en/de

EU Declaration of Conformity
EU-Konformitätserklärung

CE 0123

Document No. / Dokument Nr.	**MDR206-012-2208-001-0**
Date / Datum	**2022-08-15**
Place / Ort	**USA - Telford**
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Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Authorised representative /
Europäischer Bevollmächtigter:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Single registration number (SRN)/
einmalige Registrierungsnummer:

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

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
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

meets the following provisions:
mit den folgenden Bestimmungen übereinstimmt:

European regulation (EU) 2017/745 on medical devices. An examination of the quality management System has been carried out following Annex IX (Chapters I and III and section 4) of the regulation by the Notified Body:/ Verordnung (EU) 2017/745 über Medizinprodukte. Eine Überprüfung des Qualitätsmanagementsystems, nach den Regeln wie in Anhang IX (Kapitel I and III und Abschnitt 4) der Verordnung beschrieben, wurde durch die Benannte Stelle vorgenommen: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
The quality management system also complies to EN ISO 9001 and EN ISO 13485./ Das Qualitätsmanagementsystem erfüllt weiterhin die Anforderungen gemäß EN ISO 9001 und EN ISO 13485.
Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment/ Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten

Draeger Medical Systems, Inc.
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Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments /

Richtlinie 2014/31/EU DES EUROPÄISCHEN PARLAMENTS UND DES RATES vom 26. Februar 2014 zur Angleichung der Rechtsvorschriften der Mitgliedstaaten betreffend die Bereitstellung nichtselbsttätiger Waagen auf dem Markt

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.

Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Digitally signed by Tom Hirte
Date: 2022.08.18 08:40:30 -04'00'

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau
Digitally signed by Darlene Thibodeau
Date: 2022.08.18 09:23:03 -04'00'

Darlene Thibodeau

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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Product Name / Produktbezeichnung	**Device Category / Produktkategorie**
Babyroo TN300	**Infant Radiant Warmer**
Applied Standards in full or in part / Vollständig oder teilweise angewendete Normen:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 62366-1: 2015 COR 1 2016	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304: 2006/A1: 2015	Medical device software – Software lifecycle processes
IEC 60601-2-21: 2009/A1: 2016	Medical electrical equipment – Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers
IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 18562-1: 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process

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ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
ISO 17664: 2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 17664-2: 2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
EN 50419: 2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Extend of conformity assessment / Umfang der Konformitätsbewertung		
Part Number / Sachnummer	Product Name / Produktbezeichnung	Basic UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

bg

CE 0123

ЕС декларация за съответствие

Документ №	**MDR206-012-2208-001-0**
Дата	**2022-08-15**
Място	**USA - Telford**
Страница	**1 / 5**

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Еднократен регистрационен номер (SRN): Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

с настоящото декларира на своя отговорност, че

Име на продукта	Категория на уреда	Клас на уреда	Код UMDNS / Код GMDN / Код EMDN
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

отговаря на следните разпоредби:

ЕВРОПЕЙСКИ РЕГЛАМЕНТ (ЕС) 2017/745 относно медицински изделия. Извършено е проучване на системата за управление на качеството в съответствие с анекс IX (глави I и III и раздел 4) на регламента от нотифицирания орган: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Системата за управление на качеството също отговаря на EN ISO 9001 и EN ISO 13485.
ДИРЕКТИВА 2011/65/ЕС НА ЕВРОПЕЙСКИЯ ПАРЛАМЕНТ И НА СЪВЕТА от 8 юни 2011 година относно ограничението за употребата на определени опасни вещества в електрическото и електронното оборудване
ДИРЕКТИВА 2014/31/ЕС НА ЕВРОПЕЙСКИЯ ПАРЛАМЕНТ И НА СЪВЕТА от 26 февруари 2014 година за хармонизиране на законодателствата на държавите членки за предоставянето на пазара на везни с неавтоматично действие

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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ЕС декларация за съответствие

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Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

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Дата **2022-08-15**
Място **USA - Telford**

Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Име на продукта	**Категория на уреда**
Babyroo TN300	**Infant Radiant Warmer**
Напълно или частично приложени стандарти:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 62366-1: 2015 COR 1 2016	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304: 2006/A1: 2015	Medical device software – Software lifecycle processes
IEC 60601-2-21: 2009/A1: 2016	Medical electrical equipment – Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers
IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 18562-1: 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

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ЕС декларация за съответствие

ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
ISO 17664: 2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 17664-2: 2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
EN 50419: 2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

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ЕС декларация за съответствие

Документ №	**MDR206-012-2208-001-0**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Обхват на оценката на съответствие		
Номер на частта	Име на продукта	Основен идентификатор UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

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Declaración UE de conformidad

N.º de documento	**MDR206-012-2208-001-0**
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Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Representante autorizado:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Número de registro único (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

por la presente declara bajo su exclusiva responsabilidad que

Nombre del producto	Categoría del dispositivo	Clase del dispositivo	Código UMDNS / Código GMDN / Código EMDN
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

cumple las siguientes disposiciones:

REGLAMENTO EUROPEO (UE) 2017/745 sobre los productos sanitarios. Se ha efectuado un examen del sistema de gestión de la calidad siguiendo el anexo IX (capítulos I y III y sección 4) del reglamento del organismo notificado: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
El sistema de gestión de la calidad también cumple con EN ISO 9001 y EN ISO 13485.
DIRECTIVA 2011/65/UE DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos
DIRECTIVA 2014/31/UE DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 26 de febrero de 2014 sobre la armonización de las legislaciones de los Estados miembros en materia de comercialización de instrumentos de pesaje de funcionamiento no automático

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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Declaración UE de conformidad

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Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Nombre del producto	**Categoría del dispositivo**
Babyroo TN300	**Infant Radiant Warmer**
Normas aplicadas total o parcialmente:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
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IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
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IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 18562-1: 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Declaración UE de conformidad

