Document Release Sign-Off Page

Additional Information
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Affected Document Items			
Number	**Revision**	**Title**	**State**
11174528	03	Declaration of conformity	Released

Document Review Signature Information				
Meaning of e-Signature	**Name (First- and Last Name)**	**User ID**	**Date/ Time (UTC, 24h)**	**Function**
Author	Florian Zechlin	zechlinf	2025-03-18 11:03:01	/
Reviewer	Jakob Kleissl	kleisslj	2025-03-18 21:40:40	/

en/de

EU Declaration of Conformity
EU-Konformitätserklärung

CE 0123

Document No. / Dokument Nr.	**MDR107-039-2503-001-0**
Date / Datum	**2025-03-18**
Place / Ort	**Germany - Lübeck**
Page / Seite	**1 / 4**

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

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

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

Product Name / Produktbezeichnung	Device Category / Produktkategorie	Device Class / Geräteklasse	UMDNS Code / GMDN Code / EMDN Code
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

meets the following provisions:
mit den folgenden Bestimmungen übereinstimmt:

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

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

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

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

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

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

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EU Declaration of Conformity
EU-Konformitätserklärung

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Document No. / Dokument Nr.	**MDR107-039-2503-001-0**
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Leiter Program Dräger ONE
BU Patient Monitoring
Medical Division

Jakob Kleissl

Regulatory Affairs Manager
Program Dräger ONE
BU Patient Monitoring
Medical Division

Florian Zechlin

Drägerwerk AG & Co. KGaA
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IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk
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Chairman of the Supervisory Board for
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Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
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EU Declaration of Conformity
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Product Name / Produktbezeichnung	**Device Category / Produktkategorie**
Mobile Patient Watch	Bedside information system application software
Applied Standards in full or in part / Vollständig oder teilweise angewendete Normen:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
EN 62366-1:2015+A1:2020 *(IEC 62366-1:2015 COR 1 2016 AMD 1:2020)*	Medical devices - Part 1: Application of usability engineering to medical devices
IEC TR 60601-4-5:2021	Medical electrical equipment – Part 4-5 Guidance and Interpretation – Safety related technical security specifications for medical devices
EN ISO 14971:2019+A11:2021 *(ISO 14971:2019)*	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – part 1: General requirements
EN ISO 13485:2016 *(ISO 13485:2016)*	Medical Devices; Quality management systems; Requirements for Regulatory Purposes
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer

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EU Declaration of Conformity
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Document No. / Dokument Nr.	**MDR107-039-2503-001-0**
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Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Extend of conformity assessment / Umfang der Konformitätsbewertung		
Part Number / Sachnummer	Product Name / Produktbezeichnung	Basic UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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CE 0123

ЕС декларация за съответствие

Документ №	**MDR107-039-2503-001-0**
Дата	**2025-03-18**
Място	**Germany - Lübeck**
Страница	**1 / 3**

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

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

с настоящото декларира на своя отговорност, че

Име на продукта	Категория на уреда	Клас на уреда	Код UMDNS / Код GMDN / Код EMDN
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

отговаря на следните разпоредби:

ЕВРОПЕЙСКИ РЕГЛАМЕНТ (ЕС) 2017/745 относно медицински изделия. Извършено е проучване на системата за управление на качеството в съответствие с анекс IX (глави I и III и раздел 4) на регламента от нотифицирания орган: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Системата за управление на качеството също отговаря на EN ISO 9001 и EN ISO 13485.

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

Това е превод на оригиналния документ (en/de) и затова не е подписан.
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Für die Unterschrift im Namen von Dräger siehe "Document Release Sign-Off Page" auf Seite 1.

Leiter Program Dräger ONE
BU Patient Monitoring
Medical Division

Jakob Kleissl

Regulatory Affairs Manager
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BU Patient Monitoring
Medical Division

Florian Zechlin

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ЕС декларация за съответствие

Документ №	**MDR107-039-2503-001-0**
Дата	**2025-03-18**
Място	**Germany - Lübeck**
Страница	**2 / 3**

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

Име на продукта	**Категория на уреда**
Mobile Patient Watch	Bedside information system application software
Напълно или частично приложени стандарти:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
EN 62366-1:2015+A1:2020 *(IEC 62366-1:2015 COR 1 2016 AMD 1:2020)*	Medical devices - Part 1: Application of usability engineering to medical devices
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EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – part 1: General requirements
EN ISO 13485:2016 *(ISO 13485:2016)*	Medical Devices; Quality management systems; Requirements for Regulatory Purposes
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer

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CE 0123

ЕС декларация за съответствие

Документ №	**MDR107-039-2503-001-0**
Дата	**2025-03-18**
Място	**Germany - Lübeck**
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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
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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

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CE 0123

Declaración UE de conformidad

N.º de documento	**MDR107-039-2503-001-0**
Fecha	**2025-03-18**
Lugar	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

por la presente declara bajo su exclusiva responsabilidad que

Nombre del producto	Categoría del dispositivo	Clase del dispositivo	Código UMDNS / Código GMDN / Código EMDN
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

cumple las siguientes disposiciones:

REGLAMENTO EUROPEO (UE) 2017/745 sobre los productos sanitarios. Se ha efectuado un examen del sistema de gestión de la calidad siguiendo el anexo IX (capítulos I y III y sección 4) del reglamento del organismo notificado: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
El sistema de gestión de la calidad también cumple con EN ISO 9001 y EN ISO 13485.

