

en/de



EU Declaration of Conformity EU-Konformitätserklärung

Document No. / Dokument Nr.

MDR108-003-2105-009-0

Date / Datum

2021-05-12

Place / Ort

Germany - Lübeck

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

Authorised representative /
Europäischer Bevollmächtigter:

N/A

Single registration number (SRN)/
einmalige Registrierungsnummer:

not yet applicable /
noch nicht anwendbar

**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
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369- standardized small- bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

**meets the following provisions:
mit den folgenden Bestimmungen übereinstimmt:**

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices/ Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rates vom 5. April 2017 über Medizinprodukte
The quality management system also complies to EN ISO 9001 and EN ISO 13485./ Das Qualitätsmanagementsystem erfüllt weiterhin die Anforderungen gemäß EN ISO 9001 und EN ISO 13485.

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

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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Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms



Dr. Stefan Schimpf

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

Product Name / Produktbezeichnung	Device Category / Produktkategorie
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Applied Standards in full or in part / Vollständig oder teilweise angewendete Normen:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with 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
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



ЕС декларация за съответствие

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

Упълномощен представител:

N/A

Еднократен регистрационен номер (SRN):

още не се прилага

с настоящото декларира на своя отговорност, че

Име на продукта	Категория на уреда	Клас на уреда	Код UMDNS / Код EMDN	Код GMDN /
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302	
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302	
NBP Adapters	Non-ISO 80369- standardized small- bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302	

отговаря на следните разпоредби:

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

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.

bg

Dräger



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Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

Dr. Stefan Schimpf

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Име на продукта	Категория на уреда
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Напълно или частично приложени стандарти:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
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EN 1041:2008 + A1 2013	Information supplied by the manufacturer with medical devices



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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
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
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MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



Declaración UE de conformidad

N.º de documento

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Lugar

Germany - Lübeck

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

Representante autorizado:

N/A

Número de registro único (SRN):

no aplicable aún

por la presente declara bajo su exclusiva responsabilidad que

Nombre del producto	Categoría del dispositivo	Clase del dispositivo	Código UMDNS / Código GMDN / Código EMDN
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

cumple las siguientes disposiciones:

REGLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 5 de abril de 2017 sobre los productos sanitarios

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.

es

Dräger



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Nombre del producto	Categoría del dispositivo
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Normas aplicadas total o parcialmente:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
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ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
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Alcance de la evaluación de conformidad		
Número de referencia	Nombre del producto	UDI-DI básico
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
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MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



EU prohlášení o shodě

Č. dokumentu

Datum

Místo

Strana

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Germany - Lübeck

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

Zplnomocněným zástupcem:

N/A

Jednorázové registrační číslo (SRN):

ještě se neuplatňuje

tímto prohlašuje na svou výhradní zodpovědnost, že

Název produktu	Kategorie prostředku	Třída prostředku	Kód UMDNS / Kód EMDN	Kód GMDN /
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302	
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302	
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302	

splňuje následující ustanovení:

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY (EU) 2017/745 ze dne 5. dubna 2017 o zdravotnických prostředcích
System 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

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

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

Dr. Stefan Schimpf

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 prohlášení o shodě

Č. dokumentu

Datum

Místo

Strana

MDR108-003-2105-009-0

2021-05-12

Germany - Lübeck

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

Název produktu	Kategorie prostředku
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Použité normy, v celku nebo z části:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices



EU prohlášení o shodě

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Místo

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2021-05-12

Germany - Lübeck

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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
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE

da



EU-overensstemmelseserklæring

Dokumentnr.

