en/de

EU Declaration of Conformity
EU-Konformitätserklärung

Document No. / Dokument Nr.	**MDR108-033-2107-002-0**
Date / Datum	**2021-07-20**
Place / Ort	**Germany - Lübeck**
Page / Seite	**1 / 4**

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

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

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

Product Name / Produktbezeichnung	Device Category / Produktkategorie	Device Class / Geräteklasse	UMDNS Code / GMDN Code / EMDN Code
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

meets the following provisions:
mit den folgenden Bestimmungen übereinstimmt:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices/ Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rates vom 5. April 2017 über Medizinprodukte
Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment/ Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten
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 Competence Center
Anesthesiology

Dr. Christian Engeln

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

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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

Product Name / Produktbezeichnung	**Device Category / Produktkategorie**
VarioLux	**Light, examination**
Applied Standards in full or in part / Vollständig oder teilweise angewendete Normen:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

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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
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

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ЕС декларация за съответствие

Документ №	**MDR108-033-2107-002-0**
Дата	**2021-07-20**
Място	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

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

с настоящото декларира на своя отговорност, че

Име на продукта	Категория на уреда	Клас на уреда	Код UMDNS / Код GMDN / Код EMDN
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

отговаря на следните разпоредби:

РЕГЛАМЕНТ (ЕС) 2017/745 НА ЕВРОПЕЙСКИЯ ПАРЛАМЕНТ И НА СЪВЕТА от 5 април 2017 година за медицинските изделия
ДИРЕКТИВА 2011/65/ЕС НА ЕВРОПЕЙСКИЯ ПАРЛАМЕНТ И НА СЪВЕТА от 8 юни 2011 година относно ограничението за употребата на определени опасни вещества в електрическото и електронното оборудване
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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IBAN: DE15 2305 0101 0001 0711 17
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General partner: Drägerwerk Verwaltungs AG
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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

ЕС декларация за съответствие

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

Име на продукта	**Категория на уреда**
VarioLux	**Light, examination**
Напълно или частично приложени стандарти:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
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EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

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ЕС декларация за съответствие

Документ №	**MDR108-033-2107-002-0**
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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
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

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Declaración UE de conformidad

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

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

por la presente declara bajo su exclusiva responsabilidad que

Nombre del producto	Categoría del dispositivo	Clase del dispositivo	Código UMDNS / Código GMDN / Código EMDN
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

cumple las siguientes disposiciones:

REGLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 5 de abril de 2017 sobre los productos sanitarios
DIRECTIVA 2011/65/UE DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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**
VarioLux	**Light, examination**
Normas aplicadas total o parcialmente:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
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Declaración UE de conformidad

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Moislinger Allee 53-55
23542 Lübeck
Germany

Alcance de la evaluación de conformidad		
Número de referencia	Nombre del producto	UDI-DI básico
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

CS

EU prohlášení o shodě

Č. dokumentu	**MDR108-033-2107-002-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

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

tímto prohlašuje na svou výhradní zodpovědnost, že

Název produktu	Kategorie prostředku	Třída prostředku	Kód UMDNS / Kód GMDN / Kód EMDN
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

splňuje následující ustanovení:

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY (EU) 2017/745 ze dne 5. dubna 2017 o zdravotnických prostředcích
SMĚRNICE EVROPSKÉHO PARLAMENTU A RADY 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

Drägerwerk AG & Co. KGaA
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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
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EU prohlášení o shodě

Č. dokumentu	**MDR108-033-2107-002-0**
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Strana	**2 / 3**

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

Název produktu	**Kategorie prostředku**
VarioLux	**Light, examination**
Použité normy, v celku nebo z části:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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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EU prohlášení o shodě

Č. dokumentu	**MDR108-033-2107-002-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Rozsah posuzování shody		
Číslo dílu	Název produktu	Základní UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

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EU-overensstemmelseserklæring