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

Esta es una traducción del documento original (en/de) y, por lo tanto, no lleva firma.
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Für die Unterschrift im Namen von Dräger siehe "Document Release Sign-Off Page" auf Seite 1.

Leiter Program Dräger ONE
BU Patient Monitoring
Medical Division

Jakob Kleissl

Regulatory Affairs Manager
Program Dräger ONE
BU Patient Monitoring
Medical Division

Florian Zechlin

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CE 0123

Declaración UE de conformidad

N.º de documento	**MDR107-039-2503-001-0**
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Lugar	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Nombre del producto	**Categoría del dispositivo**
Mobile Patient Watch	Bedside information system application software
Normas aplicadas total o parcialmente:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
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Executive Board:
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Declaración UE de conformidad

N.º de documento	**MDR107-039-2503-001-0**
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Página	**3 / 3**

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

Alcance de la evaluación de conformidad		
Número de referencia	Nombre del producto	UDI-DI básico
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

CS

CE 0123

EU prohlášení o shodě

Č. dokumentu	**MDR107-039-2503-001-0**
Datum	**2025-03-18**
Místo	**Germany - Lübeck**
Strana	**1 / 3**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

tímto prohlašuje na svou výhradní zodpovědnost, že

Název produktu	Kategorie prostředku	Třída prostředku	Kód UMDNS / Kód GMDN / Kód EMDN
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

splňuje následující ustanovení:

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY (EU) 2017/745 o zdravotnických prostředcích. Kontrola systému managementu kvality byla provedena oznámeným subjektem podle přílohy IX (kapitol I a III a oddílu 4) nařízení: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Systém managementu kvality splňuje rovněž požadavky norem EN ISO 9001 a EN ISO 13485.

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

Toto je překlad původního dokumentu (en/de), a proto nenese podpis.
For the signature on behalf of Dräger see the Document Release Sign-Off Page on page 1./
Für die Unterschrift im Namen von Dräger siehe "Document Release Sign-Off Page" auf Seite 1.

Leiter Program Dräger ONE
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Medical Division

Jakob Kleissl

Regulatory Affairs Manager
Program Dräger ONE
BU Patient Monitoring
Medical Division

Florian Zechlin

CS

CE 0123

EU prohlášení o shodě

Č. dokumentu	**MDR107-039-2503-001-0**
Datum	**2025-03-18**
Místo	**Germany - Lübeck**
Strana	**2 / 3**

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

Název produktu	**Kategorie prostředku**
Mobile Patient Watch	Bedside information system application software
Použité normy, v celku nebo z části:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
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EU prohlášení o shodě

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Místo	**Germany - Lübeck**
Strana	**3 / 3**

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

Rozsah posuzování shody		
Číslo dílu	Název produktu	Základní UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

Drägerwerk AG & Co. KGaA
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Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

da

CE 0123

EU-overensstemmelseserklæring

Dokumentnr.	**MDR107-039-2503-001-0**
Dato	**2025-03-18**
Sted	**Germany - Lübeck**
Side	**1 / 3**

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

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

Individuelt registreringsnummer (SRN): DE-MF-000005329

erklærer hermed på eget ansvar, at

Produktnavn	Apparatkategori	Apparatklasse	UMDNS-kode / GMDN-kode / EMDN-kode
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

opfylder følgende bestemmelser:

EUROPÆISK FORORDNING (EU) 2017/745 om medicinsk udstyr. En undersøgelse af kvalitetsstyringssystemet er blevet foretaget i overensstemmelse med bilag IX (kapitel I og III og afsnit 4) til forordningen af det bemyndigede organ: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitetsstyringssystemet overholder ligeledes EN ISO 9001 og EN ISO 13485.

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

Dette er en oversættelse af det originale dokument (en/de) og er derfor ikke forsynet med en underskrift.
For the signature on behalf of Dräger see the Document Release Sign-Off Page on page 1./
Für die Unterschrift im Namen von Dräger siehe "Document Release Sign-Off Page" auf Seite 1.