MDR108-003-2105-009-0

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Sted

Germany - Lübeck

Side

1 / 3

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

Autoriseret repræsentant:

N/A

Individuelt registreringsnummer (SRN):

finder endnu ikke anvendelse

erklærer hermed på eget ansvar, at

Produktnavn	Apparatkategori	Apparatklasse	UMDNS-kode / GMDN-kode / EMDN-kode
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

opfylder følgende bestemmelser:

EUROPA-PARLAMENTETS OG RÅDETS FORORDNING (EU) 2017/745 af 5. april 2017 om medicinsk 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
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories

Head of Product Qualification
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Gert-Hartwig Lescow
Dr. Reiner Piske
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2021-05-12

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Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Produktnavn	Apparatkategori
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Standarder, der anvendes helt eller delvist:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices

da



EU-overensstemmelseserklæring

Dokumentnr.

MDR108-003-2105-009-0

Dato

2021-05-12

Sted

Germany - Lübeck

Side

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

Overensstemmelsesvurderingens omfang		
Varenummer	Produktnavn	Basic UDI-DI
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE

et



ELi vastavusdeklaratsioon

Dokumendi nr
Kuupäev
Koht
Lk

MDR108-003-2105-009-0
2021-05-12
Germany - Lübeck
1 / 3

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

Volitatud esindaja:

N/A

Kordumatu registreerimisnumber (SRN):

pole veel kohaldatav

kinnitab käesolevaga oma ainuvastutusel, et

Toote nimi	Seadme kategooria	Seadme klass	UMDNS-kood / GMDN-kood / EMDN-kood
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

vastab järgmistele nõuetele:

EUROOPA PARLAMENDI JA NÕUKOGU MÄÄRUS (EL) 2017/745 5. aprill 2017, milles käsitletakse meditsiiniseadmeid
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

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

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

et



ELi vastavusdeklaratsioon

Dokumendi nr
Kuupäev
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Lk

MDR108-003-2105-009-0
2021-05-12
Germany - Lübeck
2 / 3

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

Toote nimi	Seadme kategooria
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Osaliselt või täielikult kohaldatud standardid:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices

et



ELi vastavusdeklaratsioon

Dokumendi nr
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MDR108-003-2105-009-0
2021-05-12
Germany - Lübeck
3 / 3

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

Vastavushinnangu ulatus		
Osa number	Toote nimi	Peamine UDI-DI
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου
Ημερομηνία
Τοποθεσία
Σελίδα

MDR108-003-2105-009-0
2021-05-12
Germany - Lübeck
1 / 4

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

Εξουσιοδοτημένος
αντιπρόσωπος:

N/A

Μεμονωμένος αριθμός εγγραφής (SRN):

δεν έχει εφαρμογή ακόμα

δηλώνει με αποκλειστική ευθύνη ότι

Όνομα προϊόντος	Κατηγορία συσκευής	Κλάση συσκευής	Κωδικός UMDNS / Κωδικός GMDN / Κωδικός EMDN
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

συμμορφώνεται με τις ακόλουθες διατάξεις:

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

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.

el

Dräger



Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου
Ημερομηνία
Τοποθεσία
Σελίδα

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23542 Lübeck
Germany

Όνομα προϊόντος	Κατηγορία συσκευής
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Πρότυπα που εφαρμόζονται πλήρως ή εν μέρει:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices



Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου
 Ημερομηνία
 Τοποθεσία
 Σελίδα

MDR108-003-2105-009-0
 2021-05-12
 Germany - Lübeck
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Drägerwerk AG & Co. KGaA
 Moislinger Allee 53-55
 23542 Lübeck
 Germany

Επέκταση αξιολόγησης της συμμόρφωσης		
Αριθμός εξαρτήματος	Όνομα προϊόντος	Βασικό UDI-DI
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
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MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



Déclaration de conformité UE

N° du document

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Ville

Germany - Lübeck

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

Mandataire:

N/A

Numéro d'enregistrement unique (SRN):

Pas encore applicable

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
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

satisfait aux dispositions suivantes :

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

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.

fr

Dräger



Déclaration de conformité UE

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Date

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Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

Dr. Stefan Schimpf

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

Nom du produit	Catégorie de l'appareil
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Normes appliquées en totalité ou en partie :	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
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Drägerwerk AG & Co. KGaA
 Moislinger Allee 53-55
 23542 Lübeck
 Germany