Dokumentnr.	**MDR108-033-2107-002-0**
Dato	**2021-07-20**
Sted	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Individuelt registreringsnummer (SRN): DE-MF-000005329

erklærer hermed på eget ansvar, at

Produktnavn	Apparatkategori	Apparatklasse	UMDNS-kode / GMDN-kode / EMDN-kode
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

opfylder følgende bestemmelser:

EUROPA-PARLAMENTETS OG RÅDETS FORORDNING (EU) 2017/745 af 5. april 2017 om medicinsk udstyr
EUROPA-PARLAMENTETS OG RÅDETS DIREKTIV 2011/65/EU af 8. juni 2011 om begrænsning af anvendelsen af visse farlige stoffer i elektrisk og elektronisk udstyr
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

da

EU-overensstemmelseserklæring

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Moislinger Allee 53-55
23542 Lübeck
Germany

Produktnavn	**Apparatkategori**
VarioLux	**Light, examination**
Standarder, der anvendes helt eller delvist:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
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EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
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EU-overensstemmelseserklæring

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Side	**3 / 3**

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

Overensstemmelsesvurderingens omfang		
Varenummer	Produktnavn	Basic UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

et

ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-033-2107-002-0**
Kuupäev	**2021-07-20**
Koht	**Germany - Lübeck**
Lk	**1 / 3**

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

Kordumatu registreerimisnumber (SRN): DE-MF-000005329

kinnitab käesolevaga oma ainuvastutusel, et

Toote nimi	Seadme kategooria	Seadme klass	UMDNS-kood / GMDN-kood / EMDN-kood
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

vastab järgmistele nõuetele:

EUROOPA PARLAMENDI JA NÕUKOGU MÄÄRUS (EL) 2017/745 5. aprill 2017, milles käsitletakse meditsiiniseadmeid
EUROOPA PARLAMENDI JA NÕUKOGU DIREKTIIV 2011/65/EL, 8. juuni 2011, teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

et

ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-033-2107-002-0**
Kuupäev	**2021-07-20**
Koht	**Germany - Lübeck**
Lk	**2 / 3**

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

Toote nimi	**Seadme kategooria**
VarioLux	**Light, examination**
Osaliselt või täielikult kohaldatud standardid:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR108-033-2107-002-0**
Kuupäev	**2021-07-20**
Koht	**Germany - Lübeck**
Lk	**3 / 3**

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

Vastavushinnangu ulatus		
Osa number	Toote nimi	Peamine UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

el

Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-033-2107-002-0**
Ημερομηνία	**2021-07-20**
Τοποθεσία	**Germany - Lübeck**
Σελίδα	**1 / 3**

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

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

δηλώνει με αποκλειστική ευθύνη ότι

Όνομα προϊόντος	Κατηγορία συσκευής	Κλάση συσκευής	Κωδικός UMDNS / Κωδικός GMDN / Κωδικός EMDN
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

συμμορφώνεται με τις ακόλουθες διατάξεις:

ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2017/745 ΤΟΥ ΕΥΡΩΠΑΪΚΟΥ ΚΟΙΝΟΒΟΥΛΙΟΥ ΚΑΙ ΤΟΥ ΣΥΜΒΟΥΛΙΟΥ της 5ης Απριλίου 2017 για τα ιατροτεχνολογικά προϊόντα
ΟΔΗΓΙΑ 2011/65/ΕΕ ΤΟΥ ΕΥΡΩΠΑΪΚΟΥ ΚΟΙΝΟΒΟΥΛΙΟΥ ΚΑΙ ΤΟΥ ΣΥΜΒΟΥΛΙΟΥ της 8ης Ιουνίου 2011 για τον περιορισμό της χρήσης ορισμένων επικίνδυνων ουσιών σε ηλεκτρικό και ηλεκτρονικό εξοπλισμό
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-033-2107-002-0**
Ημερομηνία	**2021-07-20**
Τοποθεσία	**Germany - Lübeck**
Σελίδα	**2 / 3**