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ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
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ISO 17664-2: 2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
EN 50419: 2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Alcance de la evaluación de conformidad		
Número de referencia	Nombre del producto	UDI-DI básico
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

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EU prohlášení o shodě

Č. dokumentu	**MDR206-012-2208-001-0**
Datum	**2022-08-15**
Místo	**USA - Telford**
Strana	**1 / 5**

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Zplnomocněným zástupcem:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Jednorázové registračních číslo (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

tímto prohlašuje na svou výhradní zodpovědnost, že

Název produktu	Kategorie prostředku	Třída prostředku	Kód UMDNS / Kód GMDN / Kód EMDN
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

splňuje následující ustanovení:

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY (EU) 2017/745 o zdravotnických prostředcích. Kontrola systému managementu kvality byla provedena oznámeným subjektem podle přílohy IX (kapitol I a III a oddílu 4) nařízení: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Systém managementu kvality splňuje rovněž požadavky norem EN ISO 9001 a EN ISO 13485.
SMĚRNICE EVROPSKÉHO PARLAMENTU A RADY 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních
SMĚRNICE EVROPSKÉHO PARLAMENTU A RADY 2014/31/EU ze dne 26. února 2014 o harmonizaci právních předpisů členských států týkajících se dodávání vah s neautomatickou činností na trh

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.

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EU prohlášení o shodě

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Č. dokumentu	**MDR206-012-2208-001-0**
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Strana	**2 / 5**

Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

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EU prohlášení o shodě

Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Název produktu	**Kategorie prostředku**
Babyroo TN300	**Infant Radiant Warmer**
Použité normy, v celku nebo z části:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 62366-1: 2015 COR 1 2016	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
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IEC 60601-2-21: 2009/A1: 2016	Medical electrical equipment – Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers
IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 18562-1: 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

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EU prohlášení o shodě

ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
ISO 17664: 2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 17664-2: 2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
EN 50419: 2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

CE 0123

EU prohlášení o shodě

Č. dokumentu	**MDR206-012-2208-001-0**
Datum	**2022-08-15**
Místo	**USA - Telford**
Strana	**5 / 5**

Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Rozsah posuzování shody		
Číslo dílu	Název produktu	Základní UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

da

CE 0123

EU-overensstemmelseserklæring

Dokumentnr.	**MDR206-012-2208-001-0**
Dato	**2022-08-15**
Sted	**USA - Telford**
Side	**1 / 5**

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Autoriseret repræsentant:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Individuelt registreringsnummer (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

erklærer hermed på eget ansvar, at

Produktnavn	Apparatkategori	Apparatklasse	UMDNS-kode / GMDN-kode / EMDN-kode
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

opfylder følgende bestemmelser:

EUROPÆISK FORORDNING (EU) 2017/745 om medicinsk udstyr. En undersøgelse af kvalitetsstyringssystemet er blevet foretaget i overensstemmelse med bilag IX (kapitel I og III og afsnit 4) til forordningen af det bemyndigede organ: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitetsstyringssystemet overholder ligeledes EN ISO 9001 og EN ISO 13485.
EUROPA-PARLAMENTETS OG RÅDETS DIREKTIV 2011/65/EU af 8. juni 2011 om begrænsning af anvendelsen af visse farlige stoffer i elektrisk og elektronisk udstyr
EUROPA-PARLAMENTETS OG RÅDETS DIREKTIV 2014/31/EU af 26. februar 2014 om harmonisering af medlemsstaternes lovgivning vedrørende tilgængeliggørelse på markedet af ikke-automatiske vægte

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.

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969 USA
Tel +1 215 721 5400
Fax +1 215 721 5424
info@draeger.com
www.draeger.com

da

CE 0123

EU-overensstemmelseserklæring

Dokumentnr.	**MDR206-012-2208-001-0**
Dato	**2022-08-15**
Sted	**USA - Telford**
Side	**2 / 5**

Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

Draeger Medical Systems, Inc.
3135 Quarry Road
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EU-overensstemmelseserklæring

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Dokumentnr.	**MDR206-012-2208-001-0**
Dato	**2022-08-15**
Sted	**USA - Telford**
Side	**3 / 5**

Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Produktnavn	**Apparatkategori**
Babyroo TN300	**Infant Radiant Warmer**
Standarder, der anvendes helt eller delvist:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 62366-1: 2015 COR 1 2016	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304: 2006/A1: 2015	Medical device software – Software lifecycle processes
IEC 60601-2-21: 2009/A1: 2016	Medical electrical equipment – Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers
IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 18562-1: 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

EU-overensstemmelseserklæring

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EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
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EU-overensstemmelseserklæring

Dokumentnr.	**MDR206-012-2208-001-0**
Dato	**2022-08-15**
Sted	**USA - Telford**
Side	**5 / 5**

Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Overensstemmelsesvurderingens omfang		
Varenummer	Produktnavn	Basic UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

et

CE 0123

ELi vastavusdeklaratsioon

Dokumendi nr	**MDR206-012-2208-001-0**
Kuupäev	**2022-08-15**
Koht	**USA - Telford**
Lk	**1 / 5**

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Volitatud esindaja:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Kordumatu registreerimisnumber (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

kinnitab käesolevaga oma ainuvastutusel, et

Toote nimi	Seadme kategooria	Seadme klass	UMDNS-kood / GMDN-kood / EMDN-kood
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

vastab järgmistele nõuetele:

EUROOPA MÄÄRUS (EL) 2017/745 meditsiiniseadmete kohta. Kvaliteedijuhtimise süsteemi on hinnatud teavitatud asutuses määruse IX lisa (peatükid I ja III ning jaotis 4) alusel: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvaliteedikontrolli süsteem vastab ka standarditele EN ISO 9001 ja EN ISO 13485.
EUROOPA PARLAMENDI JA NÕUKOGU DIREKTIIV 2011/65/EL, 8. juuni 2011, teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes
EUROOPA PARLAMENDI JA NÕUKOGU DIREKTIIV 2014/31/EL, 26. veebruar 2014, mitteautomaatkaalude turul kättesaadavaks tegemist käsitlevate liikmesriikide õigusaktide ühtlustamise kohta

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.