Étendue de l'évaluation de la conformité		
Référence de pièce	Nom du produit	IUD-ID de base
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
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MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
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MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



EU izjava o sukladnosti

Br. dokumenta

Datum

Mjesto

Stranica

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

Ovlašteni zastupnik:

N/A

Jedinstveni registracijski broj (SRN):

još nije primjenjivo

ovime izjavljuje pod vlastitom odgovornošću da je

Naziv proizvoda	Kategorija proizvoda	Razred proizvoda	UMDNS kod / GMDN kod / EMDN kod
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

sukladan sa sljedećim odredbama:

UREDBA (EU) 2017/745 EUROPSKOG PARLAMENTA I VIJEĆA od 5. travnja 2017. o medicinskim proizvodima
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

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

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

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

Dr. Stefan Schimpf

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Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk
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Registered office: Lübeck
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Dr. Reiner Piske
Anton Schrofner



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

Naziv proizvoda	Kategorija proizvoda
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Norme primijenjene u cijelosti ili djelomično:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
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EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
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EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices

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EU izjava o sukladnosti

Br. dokumenta

Datum

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Stranica

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2021-05-12

Germany - Lübeck

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

Opseg ocjene sukladnosti		
Broj dijela	Naziv proizvoda	Osnovni UDI-DI
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
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MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



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2021-05-12

Germany - Lübeck

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

Mandatario:

N/A

Numero di registrazione unico (SRN):

non ancora disponibile

dichiara con la presente sotto la propria responsabilità che

Nome prodotto	Categoria dispositivo	Classe dispositivo	Codice UMDNS / Codice GMDN / Codice EMDN
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

è conforme alle seguenti disposizioni:

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

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.

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

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Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
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Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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Dichiarazione di conformità UE

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Luogo

Germany - Lübeck

Pagina

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Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

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2021-05-12

Germany - Lübeck

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

Nome prodotto	Categoria dispositivo
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Standard applicati integralmente o parzialmente:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
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Germany - Lübeck

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

Estensione della valutazione di conformità		
Numero d'ordine	Nome prodotto	UDI-DI di base
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
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MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



ES atbilstības deklarācija

Dokumenta Nr.

Datums

Vieta

Lappuse

MDR108-003-2105-009-0

2021-05-12

Germany - Lübeck

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

Pilnvarotais pārstāvis:

N/A

Vienotais reģistrācijas numurs (VRN):

vēl nav piemērojams

pilnībā atbildot par to, apliecina, ka

Izstrādājuma nosaukums	Ierīces kategorija	Ierīces klase	UMDNS kods / GMDN kods / EMDN kods
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

atbilst šādiem noteikumiem:

EIROPAS PARLAMENTA UN PADOMES REGULA (ES) 2017/745 (2017. gada 5. aprīlis), kas attiecas uz medicīniskām ierīcēm

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.

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



ES atbilstības deklarācija

Dokumenta Nr.

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2021-05-12

Germany - Lübeck

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Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

Dr. Stefan Schimpf



ES atbilstības deklarācija

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

Izstrādājuma nosaukums	Ierīces kategorija
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Pilnībā vai daļēji piemērotie standarti:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices



ES atbilstības deklarācija

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Germany - Lübeck

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

Atbilstības novērtēšanas pagarinājums		
Daļas numurs	Izstrādājuma nosaukums	Pamata UDI-DI
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE

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ES atitikties deklaracija

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2021-05-12

Germany - Lübeck

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

Įgaliotasis atstovas:

N/A

Bendrasis registracijos numeris (BRN):

netaikoma

prisiimdami visą atsakomybę pareiškia, kad:

Prietaiso pavadinimas	Prietaiso kategorija	Prietaiso klasė	UMDNS kodas / GMDN kodas / EMDN kodas
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

atitinka šias nuostatas:

EUROPOS PARLAMENTO IR TARYBOS REGLAMENTAS (ES) 2017/745 2017 m. balandžio 5 d. dėl medicinos priemonių

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.