Leiter Program Dräger ONE
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Jakob Kleissl

Regulatory Affairs Manager
Program Dräger ONE
BU Patient Monitoring
Medical Division

Florian Zechlin

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EU-overensstemmelseserklæring

Dokumentnr.	**MDR107-039-2503-001-0**
Dato	**2025-03-18**
Sted	**Germany - Lübeck**
Side	**2 / 3**

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

Produktnavn	**Apparatkategori**
Mobile Patient Watch	Bedside information system application software
Standarder, der anvendes helt eller delvist:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
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IEC TR 60601-4-5:2021	Medical electrical equipment – Part 4-5 Guidance and Interpretation – Safety related technical security specifications for medical devices
EN ISO 14971:2019+A11:2021 *(ISO 14971:2019)*	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – part 1: General requirements
EN ISO 13485:2016 *(ISO 13485:2016)*	Medical Devices; Quality management systems; Requirements for Regulatory Purposes
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer

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www.draeger.com
VAT no. DE135082211

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

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
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Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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EU-overensstemmelseserklæring

Dokumentnr.	**MDR107-039-2503-001-0**
Dato	**2025-03-18**
Sted	**Germany - Lübeck**
Side	**3 / 3**

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

Overensstemmelsesvurderingens omfang		
Varenummer	Produktnavn	Basic UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR107-039-2503-001-0**
Kuupäev	**2025-03-18**
Koht	**Germany - Lübeck**
Lk	**1 / 3**

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

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

Kordumatu registreerimisnumber (SRN): DE-MF-000005329

kinnitab käesolevaga oma ainuvastutusel, et

Toote nimi	Seadme kategooria	Seadme klass	UMDNS-kood / GMDN-kood / EMDN-kood
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

vastab järgmistele nõuetele:

EUROOPA MÄÄRUS (EL) 2017/745 meditsiiniseadmete kohta. Kvaliteedijuhtimise süsteemi on hinnatud teavitatud asutuses määruse IX lisa (peatükid I ja III ning jaotis 4) alusel: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvaliteedikontrolli süsteem vastab ka standarditele EN ISO 9001 ja EN ISO 13485.

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

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Leiter Program Dräger ONE
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Jakob Kleissl

Regulatory Affairs Manager
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Florian Zechlin

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR107-039-2503-001-0**
Kuupäev	**2025-03-18**
Koht	**Germany - Lübeck**
Lk	**2 / 3**

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

Toote nimi	**Seadme kategooria**
Mobile Patient Watch	Bedside information system application software
Osaliselt või täielikult kohaldatud standardid:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
EN 62366-1:2015+A1:2020 *(IEC 62366-1:2015 COR 1 2016 AMD 1:2020)*	Medical devices - Part 1: Application of usability engineering to medical devices
IEC TR 60601-4-5:2021	Medical electrical equipment – Part 4-5 Guidance and Interpretation – Safety related technical security specifications for medical devices
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Dokumendi nr	**MDR107-039-2503-001-0**
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Lk	**3 / 3**

Drägerwerk AG & Co. KGaA
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Vastavushinnangu ulatus		
Osa number	Toote nimi	Peamine UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR107-039-2503-001-0**
Ημερομηνία	**2025-03-18**
Τοποθεσία	**Germany - Lübeck**
Σελίδα	**1 / 3**

Drägerwerk AG & Co. KGaA
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Germany

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

δηλώνει με αποκλειστική ευθύνη ότι

Όνομα προϊόντος	Κατηγορία συσκευής	Κλάση συσκευής	Κωδικός UMDNS / Κωδικός GMDN / Κωδικός EMDN
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

συμμορφώνεται με τις ακόλουθες διατάξεις:

Ευρωπαϊκός κανονισμός (ΕΕ) 2017/745 περί ιατροτεχνολογικών προϊόντων. Πραγματοποιήθηκε έλεγχος του συστήματος διαχείρισης ποιότητας σύμφωνα με το παράρτημα IX (κεφάλαια I και III και ενότητα 4) του κανονισμού από τον κοινοποιημένο οργανισμό: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Το σύστημα διαχείρισης ποιότητας συμμορφώνεται επίσης με τα πρότυπα EN ISO 9001 και EN ISO 13485.

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

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

Regulatory Affairs Manager
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Medical Division

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου **MDR107-039-2503-001-0**
Ημερομηνία **2025-03-18**
Τοποθεσία **Germany - Lübeck**
Σελίδα **2 / 3**

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

Όνομα προϊόντος	**Κατηγορία συσκευής**
Mobile Patient Watch	Bedside information system application software
Πρότυπα που εφαρμόζονται πλήρως ή εν μέρει:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
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EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR107-039-2503-001-0**
Ημερομηνία	**2025-03-18**
Τοποθεσία	**Germany - Lübeck**
Σελίδα	**3 / 3**

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

Επέκταση αξιολόγησης της συμμόρφωσης		
Αριθμός εξαρτήματος	Όνομα προϊόντος	Βασικό UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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Déclaration de conformité UE

