of Conformity
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Extend of conformity assessment / Umfang der Konformitätsbewertung		
Part Number / Sachnummer	Product Name / Produktbezeichnung	Basic UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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CE 0123

ЕС декларация за съответствие

Документ №	**MDR108-030-2212-028-0**
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Място	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Упълномощен представител: N/A

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

Еднократен регистрационен номер (SRN): DE-MF-00005329

с настоящото декларира на своя отговорност, че

Име на продукта	Категория на уреда	Клас на уреда	Код UMDNS / Код GMDN / Код EMDN
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

bg

CE 0123

ЕС декларация за съответствие

Документ №	**MDR108-030-2212-028-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Име на продукта	**Категория на уреда**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Напълно или частично приложени стандарти:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
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ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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ЕС декларация за съответствие

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ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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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
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

es

Declaración UE de conformidad

CE 0123

N.º de documento	**MDR108-030-2212-028-0**
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N/A

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

Representante autorizado:

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

Número de registro único (SRN): DE-MF-00005329

por la presente declara bajo su exclusiva responsabilidad que

Nombre del producto	Categoría del dispositivo	Clase del dispositivo	Código UMDNS / Código GMDN / Código EMDN
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

es

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Declaración UE de conformidad

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

Nombre del producto	**Categoría del dispositivo**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Normas aplicadas total o parcialmente:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
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ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

es

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Declaración UE de conformidad

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ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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Declaración UE de conformidad

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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
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

cs

CE 0123

EU prohlášení o shodě

Č. dokumentu	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Místo	**Germany - Lübeck**
Strana	**1 / 4**

N/A

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

Zplnomocněným zástupcem:

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

Jednorázové registračních číslo (SRN): DE-MF-00005329

tímto prohlašuje na svou výhradní zodpovědnost, že

Název produktu	Kategorie prostředku	Třída prostředku	Kód UMDNS / Kód GMDN / Kód EMDN
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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23558 Lübeck, Germany
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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

cs

CE 0123

EU prohlášení o shodě

Č. dokumentu	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Místo	**Germany - Lübeck**
Strana	**2 / 4**

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

Název produktu	**Kategorie prostředku**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Použité normy, v celku nebo z části:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
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EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

CS

CE 0123

EU prohlášení o shodě

Č. dokumentu	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
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ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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EU prohlášení o shodě

Č. dokumentu	**MDR108-030-2212-028-0**
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Místo	**Germany - Lübeck**
Strana	**4 / 4**

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

Rozsah posuzování shody		
Číslo dílu	Název produktu	Základní UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

da

EU-overensstemmelseserklæring

CE 0123

Dokumentnr.	**MDR108-030-2212-028-0**
Dato	**2022-12-01**
Sted	**Germany - Lübeck**
Side	**1 / 4**

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-00005329

erklærer hermed på eget ansvar, at

Produktnavn	Apparatkategori	Apparatklasse	UMDNS-kode / GMDN-kode / EMDN-kode
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

da

CE 0123

EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-030-2212-028-0**
Dato	**2022-12-01**
Sted	**Germany - Lübeck**
Side	**2 / 4**

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

Produktnavn	**Apparatkategori**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Standarder, der anvendes helt eller delvist:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
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EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

da

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EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-030-2212-028-0**
Dato	**2022-12-01**
Sted	**Germany - Lübeck**
Side	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

da

CE 0123

EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-030-2212-028-0**
Dato	**2022-12-01**
Sted	**Germany - Lübeck**
Side	**4 / 4**

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

Overensstemmelsesvurderingens omfang		
Varenummer	Produktnavn	Basic UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

et

CE 0123

ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-030-2212-028-0**
Kuupäev	**2022-12-01**
Koht	**Germany - Lübeck**
Lk	**1 / 4**

N/A

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

Volitatud esindaja:

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

Kordumatu registreerimisnumber (SRN): DE-MF-00005329

kinnitab käesolevaga oma ainuvastutusel, et

Toote nimi	Seadme kategooria	Seadme klass	UMDNS-kood / GMDN-kood / EMDN-kood
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

et

CE 0123

ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-030-2212-028-0**
Kuupäev	**2022-12-01**
Koht	**Germany - Lübeck**
Lk	**2 / 4**

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

Toote nimi	**Seadme kategooria**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Osaliselt või täielikult kohaldatud standardid:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
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ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-030-2212-028-0**
Kuupäev	**2022-12-01**
Koht	**Germany - Lübeck**
Lk	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-030-2212-028-0**
Kuupäev	**2022-12-01**
Koht	**Germany - Lübeck**
Lk	**4 / 4**