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
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Postal address:
23542 Lübeck, Germany
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info@draeger.com
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Swift-Code: NOLADE21SPL

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

It

Dräger



ES atitikties deklaracija

Dokumento Nr.
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2021-05-12
Germany - Lübeck
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Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

Dr. Stefan Schimpf

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
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Dr. Reiner Piske
Anton Schrofner

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Dräger**ES atitikties deklaracija**

Dokumento Nr.

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Psl.

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

Prietaiso pavadinimas	Prietaiso kategorija
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Iš dalies ar visa apimtimi taikyti standartai:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices

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ES atitikties deklaracija

Dokumento Nr.

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Vieta

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2021-05-12

Germany - Lübeck

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

Išsami informacija apie atitikties vertinimą		
Prekės kodas	Prietaiso pavadinimas	Pagrindinis UDI-DI
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



EU megfelelőségi nyilatkozat

Dokumentum száma

Dátum

Hely

Oldal

MDR108-003-2105-009-0

2021-05-12

Germany - Lübeck

1 / 3

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

Meghatalmazott képviselő:

N/A

Egyedi regisztrációs szám (SRN):

még nem alkalmazandó

saját kizárólagos felelősségére kijelenti, hogy a

Termék neve	Készülékkategória	Készülékosztály	UMDNS-kód / GMDN-kód / EMDN-kód
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

megfelel a következő rendelkezéseknek:

AZ EURÓPAI PARLAMENT ÉS A TANÁCS (EU) 2017/745 RENDELETE (2017. április 5.) az orvostechikai eszközökről

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

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
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Swift-Code: NOLADE21SPL

Dr. Stefan Schimpf

Registered office: Lübeck
Commercial register:
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General partner: Drägerwerk
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Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner



EU megfelelőségi nyilatkozat

Dokumentum száma

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2021-05-12

Germany - Lübeck

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

Termék neve	Készülékkategória
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Teljesen vagy részben alkalmazott szabványok:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices



EU megfelelőségi nyilatkozat

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

A megfelelőségértékelés meghosszabbítása		
Cikkszám	Termék neve	Alapvető UDI-DI
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
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MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



EU-verklaring van overeenstemming

Documentnr.

MDR108-003-2105-009-0

Datum

2021-05-12

Plaats

Germany - Lübeck

Pagina

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

Gemachtigde:

N/A

Enkelvoudig registratienummer (SRN):

nog niet van toepassing

verklaart hierbij onder haar volledige eigen verantwoordelijkheid dat

Productnaam	Apparaatcategorie	Apparaatklasse	UMDNS-code / GMDN-code / EMDN-code
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

voldoet aan de volgende bepalingen:

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

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.

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

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EU-verklaring van overeenstemming

Documentnr.

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Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

Dr. Stefan Schimpf

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

Productnaam	Apparaatcategorie
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Volledig of gedeeltelijk toegepaste normen:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices



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

Reikwijdte van conformiteitsbeoordeling		
Onderdeelnummer	Productnaam	Basis UDI-DI
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



Deklaracja zgodności UE

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

Upoważniony przedstawiciel:

N/A

Pojedynczy numer rejestracyjny (SRN):

jeszcze nie dotyczy

deklaruje niniejszym na swoją wyłączną odpowiedzialność, że

Nazwa produktu	Kategoria urządzenia	Klasa urządzenia	Kod UMDNS / Kod EMDN	Kod GMDN /
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302	
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302	
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302	

spełnia wymogi następujących przepisów:

ROZPORZĄDZENIE PARLAMENTU EUROPEJSKIEGO I RADY (UE) 2017/745 z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych

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.