N° du document	**MDR107-039-2503-001-0**
Date	**2025-03-18**
Ville	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
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Germany

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

déclare par la présente et sous sa seule responsabilité que le

Nom du produit	Catégorie de l'appareil	Classe de l'appareil	Code UMDNS / Code GMDN / Code EMDN
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

satisfait aux dispositions suivantes :

RÉGLEMENTATION EUROPÉENNE (UE) 2017/745 sur les dispositifs médicaux. Une vérification du système de gestion de la qualité a été réalisée conformément à l'annexe IX (chapitres I et III, ainsi que section 4) de la réglementation suivante par l'organisme notifié : **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Le système de gestion de la qualité satisfait également aux normes EN ISO 9001 et EN ISO 13485.

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

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

N° du document	**MDR107-039-2503-001-0**
Date	**2025-03-18**
Ville	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
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Nom du produit	**Catégorie de l'appareil**
Mobile Patient Watch	Bedside information system application software
Normes appliquées en totalité ou en partie :	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
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Swift-Code: NOLADE21SPL

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Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
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Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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Déclaration de conformité UE

N° du document	**MDR107-039-2503-001-0**
Date	**2025-03-18**
Ville	**Germany - Lübeck**
Page	**3 / 3**

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

Étendue de l'évaluation de la conformité		
Référence de pièce	Nom du produit	IUD-ID de base
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

Drägerwerk AG & Co. KGaA
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Drägerwerk AG & Co. KGaA and
Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
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EU izjava o sukladnosti

Br. dokumenta	**MDR107-039-2503-001-0**
Datum	**2025-03-18**
Mjesto	**Germany - Lübeck**
Stranica	**1 / 3**

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

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

ovime izjavljuje pod vlastitom odgovornošću da je

Naziv proizvoda	Kategorija proizvoda	Razred proizvoda	UMDNS kod / GMDN kod / EMDN kod
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

sukladan sa sljedećim odredbama:

UREDBA (EU) 2017/745 o medicinskim proizvodima. Ocjena sustava upravljanja kvalitetom provedena je prema Prilogu IX. (poglavlju I. i III. i stavku 4.) uredbe od strane prijavljenog tijela: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sustav upravljanja kvalitetom također je sukladan normama EN ISO 9001 i EN ISO 13485.

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

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

Br. dokumenta	**MDR107-039-2503-001-0**
Datum	**2025-03-18**
Mjesto	**Germany - Lübeck**
Stranica	**2 / 3**

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

Naziv proizvoda	**Kategorija proizvoda**
Mobile Patient Watch	Bedside information system application software
Norme primijenjene u cijelosti ili djelomično:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
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EU izjava o sukladnosti

Br. dokumenta	**MDR107-039-2503-001-0**
Datum	**2025-03-18**
Mjesto	**Germany - Lübeck**
Stranica	**3 / 3**

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

Opseg ocjene sukladnosti		
Broj dijela	Naziv proizvoda	Osnovni UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

Drägerwerk AG & Co. KGaA
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23558 Lübeck, Germany
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Dichiarazione di conformità UE

N. documento	**MDR107-039-2503-001-0**
Data	**2025-03-18**
Luogo	**Germany - Lübeck**
Pagina	**1 / 3**

Drägerwerk AG & Co. KGaA
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EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

dichiara con la presente sotto la propria responsabilità che

Nome prodotto	Categoria dispositivo	Classe dispositivo	Codice UMDNS / Codice GMDN / Codice EMDN
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

è conforme alle seguenti disposizioni:

REGOLAMENTO EUROPEO (UE) 2017/745 relativo ai dispositivi medici. È stata effettuata una verifica del sistema di gestione della qualità ai sensi dell'allegato IX (capitoli I e III e sezione 4) del regolamento dell'organismo notificato: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Il sistema di gestione della qualità è altresì conforme alle norme EN ISO 9001 e EN ISO 13485.

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

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Leiter Program Dräger ONE
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Medical Division

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Florian Zechlin

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Dichiarazione di conformità UE

N. documento	**MDR107-039-2503-001-0**
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Luogo	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Nome prodotto	**Categoria dispositivo**
Mobile Patient Watch	Bedside information system application software
Standard applicati integralmente o parzialmente:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
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IEC TR 60601-4-5:2021	Medical electrical equipment – Part 4-5 Guidance and Interpretation – Safety related technical security specifications for medical devices
EN ISO 14971:2019+A11:2021 *(ISO 14971:2019)*	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – part 1: General requirements
EN ISO 13485:2016 *(ISO 13485:2016)*	Medical Devices; Quality management systems; Requirements for Regulatory Purposes
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer

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Dichiarazione di conformità UE

N. documento	**MDR107-039-2503-001-0**
Data	**2025-03-18**
Luogo	**Germany - Lübeck**
Pagina	**3 / 3**

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

Estensione della valutazione di conformità		
Numero d'ordine	Nome prodotto	UDI-DI di base
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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