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

Όνομα προϊόντος	**Κατηγορία συσκευής**
VarioLux	**Light, examination**
Πρότυπα που εφαρμόζονται πλήρως ή εν μέρει:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
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EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

el

Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR108-033-2107-002-0**
Ημερομηνία	**2021-07-20**
Τοποθεσία	**Germany - Lübeck**
Σελίδα	**3 / 3**

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

Επέκταση αξιολόγησης της συμμόρφωσης		
Αριθμός εξαρτήματος	Όνομα προϊόντος	Βασικό UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

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Déclaration de conformité UE

N° du document	**MDR108-033-2107-002-0**
Date	**2021-07-20**
Ville	**Germany - Lübeck**
Page	**1 / 3**

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

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

déclare par la présente et sous sa seule responsabilité que le

Nom du produit	Catégorie de l'appareil	Classe de l'appareil	Code UMDNS / Code GMDN / Code EMDN
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

satisfait aux dispositions suivantes :

RÈGLEMENT (UE) 2017/745 DU PARLEMENT EUROPÉEN ET DU CONSEIL du 5 avril 2017 relatif aux dispositifs médicaux
DIRECTIVE 2011/65/UE DU PARLEMENT EUROPÉEN ET DU CONSEIL du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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

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

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

Déclaration de conformité UE

N° du document	**MDR108-033-2107-002-0**
Date	**2021-07-20**
Ville	**Germany - Lübeck**
Page	**2 / 3**

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

Nom du produit	**Catégorie de l'appareil**
VarioLux	**Light, examination**
Normes appliquées en totalité ou en partie :	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
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EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

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Déclaration de conformité UE

N° du document	**MDR108-033-2107-002-0**
Date	**2021-07-20**
Ville	**Germany - Lübeck**
Page	**3 / 3**

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
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

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EU izjava o sukladnosti

Br. dokumenta	**MDR108-033-2107-002-0**
Datum	**2021-07-20**
Mjesto	**Germany - Lübeck**
Stranica	**1 / 3**

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

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

ovime izjavljuje pod vlastitom odgovornošću da je

Naziv proizvoda	Kategorija proizvoda	Razred proizvoda	UMDNS kod / GMDN kod / EMDN kod
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

sukladan sa sljedećim odredbama:

UREDBA (EU) 2017/745 EUROPSKOG PARLAMENTA I VIJEĆA od 5. travnja 2017. o medicinskim proizvodima
DIREKTIVA 2011/65/EU EUROPSKOG PARLAMENTA I VIJEĆA od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

EU izjava o sukladnosti

Br. dokumenta	**MDR108-033-2107-002-0**
Datum	**2021-07-20**
Mjesto	**Germany - Lübeck**
Stranica	**2 / 3**

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

Naziv proizvoda	**Kategorija proizvoda**
VarioLux	**Light, examination**
Norme primijenjene u cijelosti ili djelomično:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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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EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

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EU izjava o sukladnosti

Br. dokumenta	**MDR108-033-2107-002-0**
Datum	**2021-07-20**
Mjesto	**Germany - Lübeck**
Stranica	**3 / 3**

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

Opseg ocjene sukladnosti		
Broj dijela	Naziv proizvoda	Osnovni UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

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Dichiarazione di conformità UE

N. documento	**MDR108-033-2107-002-0**
Data	**2021-07-20**
Luogo	**Germany - Lübeck**
Pagina	**1 / 3**

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

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

dichiara con la presente sotto la propria responsabilità che

Nome prodotto	Categoria dispositivo	Classe dispositivo	Codice UMDNS / Codice GMDN / Codice EMDN
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

è conforme alle seguenti disposizioni:

REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO del 5 aprile 2017 relativo ai dispositivi medici
DIRETTIVA 2011/65/UE DEL PARLAMENTO EUROPEO E DEL CONSIGLIO dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

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

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

Dichiarazione di conformità UE

N. documento	**MDR108-033-2107-002-0**
Data	**2021-07-20**
Luogo	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Nome prodotto	**Categoria dispositivo**
VarioLux	**Light, examination**
Standard applicati integralmente o parzialmente:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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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EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