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969 USA
Tel +1 215 721 5400
Fax +1 215 721 5424
info@draeger.com
www.draeger.com

CE 0123

ELi vastavusdeklaratsioon

Dokumendi nr	**MDR206-012-2208-001-0**
Kuupäev	**2022-08-15**
Koht	**USA - Telford**
Lk	**2 / 5**

Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969 USA
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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR206-012-2208-001-0**
Kuupäev	**2022-08-15**
Koht	**USA - Telford**
Lk	**3 / 5**

Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Toote nimi	**Seadme kategooria**
Babyroo TN300	**Infant Radiant Warmer**
Osaliselt või täielikult kohaldatud standardid:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
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IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304: 2006/A1: 2015	Medical device software – Software lifecycle processes
IEC 60601-2-21: 2009/A1: 2016	Medical electrical equipment – Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers
IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
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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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ELi vastavusdeklaratsioon

ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
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EN 50419: 2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

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ELi vastavusdeklaratsioon

Dokumendi nr	**MDR206-012-2208-001-0**
Kuupäev	**2022-08-15**
Koht	**USA - Telford**
Lk	**5 / 5**

Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Vastavushinnangu ulatus		
Osa number	Toote nimi	Peamine UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

CE 0123

Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR206-012-2208-001-0**
Ημερομηνία	**2022-08-15**
Τοποθεσία	**USA - Telford**
Σελίδα	**1 / 5**

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Εξουσιοδοτημένος αντιπρόσωπος:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Μεμονωμένος αριθμός εγγραφής (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

δηλώνει με αποκλειστική ευθύνη ότι

Όνομα προϊόντος	Κατηγορία συσκευής	Κλάση συσκευής	Κωδικός UMDNS / Κωδικός GMDN / Κωδικός EMDN
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

συμμορφώνεται με τις ακόλουθες διατάξεις:

Ευρωπαϊκός κανονισμός (ΕΕ) 2017/745 περί ιατροτεχνολογικών προϊόντων. Πραγματοποιήθηκε έλεγχος του συστήματος διαχείρισης ποιότητας σύμφωνα με το παράρτημα IX (κεφάλαια I και III και ενότητα 4) του κανονισμού από τον κοινοποιημένο οργανισμό: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Το σύστημα διαχείρισης ποιότητας συμμορφώνεται επίσης με τα πρότυπα EN ISO 9001 και EN ISO 13485.
ΟΔΗΓΙΑ 2011/65/ΕΕ ΤΟΥ ΕΥΡΩΠΑΪΚΟΥ ΚΟΙΝΟΒΟΥΛΙΟΥ ΚΑΙ ΤΟΥ ΣΥΜΒΟΥΛΙΟΥ της 8ης Ιουνίου 2011 για τον περιορισμό της χρήσης ορισμένων επικίνδυνων ουσιών σε ηλεκτρικό και ηλεκτρονικό εξοπλισμό
ΟΔΗΓΙΑ 2014/31/ΕΕ ΤΟΥ ΕΥΡΩΠΑΪΚΟΥ ΚΟΙΝΟΒΟΥΛΙΟΥ ΚΑΙ ΤΟΥ ΣΥΜΒΟΥΛΙΟΥ της 26ης Φεβρουαρίου 2014 για την εναρμόνιση των νομοθεσιών των κρατών μελών σχετικά με τη διαθεσιμότητα στην αγορά οργάνων ζύγισης μη αυτόματης λειτουργίας

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

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

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR206-012-2208-001-0**
Ημερομηνία	**2022-08-15**
Τοποθεσία	**USA - Telford**
Σελίδα	**2 / 5**

Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR206-012-2208-001-0**
Ημερομηνία	**2022-08-15**
Τοποθεσία	**USA - Telford**
Σελίδα	**3 / 5**

Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Όνομα προϊόντος	**Κατηγορία συσκευής**
Babyroo TN300	**Infant Radiant Warmer**
Πρότυπα που εφαρμόζονται πλήρως ή εν μέρει:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
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Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR206-012-2208-001-0**
Ημερομηνία	**2022-08-15**
Τοποθεσία	**USA - Telford**
Σελίδα	**4 / 5**

ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
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EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
EN 50419: 2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

CE 0123

Δήλωση συμμόρφωσης ΕΕ

Αρ. εγγράφου	**MDR206-012-2208-001-0**
Ημερομηνία	**2022-08-15**
Τοποθεσία	**USA - Telford**
Σελίδα	**5 / 5**

Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Επέκταση αξιολόγησης της συμμόρφωσης		
Αριθμός εξαρτήματος	Όνομα προϊόντος	Βασικό UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

CE 0123

Déclaration de conformité UE

N° du document	**MDR206-012-2208-001-0**
Date	**2022-08-15**
Ville	**USA - Telford**
Page	**1 / 5**

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Mandataire:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Numéro d'enregistrement unique (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

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
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

satisfait aux dispositions suivantes :

RÉGLEMENTATION EUROPÉENNE (UE) 2017/745 sur les dispositifs médicaux. Une vérification du système de gestion de la qualité a été réalisée conformément à l'annexe IX (chapitres I et III, ainsi que section 4) de la réglementation suivante par l'organisme notifié : **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Le système de gestion de la qualité satisfait également aux normes EN ISO 9001 et EN ISO 13485.
DIRECTIVE 2011/65/UE DU PARLEMENT EUROPÉEN ET DU CONSEIL du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques
DIRECTIVE 2014/31/UE DU PARLEMENT EUROPÉEN ET DU CONSEIL du 26 février 2014 relative à l'harmonisation des législations des États membres concernant la mise à disposition sur le marché des instruments de pesage à fonctionnement non automatique

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.