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

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

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

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ES atbilstības deklarācija

Dokumenta Nr.	**MDR107-039-2503-001-0**
Datums	**2025-03-18**
Vieta	**Germany - Lübeck**
Lappuse	**1 / 3**

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

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

pilnībā atbildot par to, apliecina, ka

Izstrādājuma nosaukums	Ierīces kategorija	Ierīces klase	UMDNS kods / GMDN kods / EMDN kods
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

atbilst šādiem noteikumiem:

EIROPAS REGULA (ES) 2017/745 par medicīnas ierīcēm. Kvalitātes vadības sistēmas pārbaudi veikusi pilnvarotā iestāde saskaņā ar regulas IX. pielikumu (nodaļas I un III, 4. sadaļa): **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitātes vadības sistēma atbilst arī EN ISO 9001 un EN ISO 13485.

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

Šis ir oriģinālā dokumenta (en/de) tulkojums, tādēļ uz tā nav paraksta.
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Für die Unterschrift im Namen von Dräger siehe "Document Release Sign-Off Page" auf Seite 1.

Leiter Program Dräger ONE
BU Patient Monitoring
Medical Division

Jakob Kleissl

Regulatory Affairs Manager
Program Dräger ONE
BU Patient Monitoring
Medical Division

Florian Zechlin

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ES atbilstības deklarācija

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

Izstrādājuma nosaukums	**Ierīces kategorija**
Mobile Patient Watch	Bedside information system application software
Pilnībā vai daļēji piemērotie standarti:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
EN 62366-1:2015+A1:2020 *(IEC 62366-1:2015 COR 1 2016 AMD 1:2020)*	Medical devices - Part 1: Application of usability engineering to medical devices
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Drägerwerk AG & Co. KGaA
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Germany

Atbilstības novērtēšanas pagarinājums		
Daļas numurs	Izstrādājuma nosaukums	Pamata UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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ES atitikties deklaracija

Dokumento Nr.	**MDR107-039-2503-001-0**
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Psl.	**1 / 3**

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

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

prisiimdami visą atsakomybę pareiškia, kad:

Prietaiso pavadinimas	Prietaiso kategorija	Prietaiso klasė	UMDNS kodas / GMDN kodas / EMDN kodas
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

atitinka šias nuostatas:

EUROPOS PARLAMENTO IR TARYBOS REGLAMENTA (ES) 2017/745 dėl medicinos prietaisų. Notifikuotoji įstaiga, atlikusi kokybės valdymo sistemos patikrinimą pagal reglamento IX priedą (I ir III skyrius bei 4 skirsnį): **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kokybės valdymo sistema taip pat atitinka EN ISO 9001 ir EN ISO 13485 standartus.

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

Tai yra originalaus dokumento vertimas (iš anglų / vokiečių k.), todėl nereikia parašo.
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Prietaiso pavadinimas	**Prietaiso kategorija**
Mobile Patient Watch	Bedside information system application software
Iš dalies ar visa apimtimi taikyti standartai:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
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Executive Board:
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Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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ES atitikties deklaracija

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Dokumento Nr.	**MDR107-039-2503-001-0**
Data	**2025-03-18**
Vieta	**Germany - Lübeck**
Psl.	**3 / 3**

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

Išsami informacija apie atitikties vertinimą		
Prekės kodas	Prietaiso pavadinimas	Pagrindinis UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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Dr. Reiner Piske
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EU megfelelőségi nyilatkozat

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Dokumentum száma	**MDR107-039-2503-001-0**
Dátum	**2025-03-18**
Hely	**Germany - Lübeck**
Oldal	**1 / 3**

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
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EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

saját kizárólagos felelősségére kijelenti, hogy a

Termék neve	Készülékkategória	Készülékosztály	UMDNS-kód / GMDN-kód / EMDN-kód
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

megfelel a következő rendelkezéseknek:

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

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

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Leiter Program Dräger ONE
BU Patient Monitoring
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Jakob Kleissl

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

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EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR107-039-2503-001-0**
Dátum	**2025-03-18**
Hely	**Germany - Lübeck**
Oldal	**2 / 3**

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

Termék neve	**Készülékkategória**
Mobile Patient Watch	Bedside information system application software
Teljesen vagy részben alkalmazott szabványok:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
EN 62366-1:2015+A1:2020 *(IEC 62366-1:2015 COR 1 2016 AMD 1:2020)*	Medical devices - Part 1: Application of usability engineering to medical devices
IEC TR 60601-4-5:2021	Medical electrical equipment – Part 4-5 Guidance and Interpretation – Safety related technical security specifications for medical devices
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EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR107-039-2503-001-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

A megfelelőségértékelés meghosszabbítása		
Cikkszám	Termék neve	Alapvető UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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EU-verklaring van overeenstemming