Dichiarazione di conformità UE

N. documento	**MDR108-033-2107-002-0**
Data	**2021-07-20**
Luogo	**Germany - Lübeck**
Pagina	**3 / 3**

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
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

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ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-033-2107-002-0**
Datums	**2021-07-20**
Vieta	**Germany - Lübeck**
Lappuse	**1 / 3**

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

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

pilnībā atbildot par to, apliecina, ka

Izstrādājuma nosaukums	Ierīces kategorija	Ierīces klase	UMDNS kods / GMDN kods / EMDN kods
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

atbilst šādiem noteikumiem:

EIROPAS PARLAMENTA UN PADOMES REGULA (ES) 2017/745 (2017. gada 5. aprīlis), kas attiecas uz medicīniskām ierīcēm
EIROPAS PARLAMENTA UN PADOMES DIREKTĪVA 2011/65/ES (2011. gada 8. jūnijs) par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
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Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-033-2107-002-0**
Datums	**2021-07-20**
Vieta	**Germany - Lübeck**
Lappuse	**2 / 3**

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

Izstrādājuma nosaukums	**Ierīces kategorija**
VarioLux	**Light, examination**
Pilnībā vai daļēji piemērotie standarti:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

ES atbilstības deklarācija

Dokumenta Nr.	**MDR108-033-2107-002-0**
Datums	**2021-07-20**
Vieta	**Germany - Lübeck**
Lappuse	**3 / 3**

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

Atbilstības novērtēšanas pagarinājums		
Daļas numurs	Izstrādājuma nosaukums	Pamata UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

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ES atitikties deklaracija

Dokumento Nr.	**MDR108-033-2107-002-0**
Data	**2021-07-20**
Vieta	**Germany - Lübeck**
Psl.	**1 / 3**

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

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

prisiimdami visą atsakomybę pareiškia, kad:

Prietaiso pavadinimas	Prietaiso kategorija	Prietaiso klasė	UMDNS kodas / GMDN kodas / EMDN kodas
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

atitinka šias nuostatas:

EUROPOS PARLAMENTO IR TARYBOS REGLAMENTAS (ES) 2017/745 2017 m. balandžio 5 d. dėl medicinos priemonių
EUROPOS PARLAMENTO IR TARYBOS DIREKTYVA 2011/65/ES 2011 m. birželio 8 d. dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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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
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ES atitikties deklaracija

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Moislinger Allee 53-55
23542 Lübeck
Germany

Prietaiso pavadinimas	**Prietaiso kategorija**
VarioLux	**Light, examination**
Iš dalies ar visa apimtimi taikyti standartai:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

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ES atitikties deklaracija

Dokumento Nr.	**MDR108-033-2107-002-0**
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Vieta	**Germany - Lübeck**
Psl.	**3 / 3**

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

Išsami informacija apie atitikties vertinimą		
Prekės kodas	Prietaiso pavadinimas	Pagrindinis UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

hu

EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-033-2107-002-0**
Dátum	**2021-07-20**
Hely	**Germany - Lübeck**
Oldal	**1 / 3**

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

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

saját kizárólagos felelősségére kijelenti, hogy a

Termék neve	Készülékkategória	Készülékosztály	UMDNS-kód / GMDN-kód / EMDN-kód
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

megfelel a következő rendelkezéseknek:

AZ EURÓPAI PARLAMENT ÉS A TANÁCS (EU) 2017/745 RENDELETE (2017. április 5.) az orvostechnikai eszközökről
AZ EURÓPAI PARLAMENT ÉS A TANÁCS 2011/65/EU IRÁNYELVE (2011. június 8.) egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-033-2107-002-0**
Dátum	**2021-07-20**
Hely	**Germany - Lübeck**
Oldal	**2 / 3**