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

Nazwa produktu	Kategoria urządzenia
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Zastosowane normy (w całości lub w części):	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
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EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
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EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices



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2021-05-12

Germany - Lübeck

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

Zakres oceny zgodności		
Numer części	Nazwa produktu	Basic UDI-DI
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
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MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



Declaração de conformidade da UE

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

Mandatário:

N/A

O número de registro único (SRN):

ainda não aplicável

declara, sob exclusiva responsabilidade, que

Nome do produto	Categoria do equipamento	Classe do equipamento	Código UMDNS / Código GMDN / Código EMDN
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

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

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.

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Página

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Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

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

Nome do produto	Categoria do equipamento
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Normas aplicadas total ou parcialmente:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
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EN 15223-1:2016 COR 2017 (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 with medical devices



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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
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
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MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



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

Reprezentant autorizat:

N/A

Număr unic de înregistrare (SRN):

nu se aplică încă

declară prin prezenta pe proprie răspundere că

Numele produsului	Categoria dispozitivului	Clasa dispozitivului	Codul UMDNS / Codul GMDN / Codul EMDN
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

îndeplinește următoarele cerințe:

REGULAMENTUL (UE) 2017/745 AL PARLAMENTULUI EUROPEAN ȘI AL CONSILIULUI din 5 aprilie 2017 privind dispozitivele medicale

Sistemul de management al calității îndeplinește de asemenea cerințele standardelor EN ISO 9001 și EN ISO 13485.

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

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

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Business Unit Hospital Consumables & Accessories

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

Dr. Stefan Schimpf

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



Declarație de conformitate UE

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

Numele produsului	Categoria dispozitivului
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Standarde aplicate în totalitate sau parțial:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices



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

Evaluarea extinsă a conformității		
Cod articol	Numele produsului	UDI-DI de bază
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE

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Dräger**EÚ vyhlásenie o zhode**

Dokument č.

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

Splnomocnený zástupca:

N/A

Jedinečné registračné číslo (SRN):

ešte sa nevzťahuje

týmto na vlastnú zodpovednosť vyhlasuje, že

Názov výrobku	Kategória zariadenia	Trieda zariadenia	Kód UMDNS / Kód EMDN	Kód GMDN /
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302	
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302	
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302	

spĺňa nasledujúce nariadenia:

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

Head of Product Qualification
 Research & Development
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Timo Harms

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 Dr. Reiner Piske
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23542 Lübeck
Germany

Názov výrobku	Kategória zariadenia
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Použité normy v úplnom alebo v čiastočnom znení:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices

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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
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



Izjava EU o skladnosti

Št. dokumenta

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Germany - Lübeck

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

Pooblaščen predstavnik:

N/A

Enotna registrska številka (SRN):

se še ne uporablja

izjavlja z vso odgovornostjo, da

Ime izdelka	Kategorija naprave	Razred naprave	Koda UMDNS / Koda GMDN / Koda EMDN
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

izpolnjuje naslednje določbe:

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

Head of Product Qualification
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Business Unit Hospital Consumables & Accessories

Timo Harms

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Executive Board:
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23542 Lübeck
Germany

Ime izdelka	Kategorija naprave
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
V celoti ali deloma uporabljeni standardi:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices



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

Obseg ugotavljanja skladnosti		
Kataloška številka	Ime izdelka	Basic UDI-DI
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



EU-vaatimustenmukaisuusvakuutus

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

Valtuutetulla edustajalla:

N/A

Rekisterinumero:

ei sovelleta toistaiseksi

vakuuttaa täten yksinomaisella vastuullaan, että

Tuotenimi	Laitteen luokitus	Laiteluokka	UMDNS-koodi / GMDN-koodi / EMDN-koodi
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

täyttää seuraavat vaatimukset:

EUROOPAN PARLAMENTIN JA NEUVOSTON ASETUS (EU) 2017/745, annettu 5 päivänä huhtikuuta 2017, lääkinnällisistä laitteista

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.