Documentnr.	**MDR107-039-2503-001-0**
Datum	**2025-03-18**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

Enkelvoudig registratienummer (SRN): DE-MF-000005329

verklaart hierbij onder haar volledige eigen verantwoordelijkheid dat

Productnaam	Apparaatcategorie	Apparaatklasse	UMDNS-code / GMDN-code / EMDN-code
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

voldoet aan de volgende bepalingen:

EUROPESE VERORDENING (EU) 2017/745 voor medische hulpmiddelen. De aangemelde instantie heeft het kwaliteitsborgingssysteem onderzocht overeenkomstig Bijlage IX (hoofdstukken I en III en deel 4) van de verordening: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Het kwaliteitsmanagementsysteem voldoet ook aan EN ISO 9001 en EN ISO 13485.

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

Dit is een vertaling van het originele document en benodigt derhalve geen ondertekening.
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Leiter Program Dräger ONE
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Medical Division

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BU Patient Monitoring
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EU-verklaring van overeenstemming

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

Productnaam	**Apparaatcategorie**
Mobile Patient Watch	Bedside information system application software
Volledig of gedeeltelijk toegepaste normen:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Reikwijdte van conformiteitsbeoordeling		
Onderdeelnummer	Productnaam	Basis UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

Drägerwerk AG & Co. KGaA
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Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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CE 0123

Deklaracja zgodności UE

Nr dokumentu	**MDR107-039-2503-001-0**
Data	**2025-03-18**
Miejsce	**Germany - Lübeck**
Strona	**1 / 3**

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

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

deklaruje niniejszym na swoją wyłączną odpowiedzialność, że

Nazwa produktu	Kategoria urządzenia	Klasa urządzenia	Kod UMDNS / Kod GMDN / Kod EMDN
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

spełnia wymogi następujących przepisów:

ROZPORZĄDZENIE PARLAMENTU EUROPEJSKIEGO I RADY (EU) 2017/745 w sprawie wyrobów medycznych. Zostało przeprowadzone badanie systemu zarządzania jakością zgodnie z Załącznikiem IX (rozdziały I i III, sekcja 4) Rozporządzenia przez jednostkę notyfikowaną: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
System zarządzania jakością spełnia też normy EN ISO 9001 i EN ISO 13485.

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

Jest to tłumaczenie oryginalnego dokumentu i dlatego nie jest opatrzone podpisem.
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Leiter Program Dräger ONE
BU Patient Monitoring
Medical Division

Jakob Kleissl

Regulatory Affairs Manager
Program Dräger ONE
BU Patient Monitoring
Medical Division

Florian Zechlin

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Deklaracja zgodności UE

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Data	**2025-03-18**
Miejsce	**Germany - Lübeck**
Strona	**2 / 3**

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

Nazwa produktu	**Kategoria urządzenia**
Mobile Patient Watch	Bedside information system application software
Zastosowane normy (w całości lub w części):	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
EN 62366-1:2015+A1:2020 *(IEC 62366-1:2015 COR 1 2016 AMD 1:2020)*	Medical devices - Part 1: Application of usability engineering to medical devices
IEC TR 60601-4-5:2021	Medical electrical equipment – Part 4-5 Guidance and Interpretation – Safety related technical security specifications for medical devices
EN ISO 14971:2019+A11:2021 *(ISO 14971:2019)*	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – part 1: General requirements
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Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

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

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

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Strona	**3 / 3**

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

Zakres oceny zgodności		
Numer części	Nazwa produktu	Basic UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

Drägerwerk AG & Co. KGaA
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Declaração de conformidade da UE

Nº. do documento	**MDR107-039-2503-001-0**
Data	**2025-03-18**
Local	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

declara, sob exclusiva responsabilidade, que

Nome do produto	Categoria do equipamento	Classe do equipamento	Código UMDNS / Código GMDN / Código EMDN
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

está em conformidade com as seguintes disposições:

REGULAMENTO (UE) 2017/745 relativo aos dispositivos médicos. Um exame do sistema de gerenciamento de qualidade foi realizado seguindo o Anexo IX (Capítulos I e III e a seção 4) do regulamento pelo Órgão notificado: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
O sistema de gerenciamento de qualidade também está em conformidade com a EN ISO 9001 e a EN ISO 13485.