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

Termék neve	**Készülékkategória**
VarioLux	**Light, examination**
Teljesen vagy részben alkalmazott szabványok:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
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EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

hu

EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR108-033-2107-002-0**
Dátum	**2021-07-20**
Hely	**Germany - Lübeck**
Oldal	**3 / 3**

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

A megfelelőségértékelés meghosszabbítása		
Cikkszám	Termék neve	Alapvető UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

nl

EU-verklaring van overeenstemming

Documentnr.	**MDR108-033-2107-002-0**
Datum	**2021-07-20**
Plaats	**Germany - Lübeck**
Pagina	**1 / 3**

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

Enkelvoudig registratienummer (SRN): DE-MF-000005329

verklaart hierbij onder haar volledige eigen verantwoordelijkheid dat

Productnaam	Apparaatcategorie	Apparaatklasse	UMDNS-code / GMDN-code / EMDN-code
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

voldoet aan de volgende bepalingen:

VERORDENING (EU) 2017/745 VAN HET EUROPEES PARLEMENT EN DE RAAD van 5 april 2017 betreffende medische hulpmiddelen
RICHTLIJN 2011/65/EU VAN HET EUROPEES PARLEMENT EN DE RAAD van 8 juni 2011 betreffende beperking van het gebruik van bepaalde gevaarlijke stoffen in elektrische en elektronische apparatuur.
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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

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

EU-verklaring van overeenstemming

Documentnr.	**MDR108-033-2107-002-0**
Datum	**2021-07-20**
Plaats	**Germany - Lübeck**
Pagina	**2 / 3**

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

Productnaam	**Apparaatcategorie**
VarioLux	**Light, examination**
Volledig of gedeeltelijk toegepaste normen:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

EU-verklaring van overeenstemming

Documentnr.	**MDR108-033-2107-002-0**
Datum	**2021-07-20**
Plaats	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Reikwijdte van conformiteitsbeoordeling		
Onderdeelnummer	Productnaam	Basis UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

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Deklaracja zgodności UE

Nr dokumentu	**MDR108-033-2107-002-0**
Data	**2021-07-20**
Miejsce	**Germany - Lübeck**
Strona	**1 / 3**

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

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

deklaruje niniejszym na swoją wyłączną odpowiedzialność, że

Nazwa produktu	Kategoria urządzenia	Klasa urządzenia	Kod UMDNS / Kod GMDN / Kod EMDN
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

spełnia wymogi następujących przepisów:

ROZPORZĄDZENIE PARLAMENTU EUROPEJSKIEGO I RADY (UE) 2017/745 z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych
DYREKTYWA PARLAMENTU EUROPEJSKIEGO I RADY 2011/65/UE z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

Drägerwerk AG & Co. KGaA
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Sparkasse zu Lübeck
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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:
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Executive Board:
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Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

Deklaracja zgodności UE

Nr dokumentu	**MDR108-033-2107-002-0**
Data	**2021-07-20**
Miejsce	**Germany - Lübeck**
Strona	**2 / 3**

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

Nazwa produktu	**Kategoria urządzenia**
VarioLux	**Light, examination**
Zastosowane normy (w całości lub w części):	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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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EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

pl

Deklaracja zgodności UE

Nr dokumentu	**MDR108-033-2107-002-0**
Data	**2021-07-20**
Miejsce	**Germany - Lübeck**
Strona	**3 / 3**

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

Zakres oceny zgodności		
Numer części	Nazwa produktu	Basic UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
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MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

pt

Declaração de conformidade da UE

Nº. do documento	**MDR108-033-2107-002-0**
Data	**2021-07-20**
Local	**Germany - Lübeck**
Página	**1 / 3**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

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

declara, sob exclusiva responsabilidade, que

Nome do produto	Categoria do equipamento	Classe do equipamento	Código UMDNS / Código GMDN / Código EMDN
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

está em conformidade com as seguintes disposições:

REGULAMENTO (UE) 2017/745 DO PARLAMENTO EUROPEU E DO CONSELHO de 5 de abril de 2017 relativo aos dispositivos médicos
DIRETIVA 2011/65/UE DO PARLAMENTO EUROPEU E DO CONSELHO de 8 de junho de 2011 relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrônicos
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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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

Declaração de conformidade da UE

Nº. do documento	**MDR108-033-2107-002-0**
Data	**2021-07-20**
Local	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Nome do produto	**Categoria do equipamento**
VarioLux	**Light, examination**
Normas aplicadas total ou parcialmente:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

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Declaração de conformidade da UE

Nº. do documento	**MDR108-033-2107-002-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Extensão da avaliação de conformidade		
Número da peça	Nome do produto	UDI-DI básico
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

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Declaraţie de conformitate UE

Nr. document	**MDR108-033-2107-002-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

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

declară prin prezenta pe proprie răspundere că

Numele produsului	Categoria dispozitivului	Clasa dispozitivului	Codul UMDNS / Codul GMDN / Codul EMDN
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

îndeplinește următoarele cerințe:

REGULAMENTUL (UE) 2017/745 AL PARLAMENTULUI EUROPEAN ȘI AL CONSILIULUI din 5 aprilie 2017 privind dispozitivele medicale
DIRECTIVA 2011/65/UE A PARLAMENTULUI EUROPEAN ȘI A CONSILIULUI din 8 iunie 2011 privind restricțiile de utilizare a anumitor substanțe periculoase în echipamentele electrice și electronice
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

Declaraţie de conformitate UE

Nr. document	**MDR108-033-2107-002-0**
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Localitatea	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Numele produsului	**Categoria dispozitivului**
VarioLux	**Light, examination**
Standarde aplicate în totalitate sau parţial:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

Declaraţie de conformitate UE

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

Evaluarea extinsă a conformităţii		
Cod articol	Numele produsului	UDI-DI de bază
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

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EÚ vyhlásenie o zhode

Dokument č.	**MDR108-033-2107-002-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

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

týmto na vlastnú zodpovednosť vyhlasuje, že

Názov výrobku	Kategória zariadenia	Trieda zariadenia	Kód UMDNS / Kód GMDN / Kód EMDN
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

spĺňa nasledujúce nariadenia:

NARIADENIE EURÓPSKEHO PARLAMENTU A RADY (EÚ) 2017/745 z 5. apríla 2017 o zdravotníckych pomôckach
SMERNICA EURÓPSKEHO PARLAMENTU A RADY 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

EÚ vyhlásenie o zhode

Dokument č.	**MDR108-033-2107-002-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Názov výrobku	**Kategória zariadenia**
VarioLux	**Light, examination**
Použité normy v úplnom alebo v čiastočnom znení:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

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EÚ vyhlásenie o zhode

Dokument č.	**MDR108-033-2107-002-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Rozsah posúdenia zhody		
Objednávacie číslo	Názov výrobku	Základné UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

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Izjava EU o skladnosti

Št. dokumenta	**MDR108-033-2107-002-0**
Datum	**2021-07-20**
Kraj	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

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

izjavlja z vso odgovornostjo, da

Ime izdelka	Kategorija naprave	Razred naprave	Koda UMDNS / Koda GMDN / Koda EMDN
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

izpolnjuje naslednje določbe:

UREDBA (EU) 2017/745 EVROPSKEGA PARLAMENTA IN SVETA z dne 5. aprila 2017 o medicinskih pripomočkih
DIREKTIVA 2011/65/EU EVROPSKEGA PARLAMENTA IN SVETA z dne 8. junija 2011 o omejevanju uporabe nekaterih nevarnih snovi v električni in elektronski opremi
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

Izjava EU o skladnosti

Št. dokumenta	**MDR108-033-2107-002-0**
Datum	**2021-07-20**
Kraj	**Germany - Lübeck**
Stran	**2 / 3**

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

Ime izdelka	**Kategorija naprave**
VarioLux	**Light, examination**
V celoti ali deloma uporabljeni standardi:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