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

Vastavushinnangu ulatus		
Osa number	Toote nimi	Peamine UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-030-2212-028-0**
Ημερομηνία	**2022-12-01**
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-00005329

δηλώνει με αποκλειστική ευθύνη ότι

Όνομα προϊόντος	Κατηγορία συσκευής	Κλάση συσκευής	Κωδικός UMDNS / Κωδικός GMDN / Κωδικός EMDN
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
Tel +49 451 882-0
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info@draeger.com
www.draeger.com
VAT no. DE135082211

Bank details:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

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

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

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου **MDR108-030-2212-028-0**
Ημερομηνία **2022-12-01**
Τοποθεσία **Germany - Lübeck**
Σελίδα **2 / 4**

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

Όνομα προϊόντος	**Κατηγορία συσκευής**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Πρότυπα που εφαρμόζονται πλήρως ή εν μέρει:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-030-2212-028-0**
Ημερομηνία	**2022-12-01**
Τοποθεσία	**Germany - Lübeck**
Σελίδα	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-030-2212-028-0**
Ημερομηνία	**2022-12-01**
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
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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Déclaration de conformité UE

CE 0123

N° du document	**MDR108-030-2212-028-0**
Date	**2022-12-01**
Ville	**Germany - Lübeck**
Page	**1 / 4**

N/A

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

Mandataire:

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

Numéro d'enregistrement unique (SRN): DE-MF-00005329

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
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

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Déclaration de conformité UE

N° du document	**MDR108-030-2212-028-0**
Date	**2022-12-01**
Ville	**Germany - Lübeck**
Page	**2 / 4**

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

Nom du produit	**Catégorie de l'appareil**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Normes appliquées en totalité ou en partie :	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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Déclaration de conformité UE

N° du document	**MDR108-030-2212-028-0**
Date	**2022-12-01**
Ville	**Germany - Lübeck**
Page	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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CE 0123

Déclaration de conformité UE

N° du document	**MDR108-030-2212-028-0**
Date	**2022-12-01**
Ville	**Germany - Lübeck**
Page	**4 / 4**

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
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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EU izjava o sukladnosti

Br. dokumenta	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Mjesto	**Germany - Lübeck**
Stranica	**1 / 4**

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-00005329

ovime izjavljuje pod vlastitom odgovornošću da je

Naziv proizvoda	Kategorija proizvoda	Razred proizvoda	UMDNS kod / GMDN kod / EMDN kod
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

hr

CE 0123

EU izjava o sukladnosti

Br. dokumenta	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Mjesto	**Germany - Lübeck**
Stranica	**2 / 4**

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

Naziv proizvoda	**Kategorija proizvoda**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Norme primijenjene u cijelosti ili djelomično:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
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EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
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EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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EU izjava o sukladnosti

Br. dokumenta	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Mjesto	**Germany - Lübeck**
Stranica	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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CE 0123

EU izjava o sukladnosti

Br. dokumenta	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Mjesto	**Germany - Lübeck**
Stranica	**4 / 4**

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

Opseg ocjene sukladnosti		
Broj dijela	Naziv proizvoda	Osnovni UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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CE 0123

Dichiarazione di conformità UE

N. documento	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Luogo	**Germany - Lübeck**
Pagina	**1 / 4**

N/A

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

Mandatario:

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

Numero di registrazione unico (SRN): DE-MF-00005329

dichiara con la presente sotto la propria responsabilità che

Nome prodotto	Categoria dispositivo	Classe dispositivo	Codice UMDNS / Codice GMDN / Codice EMDN
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

it

CE 0123

Dichiarazione di conformità UE

N. documento	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Luogo	**Germany - Lübeck**
Pagina	**2 / 4**

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

Nome prodotto	**Categoria dispositivo**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Standard applicati integralmente o parzialmente:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

it

CE 0123

Dichiarazione di conformità UE

N. documento	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Luogo	**Germany - Lübeck**
Pagina	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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CE 0123

Dichiarazione di conformità UE

N. documento	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Luogo	**Germany - Lübeck**
Pagina	**4 / 4**

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
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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CE 0123

ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-030-2212-028-0**
Datums	**2022-12-01**
Vieta	**Germany - Lübeck**
Lappuse	**1 / 4**

N/A

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

Pilnvarotais pārstāvis:

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

Vienotais reģistrācijas numurs (VRN): DE-MF-00005329

pilnībā atbildot par to, apliecina, ka

Izstrādājuma nosaukums	Ierīces kategorija	Ierīces klase	UMDNS kods / GMDN kods / EMDN kods
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

Director
Research & Development
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Medical Division

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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info@draeger.com
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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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ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-030-2212-028-0**
Datums	**2022-12-01**
Vieta	**Germany - Lübeck**
Lappuse	**2 / 4**

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

Izstrādājuma nosaukums	**Ierīces kategorija**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Pilnībā vai daļēji piemērotie standarti:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-030-2212-028-0**
Datums	**2022-12-01**
Vieta	**Germany - Lübeck**
Lappuse	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-030-2212-028-0**
Datums	**2022-12-01**
Vieta	**Germany - Lübeck**
Lappuse	**4 / 4**

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

Atbilstības novērtēšanas pagarinājums		
Daļas numurs	Izstrādājuma nosaukums	Pamata UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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ES atitikties deklaracija

Dokumento Nr.	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Vieta	**Germany - Lübeck**
Psl.	**1 / 4**

N/A

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

Įgaliotasis atstovas:

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

Bendrasis registracijos numeris (BRN): DE-MF-00005329

prisiimdami visą atsakomybę pareiškia, kad:

Prietaiso pavadinimas	Prietaiso kategorija	Prietaiso klasė	UMDNS kodas / GMDN kodas / EMDN kodas
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

Director
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Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

Director
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Medical Division

Kalle Heckmann

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info@draeger.com
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Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
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Registered office: Lübeck
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Local court Lübeck HRB 7395 HL

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

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ES atitikties deklaracija

Dokumento Nr.	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Vieta	**Germany - Lübeck**
Psl.	**2 / 4**

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

Prietaiso pavadinimas	**Prietaiso kategorija**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Iš dalies ar visa apimtimi taikyti standartai:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
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ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
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ES atitikties deklaracija

Dokumento Nr.	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Vieta	**Germany - Lübeck**
Psl.	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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ES atitikties deklaracija

Dokumento Nr.	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Vieta	**Germany - Lübeck**
Psl.	**4 / 4**

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

Išsami informacija apie atitikties vertinimą		
Prekės kodas	Prietaiso pavadinimas	Pagrindinis UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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EU megfelelőségi nyilatkozat

CE 0123

Dokumentum száma	**MDR108-030-2212-028-0**
Dátum	**2022-12-01**
Hely	**Germany - Lübeck**
Oldal	**1 / 4**

N/A

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

Meghatalmazott képviselő:

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

Egyedi regisztrációs szám (SRN): DE-MF-00005329

saját kizárólagos felelősségére kijelenti, hogy a

Termék neve	Készülékkategória	Készülékosztály	UMDNS-kód / GMDN-kód / EMDN-kód
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

hu

CE 0123

EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-030-2212-028-0**
Dátum	**2022-12-01**
Hely	**Germany - Lübeck**
Oldal	**2 / 4**

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

Termék neve	**Készülékkategória**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Teljesen vagy részben alkalmazott szabványok:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

hu

CE 0123

EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-030-2212-028-0**
Dátum	**2022-12-01**
Hely	**Germany - Lübeck**
Oldal	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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CE 0123

EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-030-2212-028-0**
Dátum	**2022-12-01**
Hely	**Germany - Lübeck**
Oldal	**4 / 4**

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

A megfelelőségértékelés meghosszabbítása		
Cikkszám	Termék neve	Alapvető UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

nl

EU-verklaring van overeenstemming

CE 0123

Documentnr.	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Plaats	**Germany - Lübeck**
Pagina	**1 / 4**

N/A

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

Gemachtigde:

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

Enkelvoudig registratienummer (SRN): DE-MF-00005329

verklaart hierbij onder haar volledige eigen verantwoordelijkheid dat

Productnaam	Apparaatcategorie	Apparaatklasse	UMDNS-code / GMDN-code / EMDN-code
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

Director
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Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

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

Kalle Heckmann

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www.draeger.com
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Bank details:
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IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

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

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

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EU-verklaring van overeenstemming

Documentnr.	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Plaats	**Germany - Lübeck**
Pagina	**2 / 4**

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

Productnaam	**Apparaatcategorie**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Volledig of gedeeltelijk toegepaste normen:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
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ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
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EU-verklaring van overeenstemming