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

Este documento é uma tradução do documento original (en/de) e, portanto, não precisa ser assinado.
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Leiter Program Dräger ONE
BU Patient Monitoring
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Jakob Kleissl

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Medical Division

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Declaração de conformidade da UE

Nº. do documento	**MDR107-039-2503-001-0**
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Local	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Nome do produto	**Categoria do equipamento**
Mobile Patient Watch	Bedside information system application software
Normas aplicadas total ou parcialmente:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
EN 62366-1:2015+A1:2020 *(IEC 62366-1:2015 COR 1 2016 AMD 1:2020)*	Medical devices - Part 1: Application of usability engineering to medical devices
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Declaração de conformidade da UE

Nº. do documento	**MDR107-039-2503-001-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
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Extensão da avaliação de conformidade		
Número da peça	Nome do produto	UDI-DI básico
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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Declaraţie de conformitate UE

Nr. document	**MDR107-039-2503-001-0**
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Localitatea	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
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EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

declară prin prezenta pe proprie răspundere că

Numele produsului	Categoria dispozitivului	Clasa dispozitivului	Codul UMDNS / Codul GMDN / Codul EMDN
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

îndeplinește următoarele cerințe:

REGULAMENTUL (UE) 2017/745 privind dispozitivele medicale. O analiză a sistemului de management al calităţii a fost efectuată conform Anexei IX (capitolele I şi III şi secţiunea 4) a reglementării Organismului notificat: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sistemul de management al calităţii îndeplineşte de asemenea cerinţele standardelor EN ISO 9001 şi EN ISO 13485.

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

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Leiter Program Dräger ONE
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Declaraţie de conformitate UE

Nr. document	**MDR107-039-2503-001-0**
Data	**2025-03-18**
Localitatea	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Numele produsului	**Categoria dispozitivului**
Mobile Patient Watch	Bedside information system application software
Standarde aplicate în totalitate sau parţial:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
EN 62366-1:2015+A1:2020 *(IEC 62366-1:2015 COR 1 2016 AMD 1:2020)*	Medical devices - Part 1: Application of usability engineering to medical devices
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EN ISO 13485:2016 *(ISO 13485:2016)*	Medical Devices; Quality management systems; Requirements for Regulatory Purposes
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer

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CE 0123

Declaraţie de conformitate UE

Nr. document	**MDR107-039-2503-001-0**
Data	**2025-03-18**
Localitatea	**Germany - Lübeck**
Pagina	**3 / 3**

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

Evaluarea extinsă a conformităţii		
Cod articol	Numele produsului	UDI-DI de bază
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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CE 0123

EÚ vyhlásenie o zhode

Dokument č.	**MDR107-039-2503-001-0**
Dátum	**2025-03-18**
Miesto	**Germany - Lübeck**
Strana	**1 / 3**

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
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EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

týmto na vlastnú zodpovednosť vyhlasuje, že

Názov výrobku	Kategória zariadenia	Trieda zariadenia	Kód UMDNS / Kód GMDN / Kód EMDN
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

spĺňa nasledujúce nariadenia:

EURÓPSKE NARIADENIE (EÚ) 2017/745 o zdravotníckych pomôckach. Preskúmanie systému riadenia kvality bolo vykonané notifikovaným orgánom podľa prílohy IX (kapitoly I a III a oddielu 4) nariadenia: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Systém riadenia kvality tiež spĺňa normy STN EN ISO 9001 a STN EN ISO 13485.

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

Toto je preklad pôvodného dokumentu (en/de) a preto na ňom nie je uvedený podpis.
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Leiter Program Dräger ONE
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EÚ vyhlásenie o zhode

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Strana	**2 / 3**

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

Názov výrobku	**Kategória zariadenia**
Mobile Patient Watch	Bedside information system application software
Použité normy v úplnom alebo v čiastočnom znení:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
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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
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

Drägerwerk AG & Co. KGaA
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Izjava EU o skladnosti

Št. dokumenta	**MDR107-039-2503-001-0**
Datum	**2025-03-18**
Kraj	**Germany - Lübeck**
Stran	**1 / 3**

Drägerwerk AG & Co. KGaA
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EC Certificate: G10 010578 0039
Valid until: 2030-03-17

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

izjavlja z vso odgovornostjo, da

Ime izdelka	Kategorija naprave	Razred naprave	Koda UMDNS / Koda GMDN / Koda EMDN
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

izpolnjuje naslednje določbe:

EVROPSKA UREDBA (EU) 2017/745 o medicinskih pripomočkih. Sistem upravljanja kakovosti je na podlagi Priloge IX (poglavji I in III in razdelek 4) uredbe preveril priglašeni organ: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sistem upravljanja kakovosti je skladen tudi z EN ISO 9001 in EN ISO 13485.

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

To je prevod originalnega dokumenta (en/de) in zato ni podpisan.
For the signature on behalf of Dräger see the Document Release Sign-Off Page on page 1./
Für die Unterschrift im Namen von Dräger siehe "Document Release Sign-Off Page" auf Seite 1.