Draeger Medical Systems, Inc.
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info@draeger.com
www.draeger.com

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Déclaration de conformité UE

N° du document	**MDR206-012-2208-001-0**
Date	**2022-08-15**
Ville	**USA - Telford**
Page	**2 / 5**

Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

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info@draeger.com
www.draeger.com

CE 0123

Déclaration de conformité UE

N° du document	**MDR206-012-2208-001-0**
Date	**2022-08-15**
Ville	**USA - Telford**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Nom du produit	**Catégorie de l'appareil**
Babyroo TN300	**Infant Radiant Warmer**
Normes appliquées en totalité ou en partie :	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 62366-1: 2015 COR 1 2016	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304: 2006/A1: 2015	Medical device software – Software lifecycle processes
IEC 60601-2-21: 2009/A1: 2016	Medical electrical equipment – Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers
IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 18562-1: 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

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ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
ISO 17664: 2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 17664-2: 2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Étendue de l'évaluation de la conformité		
Référence de pièce	Nom du produit	IUD-ID de base
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

hr

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EU izjava o sukladnosti

Br. dokumenta	**MDR206-012-2208-001-0**
Datum	**2022-08-15**
Mjesto	**USA - Telford**
Stranica	**1 / 5**

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Ovlašteni zastupnik:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Jedinstveni registracijski broj (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

ovime izjavljuje pod vlastitom odgovornošću da je

Naziv proizvoda	Kategorija proizvoda	Razred proizvoda	UMDNS kod / GMDN kod / EMDN kod
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

sukladan sa sljedećim odredbama:

UREDBA (EU) 2017/745 o medicinskim proizvodima. Ocjena sustava upravljanja kvalitetom provedena je prema Prilogu IX. (poglavlju I. i III. i stavku 4.) uredbe od strane prijavljenog tijela: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sustav upravljanja kvalitetom također je sukladan normama EN ISO 9001 i EN ISO 13485.
DIREKTIVA 2011/65/EU EUROPSKOG PARLAMENTA I VIJEĆA od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi
DIREKTIVA 2014/31/EU EUROPSKOG PARLAMENTA I VIJEĆA od 26. veljače 2014. o usklađivanju zakonodavstava država članica u odnosu na stavljanje na raspolaganje neautomatskih vaga na tržište

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.

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969 USA
Tel +1 215 721 5400
Fax +1 215 721 5424
info@draeger.com
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EU izjava o sukladnosti

Br. dokumenta	**MDR206-012-2208-001-0**
Datum	**2022-08-15**
Mjesto	**USA - Telford**
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Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969 USA
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EU izjava o sukladnosti

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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Naziv proizvoda	**Kategorija proizvoda**
Babyroo TN300	**Infant Radiant Warmer**
Norme primijenjene u cijelosti ili djelomično:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 62366-1: 2015 COR 1 2016	Medical devices – Part 1: Application of usability engineering to medical devices
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IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
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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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EU izjava o sukladnosti

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EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
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EU izjava o sukladnosti

Br. dokumenta	**MDR206-012-2208-001-0**
Datum	**2022-08-15**
Mjesto	**USA - Telford**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Opseg ocjene sukladnosti		
Broj dijela	Naziv proizvoda	Osnovni UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

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Dichiarazione di conformità UE

N. documento	**MDR206-012-2208-001-0**
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Luogo	**USA - Telford**
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Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Mandatario:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Numero di registrazione unico (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

dichiara con la presente sotto la propria responsabilità che

Nome prodotto	Categoria dispositivo	Classe dispositivo	Codice UMDNS / Codice GMDN / Codice EMDN
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

è conforme alle seguenti disposizioni:

REGOLAMENTO EUROPEO (UE) 2017/745 relativo ai dispositivi medici. È stata effettuata una verifica del sistema di gestione della qualità ai sensi dell'allegato IX (capitoli I e III e sezione 4) del regolamento dell'organismo notificato: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Il sistema di gestione della qualità è altresì conforme alle norme EN ISO 9001 e EN ISO 13485.
DIRETTIVA 2011/65/UE DEL PARLAMENTO EUROPEO E DEL CONSIGLIO dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche
DIRETTIVA 2014/31/UE DEL PARLAMENTO EUROPEO E DEL CONSIGLIO del 26 febbraio 2014 concernente l'armonizzazione delle legislazioni degli Stati membri relative alla messa a disposizione sul mercato di strumenti per pesare a funzionamento non automatico

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.

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Dichiarazione di conformità UE

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Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

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Dichiarazione di conformità UE

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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Nome prodotto	**Categoria dispositivo**
Babyroo TN300	**Infant Radiant Warmer**
Standard applicati integralmente o parzialmente:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
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Dichiarazione di conformità UE

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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Estensione della valutazione di conformità		
Numero d'ordine	Nome prodotto	UDI-DI di base
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

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ES atbilstības deklarācija

Dokumenta Nr.	**MDR206-012-2208-001-0**
Datums	**2022-08-15**
Vieta	**USA - Telford**
Lappuse	**1 / 5**

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Pilnvarotais pārstāvis:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Vienotais reģistrācijas numurs (VRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

pilnībā atbildot par to, apliecina, ka

Izstrādājuma nosaukums	Ierīces kategorija	Ierīces klase	UMDNS kods / GMDN kods / EMDN kods
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

atbilst šādiem noteikumiem:

EIROPAS REGULA (ES) 2017/745 par medicīnas ierīcēm. Kvalitātes vadības sistēmas pārbaudi veikusi pilnvarotā iestāde saskaņā ar regulas IX. pielikumu (nodaļas I un III, 4. sadaļa): **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitātes vadības sistēma atbilst arī EN ISO 9001 un EN ISO 13485.
EIROPAS PARLAMENTA UN PADOMES DIREKTĪVA 2011/65/ES (2011. gada 8. jūnijs) par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās
EIROPAS PARLAMENTA UN PADOMES DIREKTĪVA 2014/31/ES (2014. gada 26. februāris) par dalībvalstu tiesību aktu saskaņošanu attiecībā uz neautomātisko svaru pieejamību tirgū

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.