Documentnr.	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Plaats	**Germany - Lübeck**
Pagina	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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EU-verklaring van overeenstemming

Documentnr.	**MDR108-030-2212-028-0**
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Pagina	**4 / 4**

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

Reikwijdte van conformiteitsbeoordeling		
Onderdeelnummer	Productnaam	Basis UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

pl

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Deklaracja zgodności UE

Nr dokumentu	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Miejsce	**Germany - Lübeck**
Strona	**1 / 4**

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-00005329

deklaruje niniejszym na swoją wyłączną odpowiedzialność, że

Nazwa produktu	Kategoria urządzenia	Klasa urządzenia	Kod UMDNS / Kod GMDN / Kod EMDN
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

pl

CE 0123

Deklaracja zgodności UE

Nr dokumentu	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Miejsce	**Germany - Lübeck**
Strona	**2 / 4**

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

Nazwa produktu	**Kategoria urządzenia**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Zastosowane normy (w całości lub w części):	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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CE 0123

Deklaracja zgodności UE

Nr dokumentu	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Miejsce	**Germany - Lübeck**
Strona	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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Deklaracja zgodności UE

Nr dokumentu	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Miejsce	**Germany - Lübeck**
Strona	**4 / 4**

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

Zakres oceny zgodności		
Numer części	Nazwa produktu	Basic UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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Declaração de conformidade da UE

Nº. do documento	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Local	**Germany - Lübeck**
Página	**1 / 4**

N/A

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

Mandatário:

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

O número de registro único (SRN): DE-MF-00005329

declara, sob exclusiva responsabilidade, que

Nome do produto	Categoria do equipamento	Classe do equipamento	Código UMDNS / Código GMDN / Código EMDN
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
Tel +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
VAT no. DE135082211

Bank details:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

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

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

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CE 0123

Declaração de conformidade da UE

Nº. do documento	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Local	**Germany - Lübeck**
Página	**2 / 4**

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

Nome do produto	**Categoria do equipamento**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Normas aplicadas total ou parcialmente:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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CE 0123

Declaração de conformidade da UE

Nº. do documento	**MDR108-030-2212-028-0**
Data	**2022-12-01**
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Página	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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Declaração de conformidade da UE

Nº. do documento	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Local	**Germany - Lübeck**
Página	**4 / 4**

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
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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Declaraţie de conformitate UE

Nr. document	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Localitatea	**Germany - Lübeck**
Pagina	**1 / 4**

N/A

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

Reprezentant autorizat:

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

Număr unic de înregistrare (SRN): DE-MF-00005329

declară prin prezenta pe proprie răspundere că

Numele produsului	Categoria dispozitivului	Clasa dispozitivului	Codul UMDNS / Codul GMDN / Codul EMDN
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

ro

CE 0123

Declaraţie de conformitate UE

Nr. document	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Localitatea	**Germany - Lübeck**
Pagina	**2 / 4**

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

Numele produsului	**Categoria dispozitivului**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Standarde aplicate în totalitate sau parţial:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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Declaraţie de conformitate UE

Nr. document	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Localitatea	**Germany - Lübeck**
Pagina	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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Declaraţie de conformitate UE

Nr. document	**MDR108-030-2212-028-0**
Data	**2022-12-01**
Localitatea	**Germany - Lübeck**
Pagina	**4 / 4**

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

Evaluarea extinsă a conformităţii		
Cod articol	Numele produsului	UDI-DI de bază
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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EÚ vyhlásenie o zhode

Dokument č.	**MDR108-030-2212-028-0**
Dátum	**2022-12-01**
Miesto	**Germany - Lübeck**
Strana	**1 / 4**

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

Splnomocnený zástupca: N/A

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

Jedinečné registračné číslo (SRN): DE-MF-00005329

týmto na vlastnú zodpovednosť vyhlasuje, že

Názov výrobku	Kategória zariadenia	Trieda zariadenia	Kód UMDNS / Kód GMDN / Kód EMDN
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

sk

CE 0123

EÚ vyhlásenie o zhode

Dokument č.	**MDR108-030-2212-028-0**
Dátum	**2022-12-01**
Miesto	**Germany - Lübeck**
Strana	**2 / 4**

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

Názov výrobku	**Kategória zariadenia**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Použité normy v úplnom alebo v čiastočnom znení:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

sk

CE 0123

EÚ vyhlásenie o zhode

Dokument č.	**MDR108-030-2212-028-0**
Dátum	**2022-12-01**
Miesto	**Germany - Lübeck**
Strana	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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EÚ vyhlásenie o zhode