Leiter Program Dräger ONE
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Jakob Kleissl

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Št. dokumenta	**MDR107-039-2503-001-0**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Ime izdelka	**Kategorija naprave**
Mobile Patient Watch	Bedside information system application software
V celoti ali deloma uporabljeni standardi:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
EN 62366-1:2015+A1:2020 *(IEC 62366-1:2015 COR 1 2016 AMD 1:2020)*	Medical devices - Part 1: Application of usability engineering to medical devices
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Germany

Obseg ugotavljanja skladnosti		
Kataloška številka	Ime izdelka	Basic UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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Registered office: Lübeck
Commercial register:
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General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
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Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR107-039-2503-001-0**
Päivämäärä	**2025-03-18**
Paikka	**Germany - Lübeck**
Sivu	**1 / 3**

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

EC Certificate: G10 010578 0039
Valid until: 2030-03-17

Rekisterinumero: DE-MF-000005329

vakuuttaa täten yksinomaisella vastuullaan, että

Tuotenimi	Laitteen luokitus	Laiteluokka	UMDNS-koodi / GMDN-koodi / EMDN-koodi
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

täyttää seuraavat vaatimukset:

EUROOPAN PARLAMENTIN JA NEUVOSTON ASETUS (EU) 2017/745 lääkinnällisistä laitteista. Laatujärjestelmän on tarkastanut asetuksen liitettä IX (I ja III luvun 4 kohtaa) noudattaen seuraava ilmoitettu laitos: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Laatujärjestelmä täyttää lisäksi standardien EN ISO 9001 ja EN ISO 13485 vaatimukset.

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

Tämä on alkuperäisen (saksan-/englanninkielisen) asiakirjan käännös, eikä siinä siksi ole allekirjoitusta.
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Für die Unterschrift im Namen von Dräger siehe "Document Release Sign-Off Page" auf Seite 1.

Leiter Program Dräger ONE
BU Patient Monitoring
Medical Division

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Regulatory Affairs Manager
Program Dräger ONE
BU Patient Monitoring
Medical Division

Florian Zechlin

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Sivu	**2 / 3**

Drägerwerk AG & Co. KGaA
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Tuotenimi	**Laitteen luokitus**
Mobile Patient Watch	Bedside information system application software
Kokonaan tai osittain sovellettavat standardit:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
EN 82304-1:2017 *(ISO/IEC 82304-1:2016)*	Health software -- Part 1: General requirements for product safety
EN IEC 81001-5-1:2021 *(IEC 81001-5-1:2021)*	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
EN 62366-1:2015+A1:2020 *(IEC 62366-1:2015 COR 1 2016 AMD 1:2020)*	Medical devices - Part 1: Application of usability engineering to medical devices
IEC TR 60601-4-5:2021	Medical electrical equipment – Part 4-5 Guidance and Interpretation – Safety related technical security specifications for medical devices
EN ISO 14971:2019+A11:2021 *(ISO 14971:2019)*	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – part 1: General requirements
EN ISO 13485:2016 *(ISO 13485:2016)*	Medical Devices; Quality management systems; Requirements for Regulatory Purposes
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer

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Sivu	**3 / 3**

Drägerwerk AG & Co. KGaA
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Vaatimustenmukaisuuden arvioinnin laajuus		
Osanumero	Tuotenimi	Yksilöllinen UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9

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EU-försäkran om överensstämmelse

Dokument nr.	**MDR107-039-2503-001-0**
Datum	**2025-03-18**
Plats	**Germany - Lübeck**
Sida	**1 / 3**

Drägerwerk AG & Co. KGaA
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EC Certificate: G10 010578 0039
Valid until: 2030-03-17

Enkelt registreringsnummer (SRN): DE-MF-000005329

förklarar härmed under sitt eget ansvar att

Produktnamn	Enhetskategori	Enhetsklass	UMDNS-kod / GMDN-kod / EMDN-kod
Mobile Patient Watch	Bedside information system application software	IIb	UMDNS 17223/ GMDN 44101/ EMDN Z12040192

uppfyller följande bestämmelser:

EUROPEISKA FÖRORDNINGEN (EU) 2017/745 om medicintekniska produkter. En undersökning av kvalitetshanteringssystemet har utförts enligt bilaga IX (kapitel I och III och avsnitt 4) till förordningen av det anmälda organet: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitetshanteringssystemet uppfyller även EN ISO 9001 och EN ISO 13485.

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

Detta är en översättning av originaldokument (en/de) och därför har det inte någon signatur.
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Drägerwerk AG & Co. KGaA
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Produktnamn	**Enhetskategori**
Mobile Patient Watch	Bedside information system application software
Helt eller delvis tillämpade standarder:	
EN 62304:2006+A1:2015 *(IEC 62304:2006 AMD 1 2015)*	Medical device software - Software life-cycle processes
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Sida	**3 / 3**

Drägerwerk AG & Co. KGaA
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Omfattning bedömning av överensstämmelse		
Artikelnummer	Produktnamn	Bas UDI-DI
MS90154	MPW SW 02.xx	040486751307039XK29Z000K9