Draeger Medical Systems, Inc.
3135 Quarry Road
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ES atbilstības deklarācija

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Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

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Senior Director of QA & Compliance Medical / Safety

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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Izstrādājuma nosaukums	**Ierīces kategorija**
Babyroo TN300	**Infant Radiant Warmer**
Pilnībā vai daļēji piemērotie standarti:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
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ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Atbilstības novērtēšanas pagarinājums		
Daļas numurs	Izstrādājuma nosaukums	Pamata UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

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ES atitikties deklaracija

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Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Įgaliotasis atstovas:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Bendrasis registracijos numeris (BRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

prisiimdami visą atsakomybę pareiškia, kad:

Prietaiso pavadinimas	Prietaiso kategorija	Prietaiso klasė	UMDNS kodas / GMDN kodas / EMDN kodas
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

atitinka šias nuostatas:

EUROPOS PARLAMENTO IR TARYBOS REGLAMENTA (ES) 2017/745 dėl medicinos prietaisų. Notifikuotoji įstaiga, atlikusi kokybės valdymo sistemos patikrinimą pagal reglamento IX priedą (I ir III skyrius bei 4 skirsnį): **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kokybės valdymo sistema taip pat atitinka EN ISO 9001 ir EN ISO 13485 standartus.
EUROPOS PARLAMENTO IR TARYBOS DIREKTYVA 2011/65/ES 2011 m. birželio 8 d. dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo
EUROPOS PARLAMENTO IR TARYBOS DIREKTYVA 2014/31/ES 2014 m. vasario 26 d. dėl valstybių narių įstatymų, susijusių su neautomatinių svarstyklių tiekimu rinkai, suderinimo

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.

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969 USA
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ES atitikties deklaracija

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Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

Draeger Medical Systems, Inc.
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info@draeger.com
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CE 0123

ES atitikties deklaracija

Dokumento Nr.	**MDR206-012-2208-001-0**
Data	**2022-08-15**
Vieta	**USA - Telford**
Psl.	**3 / 5**

Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Prietaiso pavadinimas	**Prietaiso kategorija**
Babyroo TN300	**Infant Radiant Warmer**
Iš dalies ar visa apimtimi taikyti standartai:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 62366-1: 2015 COR 1 2016	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304: 2006/A1: 2015	Medical device software – Software lifecycle processes
IEC 60601-2-21: 2009/A1: 2016	Medical electrical equipment – Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers
IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 18562-1: 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

ES atitikties deklaracija

ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
ISO 17664: 2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 17664-2: 2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
EN 50419: 2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

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ES atitikties deklaracija

Dokumento Nr.	**MDR206-012-2208-001-0**
Data	**2022-08-15**
Vieta	**USA - Telford**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Išsami informacija apie atitikties vertinimą		
Prekės kodas	Prietaiso pavadinimas	Pagrindinis UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

CE 0123

EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR206-012-2208-001-0**
Dátum	**2022-08-15**
Hely	**USA - Telford**
Oldal	**1 / 5**

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Meghatalmazott képviselő:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Egyedi regisztrációs szám (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

saját kizárólagos felelősségére kijelenti, hogy a

Termék neve	Készülékkategória	Készülékosztály	UMDNS-kód / GMDN-kód / EMDN-kód
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

megfelel a következő rendelkezéseknek:

AZ EURÓPAI PARLAMENT ÉS A TANÁCS (EU) 2017/745 RENDELETE az orvostechnikai eszközökről. A minőségirányítási rendszer vizsgálatát a bejelentett szervezet az irányelv IX. melléklete (az I. és III. fejezet és a 4. szakasz) szerint végezte: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
A minőségirányítási rendszer megfelel továbbá az EN ISO 9001 és az EN ISO 13485 szabványoknak is.
AZ EURÓPAI PARLAMENT ÉS A TANÁCS 2011/65/EU IRÁNYELVE (2011. június 8.) egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról
AZ EURÓPAI PARLAMENT ÉS A TANÁCS 2014/31/EU IRÁNYELVE (2014. február 26.) a nem automatikus működésű mérlegek forgalmazására vonatkozó tagállami jogszabályok harmonizációjáról

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.

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EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR206-012-2208-001-0**
Dátum	**2022-08-15**
Hely	**USA - Telford**
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Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Termék neve	**Készülékkategória**
Babyroo TN300	**Infant Radiant Warmer**
Teljesen vagy részben alkalmazott szabványok:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 62366-1: 2015 COR 1 2016	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304: 2006/A1: 2015	Medical device software – Software lifecycle processes
IEC 60601-2-21: 2009/A1: 2016	Medical electrical equipment – Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers
IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 18562-1: 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

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EU megfelelőségi nyilatkozat

ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
ISO 17664: 2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 17664-2: 2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
EN 50419: 2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

CE 0123

EU megfelelőségi nyilatkozat

Dokumentum száma	**MDR206-012-2208-001-0**
Dátum	**2022-08-15**
Hely	**USA - Telford**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

A megfelelőségértékelés meghosszabbítása		
Cikkszám	Termék neve	Alapvető UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