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Izjava EU o skladnosti

Št. dokumenta	**MDR108-033-2107-002-0**
Datum	**2021-07-20**
Kraj	**Germany - Lübeck**
Stran	**3 / 3**

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

Obseg ugotavljanja skladnosti		
Kataloška številka	Ime izdelka	Basic UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

fi

EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-033-2107-002-0**
Päivämäärä	**2021-07-20**
Paikka	**Germany - Lübeck**
Sivu	**1 / 3**

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

Rekisterinumero: DE-MF-000005329

vakuuttaa täten yksinomaisella vastuullaan, että

Tuotenimi	Laitteen luokitus	Laiteluokka	UMDNS-koodi / GMDN-koodi / EMDN-koodi
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

täyttää seuraavat vaatimukset:

EUROOPAN PARLAMENTIN JA NEUVOSTON ASETUS (EU) 2017/745, annettu 5 päivänä huhtikuuta 2017, lääkinnällisistä laitteista
EUROOPAN PARLAMENTIN JA NEUVOSTON DIREKTIIVI 2011/65/EU, annettu 8 päivänä kesäkuuta 2011, tiettyjen vaarallisten aineiden käytön rajoittamisesta sähkö- ja elektroniikkalaitteissa
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

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

EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-033-2107-002-0**
Päivämäärä	**2021-07-20**
Paikka	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Tuotenimi	**Laitteen luokitus**
VarioLux	**Light, examination**
Kokonaan tai osittain sovellettavat standardit:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR108-033-2107-002-0**
Päivämäärä	**2021-07-20**
Paikka	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Vaatimustenmukaisuuden arvioinnin laajuus		
Osanumero	Tuotenimi	Yksilöllinen UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ

SV

EU-försäkran om överensstämmelse

Dokument nr.	**MDR108-033-2107-002-0**
Datum	**2021-07-20**
Plats	**Germany - Lübeck**
Sida	**1 / 3**

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

Enkelt registreringsnummer (SRN): DE-MF-000005329

förklarar härmed under sitt eget ansvar att

Produktnamn	Enhetskategori	Enhetsklass	UMDNS-kod / GMDN-kod / EMDN-kod
VarioLux	Light, examination	I	UMDNS 12-347/ GMDN 12276/ EMDN Z129004

uppfyller följande bestämmelser:

EUROPAPARLAMENTETS OCH RÅDETS FÖRORDNING (EU) 2017/745 av den 5 april 2017 om medicintekniska produkter
EUROPAPARLAMENTETS OCH RÅDETS DIREKTIV 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning
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 Competence Center
Anesthesiology

Dr. Christian Engeln

Head of Quality & Business Excellence
Business Unit Therapy

Dieter Kurzbach

EU-försäkran om överensstämmelse

Dokument nr.	**MDR108-033-2107-002-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Produktnamn	**Enhetskategori**
VarioLux	**Light, examination**
Helt eller delvis tillämpade standarder:	
EN 60601-1:2006 / A1:2013 *(IEC 60601-1:2005 + A1:2012)*	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 *(IEC 60601-1-2:2014)*	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 AMD 1 2015 *(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
EN 60601-2-41:2009 AMD 1 2015 *(IEC 60601-2-41:2009/A1:2013)*	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN ISO 14971: 2012 *(ISO 14971:2007)*	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 *(ISO 15223-1:2016)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

EU-försäkran om överensstämmelse

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

Omfattning bedömning av överensstämmelse		
Artikelnummer	Produktnamn	Bas UDI-DI
MP00601	VarioLux EU	040486751108033XK19Z000CZ
MP00602	VarioLux US	040486751108033XK19Z000CZ
MP00603	VarioLux GB	040486751108033XK19Z000CZ
MP00606	VarioLux AUS	040486751108033XK19Z000CZ
MP00607	VarioLux ZA	040486751108033XK19Z000CZ
MP00608	VarioLux JP	040486751108033XK19Z000CZ