fi

Dräger



EU-vaatimustenmukaisuusvakuutus

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Drägerwerk AG & Co. KGaA
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Tuotenimi	Laitteen luokitus
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Kokonaan tai osittain sovellettavat standardit:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
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EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Vaatimustenmukaisuuden arvioinnin laajuus		
Osanumero	Tuotenimi	Yksilöllinen UDI-DI
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00915	NBP cuff M, 23-33cm	0404867511080036K19Z000NL
MP00916	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00917	NBP cuff M++,23-33/53cm	0404867511080036K19Z000NL
MP00918	NBP cuff L, 31-40cm	0404867511080036K19Z000NL
MP00919	NBP cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00921	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00924	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00925	NBP Cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00926	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
MP00928	NBP Cuff M, 23-33cm	0404867511080036K19Z000NL
MP00929	NBP Cuff M+, 23-33/43cm	0404867511080036K19Z000NL
MP00930	NBP Cuff M++, 23-33/53cm	0404867511080036K19Z000NL
MP00931	NBP Cuff L, 31-40cm	0404867511080036K19Z000NL
MP00932	NBP Cuff L+, 31-40/55cm	0404867511080036K19Z000NL
MP00934	NBP Cuff XL, 38-50cm	0404867511080036K19Z000NL
MP00953	NBP extension hose, adult, 3.7m	0404867511080036K19Z000NL
MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE



EU-försäkran om överensstämmelse

Dokument nr.

MDR108-003-2105-009-0

Datum

2021-05-12

Plats

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

Auktoriserad representant:

N/A

Enkelt registreringsnummer (SRN):

inte tillämpligt ännu

förklarar härmed under sitt eget ansvar att

Produktnamn	Enhetskategori	Enhetsklass	UMDNS-kod / GMDN-kod / EMDN-kod
Blood Pressure Cuffs, reusable	Blood pressure cuff, reusable	I	UMDNS 11-073/ GMDN 34978/ EMDN Z1203020302
Blood Pressure Cuffs, disposable	Blood pressure cuff, single-use	I	UMDNS 11-073/ GMDN 37326/ EMDN Z1203020302
NBP Adapters	Non-ISO 80369-standardized small-bore linear connector, reusable	I	UMDNS 11-073/ GMDN 64085/ EMDN Z1203020302

uppfyller följande bestämmelser:

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

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.

SV

Dräger



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Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories

Head of Product Qualification
Research & Development
Business Unit Hospital Consumables & Accessories

Timo Harms

Dr. Stefan Schimpf

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

Produktnamn	Enhetskategori
Blood Pressure Cuffs, reusable, Blood Pressure Cuffs, disposable, NBP Adapters	Blood pressure cuff, reusable, Blood pressure cuff, single-use, Non-ISO80369-standardized small-bore linear connector, reusable
Helt eller delvis tillämpade standarder:	
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 +A1:2012 +COR 1 2014)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 60601-1-6:2010 AMD 1 2015 (IEC 60601-1-6:2010 AMD 1 2013)	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1: 2015 COR 2015 (IEC 62366-1:2015 COR 2016)	Medical devices - Application of usability engineering to medical
EN IEC 80601-2-30:2019 IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 81060-2:2019 (ISO 81060-2:2018)	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN ISO 80369-1:2018 (ISO 80369-1:2018)	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirement
EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 17664:2017 (ISO 17664:2017)	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices <i>(only applicable for Reusables)</i>
EN 15223-1:2016 COR 2017 (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 with medical devices



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Drägerwerk AG & Co. KGaA
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 23542 Lübeck
 Germany

Omfattning bedömning av överensstämmelse		
Artikelnummer	Produktnamn	Bas UDI-DI
MP00911	NBP Cuff XXS, 8-13cm	0404867511080036K19Z000NL
MP00912	NBP cuff XS, 12-19cm	0404867511080036K19Z000NL
MP00913	NBP Cuff S, 17-25/29cm	0404867511080036K19Z000NL
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MP00945	Adapter	0404867511080036K19K010KE
MP00957	Adapter NBP	0404867511080036K19K010KE