CE 0123

EU-verklaring van overeenstemming

Documentnr.	**MDR206-012-2208-001-0**
Datum	**2022-08-15**
Plaats	**USA - Telford**
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Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Gemachtigde:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Enkelvoudig registratienummer (SRN): Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

verklaart hierbij onder haar volledige eigen verantwoordelijkheid dat

Productnaam	Apparaatcategorie	Apparaatklasse	UMDNS-code / GMDN-code / EMDN-code
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

voldoet aan de volgende bepalingen:

EUROPESE VERORDENING (EU) 2017/745 voor medische hulpmiddelen. De aangemelde instantie heeft het kwaliteitsborgingssysteem onderzocht overeenkomstig Bijlage IX (hoofdstukken I en III en deel 4) van de verordening: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Het kwaliteitsmanagementsysteem voldoet ook aan EN ISO 9001 en EN ISO 13485.
RICHTLIJN 2011/65/EU VAN HET EUROPEES PARLEMENT EN DE RAAD van 8 juni 2011 betreffende beperking van het gebruik van bepaalde gevaarlijke stoffen in elektrische en elektronische apparatuur.
RICHTLIJN 2014/31/EU VAN HET EUROPEES PARLEMENT EN DE RAAD van 26 februari 2014 betreffende de harmonisatie van de wetgevingen van de lidstaten inzake het op de markt aanbieden van niet-automatische weegwerktuigen

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

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

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EU-verklaring van overeenstemming

Documentnr.	**MDR206-012-2208-001-0**
Datum	**2022-08-15**
Plaats	**USA - Telford**
Pagina	**2 / 5**

Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

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EU-verklaring van overeenstemming

Documentnr.	**MDR206-012-2208-001-0**
Datum	**2022-08-15**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Productnaam	**Apparaatcategorie**
Babyroo TN300	**Infant Radiant Warmer**
Volledig of gedeeltelijk toegepaste normen:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
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IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
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ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 18562-1: 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

EU-verklaring van overeenstemming

ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
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EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
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EU-verklaring van overeenstemming

Documentnr.	**MDR206-012-2208-001-0**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Reikwijdte van conformiteitsbeoordeling		
Onderdeelnummer	Productnaam	Basis UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

CE 0123

Deklaracja zgodności UE

Nr dokumentu	**MDR206-012-2208-001-0**
Data	**2022-08-15**
Miejsce	**USA - Telford**
Strona	**1 / 5**

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Upoważniony przedstawiciel:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Pojedynczy numer rejestracyjny (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

deklaruje niniejszym na swoją wyłączną odpowiedzialność, że

Nazwa produktu	Kategoria urządzenia	Klasa urządzenia	Kod UMDNS / Kod GMDN / Kod EMDN
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

spełnia wymogi następujących przepisów:

ROZPORZĄDZENIE PARLAMENTU EUROPEJSKIEGO I RADY (EU) 2017/745 w sprawie wyrobów medycznych. Zostało przeprowadzone badanie systemu zarządzania jakością zgodnie z Załącznikiem IX (rozdziały I i III, sekcja 4) Rozporządzenia przez jednostkę notyfikowaną: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
System zarządzania jakością spełnia też normy EN ISO 9001 i EN ISO 13485.
DYREKTYWA PARLAMENTU EUROPEJSKIEGO I RADY 2011/65/UE z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym
DYREKTYWA PARLAMENTU EUROPEJSKIEGO I RADY 2014/31/UE z dnia 26 lutego 2014 r. w sprawie harmonizacji ustawodawstw państw członkowskich odnoszących się do udostępniania na rynku wag nieautomatycznych

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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Deklaracja zgodności UE

Nr dokumentu	**MDR206-012-2208-001-0**
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Senior Director of Regulatory Affairs
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Deklaracja zgodności UE

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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Nazwa produktu	**Kategoria urządzenia**
Babyroo TN300	**Infant Radiant Warmer**
Zastosowane normy (w całości lub w części):	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 62366-1: 2015 COR 1 2016	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
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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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Deklaracja zgodności UE

ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
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Deklaracja zgodności UE

Nr dokumentu	**MDR206-012-2208-001-0**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Zakres oceny zgodności		
Numer części	Nazwa produktu	Basic UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

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Declaração de conformidade da UE

Nº. do documento	**MDR206-012-2208-001-0**
Data	**2022-08-15**
Local	**USA - Telford**
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Draeger Medical Systems, Inc.
3135 Quarry Road
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Mandatário:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

O número de registro único (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

declara, sob exclusiva responsabilidade, que

Nome do produto	Categoria do equipamento	Classe do equipamento	Código UMDNS / Código GMDN / Código EMDN
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

está em conformidade com as seguintes disposições:

REGULAMENTO (UE) 2017/745 relativo aos dispositivos médicos. Um exame do sistema de gerenciamento de qualidade foi realizado seguindo o Anexo IX (Capítulos I e III e a seção 4) do regulamento pelo Órgão notificado: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
O sistema de gerenciamento de qualidade também está em conformidade com a EN ISO 9001 e a EN ISO 13485.
DIRETIVA 2011/65/UE DO PARLAMENTO EUROPEU E DO CONSELHO de 8 de junho de 2011 relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrônicos
DIRETIVA 2014/31/UE DO PARLAMENTO EUROPEU E DO CONSELHO de 26 de fevereiro de 2014 relativa à harmonização da legislação dos Estados-Membros respeitante à disponibilização de instrumentos de pesagem não automáticos no mercado

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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Declaração de conformidade da UE

Nº. do documento	**MDR206-012-2208-001-0**
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Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

Draeger Medical Systems, Inc.
3135 Quarry Road
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Tel +1 215 721 5400
Fax +1 215 721 5424
info@draeger.com
www.draeger.com