Dokument č.	**MDR108-030-2212-028-0**
Dátum	**2022-12-01**
Miesto	**Germany - Lübeck**
Strana	**4 / 4**

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

Rozsah posúdenia zhody		
Objednávacie číslo	Názov výrobku	Základné UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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CE 0123

Izjava EU o skladnosti

Št. dokumenta	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Kraj	**Germany - Lübeck**
Stran	**1 / 4**

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-00005329

izjavlja z vso odgovornostjo, da

Ime izdelka	Kategorija naprave	Razred naprave	Koda UMDNS / Koda GMDN / Koda EMDN
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

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

Kalle Heckmann

sl

CE 0123

Izjava EU o skladnosti

Št. dokumenta	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Kraj	**Germany - Lübeck**
Stran	**2 / 4**

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

Ime izdelka	**Kategorija naprave**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
V celoti ali deloma uporabljeni standardi:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

sl

CE 0123

Izjava EU o skladnosti

Št. dokumenta	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Kraj	**Germany - Lübeck**
Stran	**3 / 4**

ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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CE 0123

Izjava EU o skladnosti

Št. dokumenta	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Kraj	**Germany - Lübeck**
Stran	**4 / 4**

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

Obseg ugotavljanja skladnosti		
Kataloška številka	Ime izdelka	Basic UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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CE 0123

EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-030-2212-028-0**
Päivämäärä	**2022-12-01**
Paikka	**Germany - Lübeck**
Sivu	**1 / 4**

N/A

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

Valtuutetulla edustajalla:

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

Rekisterinumero: DE-MF-00005329

vakuuttaa täten yksinomaisella vastuullaan, että

Tuotenimi	Laitteen luokitus	Laiteluokka	UMDNS-koodi / GMDN-koodi / EMDN-koodi
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

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

Timo Harms

Director
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Kalle Heckmann

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-030-2212-028-0**
Päivämäärä	**2022-12-01**
Paikka	**Germany - Lübeck**
Sivu	**2 / 4**

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

Tuotenimi	**Laitteen luokitus**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Kokonaan tai osittain sovellettavat standardit:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
EN ISO 5356-1:2015 (ISO 5356-1:2015)	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5367:2014 (ISO 5367:2014)	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 2006+A1:2013 +A12 2014+FprA2:2020 (IEC 60601-1: 2005 + COR1 2014 + A2: 2020)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 18190:2016	Anesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 20417:2021	Medical devices – Information to be supplied by the manufactuer
ISO 10651-3:1997	Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators
ISO 80601-2-84:2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-030-2212-028-0**
Päivämäärä	**2022-12-01**
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ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-030-2212-028-0**
Päivämäärä	**2022-12-01**
Paikka	**Germany - Lübeck**
Sivu	**4 / 4**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Vaatimustenmukaisuuden arvioinnin laajuus		
Osanumero	Tuotenimi	Yksilöllinen UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**

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EU-försäkran om överensstämmelse

CE 0123

Dokument nr.	**MDR108-030-2212-028-0**
Datum	**2022-12-01**
Plats	**Germany - Lübeck**
Sida	**1 / 4**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Auktoriserad representant: N/A

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

Enkelt registreringsnummer (SRN): DE-MF-00005329

förklarar härmed under sitt eget ansvar att

Produktnamn	Enhetskategori	Enhetsklass	UMDNS-kod / GMDN-kod / EMDN-kod
Flow sensor	Anesthesia and pulmonary ventilation support instruments	IIa	UMDNS14-117/ GMDN61833/ EMDNZ120301

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.

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

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

Director
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Kalle Heckmann

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

Produktnamn	**Enhetskategori**
Flow sensor	Anesthesia and pulmonary ventilation support instruments
Helt eller delvis tillämpade standarder:	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices – application of risk management to medical devices
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)	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
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EN 62366-1:2015 + Cor 1 201+A1:2020 (IEC 62366-1: 2015 COR 1 2016 AMD1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 (IEC 60601-1-6: 2010 AMD 1 2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
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Datum	**2022-12-01**
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ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

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EU-försäkran om överensstämmelse

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Sida	**4 / 4**

Drägerwerk AG & Co. KGaA
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Germany

Omfattning bedömning av överensstämmelse		
Artikelnummer	Produktnamn	Bas UDI-DI
8412034	**Flow sensor**	**040486751308030HK19Z000QH**