Declaração de conformidade da UE

CE 0123

Nº. do documento	**MDR206-012-2208-001-0**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Nome do produto	**Categoria do equipamento**
Babyroo TN300	**Infant Radiant Warmer**
Normas aplicadas total ou parcialmente:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 62366-1: 2015 COR 1 2016	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304: 2006/A1: 2015	Medical device software – Software lifecycle processes
IEC 60601-2-21: 2009/A1: 2016	Medical electrical equipment – Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers
IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 18562-1: 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Declaração de conformidade da UE

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ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
ISO 17664: 2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 17664-2: 2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
EN 50419: 2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

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Declaração de conformidade da UE

Nº. do documento	**MDR206-012-2208-001-0**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Extensão da avaliação de conformidade		
Número da peça	Nome do produto	UDI-DI básico
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

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Declaraţie de conformitate UE

Nr. document	**MDR206-012-2208-001-0**
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Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Reprezentant autorizat:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Număr unic de înregistrare (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

declară prin prezenta pe proprie răspundere că

Numele produsului	Categoria dispozitivului	Clasa dispozitivului	Codul UMDNS / Codul GMDN / Codul EMDN
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

îndeplinește următoarele cerințe:

REGULAMENTUL (UE) 2017/745 privind dispozitivele medicale. O analiză a sistemului de management al calităţii a fost efectuată conform Anexei IX (capitolele I şi III şi secţiunea 4) a reglementării Organismului notificat: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sistemul de management al calităţii îndeplineşte de asemenea cerinţele standardelor EN ISO 9001 şi EN ISO 13485.
DIRECTIVA 2011/65/UE A PARLAMENTULUI EUROPEAN ȘI A CONSILIULUI din 8 iunie 2011 privind restricțiile de utilizare a anumitor substanțe periculoase în echipamentele electrice și electronice
DIRECTIVA 2014/31/UE A PARLAMENTULUI EUROPEAN ȘI A CONSILIULUI din 26 februarie 2014 privind armonizarea legislației statelor membre referitoare la punerea la dispoziție pe piață a aparatelor de cântărit cu funcționare neautomată

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

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

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Declaraţie de conformitate UE

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Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

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Declaraţie de conformitate UE

Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Numele produsului	**Categoria dispozitivului**
Babyroo TN300	**Infant Radiant Warmer**
Standarde aplicate în totalitate sau parţial:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 62366-1: 2015 COR 1 2016	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304: 2006/A1: 2015	Medical device software – Software lifecycle processes
IEC 60601-2-21: 2009/A1: 2016	Medical electrical equipment – Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers
IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 18562-1: 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Declaraţie de conformitate UE

ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
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ISO 17664-2: 2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
EN 50419: 2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

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Declaraţie de conformitate UE

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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Evaluarea extinsă a conformităţii		
Cod articol	Numele produsului	UDI-DI de bază
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

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EÚ vyhlásenie o zhode

Dokument č.	**MDR206-012-2208-001-0**
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Miesto	**USA - Telford**
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Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Splnomocnený zástupca:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Jedinečné registračné číslo (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

týmto na vlastnú zodpovednosť vyhlasuje, že

Názov výrobku	Kategória zariadenia	Trieda zariadenia	Kód UMDNS / Kód GMDN / Kód EMDN
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

spĺňa nasledujúce nariadenia:

EURÓPSKE NARIADENIE (EÚ) 2017/745 o zdravotníckych pomôckach. Preskúmanie systému riadenia kvality bolo vykonané notifikovaným orgánom podľa prílohy IX (kapitoly I a III a oddielu 4) nariadenia: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Systém riadenia kvality tiež spĺňa normy STN EN ISO 9001 a STN EN ISO 13485.
SMERNICA EURÓPSKEHO PARLAMENTU A RADY 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach
SMERNICA EURÓPSKEHO PARLAMENTU A RADY 2014/31/EÚ z 26. februára 2014 o harmonizácii právnych predpisov členských štátov týkajúcich sa sprístupňovania váh s neautomatickou činnosťou na trhu

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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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Názov výrobku	**Kategória zariadenia**
Babyroo TN300	**Infant Radiant Warmer**
Použité normy v úplnom alebo v čiastočnom znení:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
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ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

EÚ vyhlásenie o zhode

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EÚ vyhlásenie o zhode

Dokument č.	**MDR206-012-2208-001-0**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Rozsah posúdenia zhody		
Objednávacie číslo	Názov výrobku	Základné UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

CE 0123

Izjava EU o skladnosti

Št. dokumenta	**MDR206-012-2208-001-0**
Datum	**2022-08-15**
Kraj	**USA - Telford**
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Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Pooblaščeni predstavnik:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Enotna registrska številka (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

izjavlja z vso odgovornostjo, da

Ime izdelka	Kategorija naprave	Razred naprave	Koda UMDNS / Koda GMDN / Koda EMDN
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

izpolnjuje naslednje določbe:

EVROPSKA UREDBA (EU) 2017/745 o medicinskih pripomočkih. Sistem upravljanja kakovosti je na podlagi Priloge IX (poglavji I in III in razdelek 4) uredbe preveril priglašeni organ: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sistem upravljanja kakovosti je skladen tudi z EN ISO 9001 in EN ISO 13485.
DIREKTIVA 2011/65/EU EVROPSKEGA PARLAMENTA IN SVETA z dne 8. junija 2011 o omejevanju uporabe nekaterih nevarnih snovi v električni in elektronski opremi
DIREKTIVA 2014/31/EU EVROPSKEGA PARLAMENTA IN SVETA z dne 26. februarja 2014 o harmonizaciji zakonodaj držav članic v zvezi z omogočanjem dostopnosti neavtomatskih tehtnic na trgu

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.

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969 USA
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info@draeger.com
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Izjava EU o skladnosti

Št. dokumenta	**MDR206-012-2208-001-0**
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Senior Director of Regulatory Affairs
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Tom Hirte

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Št. dokumenta	**MDR206-012-2208-001-0**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Ime izdelka	**Kategorija naprave**
Babyroo TN300	**Infant Radiant Warmer**
V celoti ali deloma uporabljeni standardi:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
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ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
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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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Izjava EU o skladnosti

ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
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Izjava EU o skladnosti

Št. dokumenta	**MDR206-012-2208-001-0**
Datum	**2022-08-15**
Kraj	**USA - Telford**
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Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Obseg ugotavljanja skladnosti		
Kataloška številka	Ime izdelka	Basic UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

CE 0123

EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro **MDR206-012-2208-001-0**
Päivämäärä **2022-08-15**
Paikka **USA - Telford**
Sivu **1 / 5**

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Valtuutetulla edustajalla:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Rekisterinumero:

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

vakuuttaa täten yksinomaisella vastuullaan, että

Tuotenimi	Laitteen luokitus	Laiteluokka	UMDNS-koodi / GMDN-koodi / EMDN-koodi
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

täyttää seuraavat vaatimukset:

EUROOPAN PARLAMENTIN JA NEUVOSTON ASETUS (EU) 2017/745 lääkinnällisistä laitteista. Laatujärjestelmän on tarkastanut asetuksen liitettä IX (I ja III luvun 4 kohtaa) noudattaen seuraava ilmoitettu laitos: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Laatujärjestelmä täyttää lisäksi standardien EN ISO 9001 ja EN ISO 13485 vaatimukset.
EUROOPAN PARLAMENTIN JA NEUVOSTON DIREKTIIVI 2011/65/EU, annettu 8 päivänä kesäkuuta 2011, tiettyjen vaarallisten aineiden käytön rajoittamisesta sähkö- ja elektroniikkalaitteissa
EUROOPAN PARLAMENTIN JA NEUVOSTON DIREKTIIVI 2014/31/EU, annettu 26 päivänä helmikuuta 2014, muiden kuin automaattisten vaakojen asettamista saataville markkinoilla koskevan jäsenvaltioiden lainsäädännön yhdenmukaistamisesta

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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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR206-012-2208-001-0**
Päivämäärä	**2022-08-15**
Paikka	**USA - Telford**
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Senior Director of Regulatory Affairs
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Tom Hirte

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info@draeger.com
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CE 0123

EU-vaatimustenmukaisuusvakuutus

Draeger Medical Systrems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Tuotenimi	**Laitteen luokitus**
Babyroo TN300	**Infant Radiant Warmer**
Kokonaan tai osittain sovellettavat standardit:	
IEC 60601-1: 2005/ A1:2012/ COR1:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 62366-1: 2015 COR 1 2016	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-8: 2006/A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304: 2006/A1: 2015	Medical device software – Software lifecycle processes
IEC 60601-2-21: 2009/A1: 2016	Medical electrical equipment – Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers
IEC 80601-2-35: 2009/A1: 2016	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use
ISO 80601-2-61: 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10079-3: 2014	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source
ISO 10651-5: 2006	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators
ISO 18562-1: 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

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ISTA 2B: 2011	ISTA Procedure 2B: Packaged products weighing over 150 lb. (68 kg) Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
ISO 17664: 2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 17664-2: 2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041: 2008/ A1:2013	Information supplied by the manufacturer of medical devices
EN 50419: 2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

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EU-vaatimustenmukaisuusvakuutus

Asiakirjan nro	**MDR206-012-2208-001-0**
Päivämäärä	**2022-08-15**
Paikka	**USA - Telford**
Sivu	**5 / 5**

Draeger Medical Systrems, Inc.
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Vaatimustenmukaisuuden arvioinnin laajuus		
Osanumero	Tuotenimi	Yksilöllinen UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**

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EU-försäkran om överensstämmelse

Dokument nr.	**MDR206-012-2208-001-0**
Datum	**2022-08-15**
Plats	**USA - Telford**
Sida	**1 / 5**

Draeger Medical Systems, Inc.
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Telford PA 18969
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Auktoriserad representant:

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

EC Certificate: G10 061092 0079 Rev. 00
Valid until: 2027-08-01

Enkelt registreringsnummer (SRN):

Manufacturer, US-MF-000020721, Draeger Medical Systems, Inc. – [United States]

förklarar härmed under sitt eget ansvar att

Produktnamn	Enhetskategori	Enhetsklass	UMDNS-kod / GMDN-kod / EMDN-kod
Babyroo TN300	Infant Radiant Warmer	IIb	UMDNS 13250/ GMDN 17433/ EMDN Z12080407

uppfyller följande bestämmelser:

EUROPEISKA FÖRORDNINGEN (EU) 2017/745 om medicintekniska produkter. En undersökning av kvalitetshanteringssystemet har utförts enligt bilaga IX (kapitel I och III och avsnitt 4) till förordningen av det anmälda organet: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Kvalitetshanteringssystemet uppfyller även EN ISO 9001 och EN ISO 13485.
EUROPAPARLAMENTETS OCH RÅDETS DIREKTIV 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning
EUROPAPARLAMENTETS OCH RÅDETS DIREKTIV 2014/31/EU av den 26 februari 2014 om harmonisering av medlemsstaternas lagstiftning om tillhandahållande på marknaden av icke-automatiska vågar

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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Senior Director of Regulatory Affairs
Business Unit Patient Monitoring

Tom Hirte

Senior Director of QA & Compliance Medical / Safety

Darlene Thibodeau

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Draeger Medical Systrems, Inc.
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Produktnamn	**Enhetskategori**
Babyroo TN300	**Infant Radiant Warmer**
Helt eller delvis tillämpade standarder:	
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Omfattning bedömning av överensstämmelse		
Artikelnummer	Produktnamn	Bas UDI-DI
MU20300	**Babyroo TN300**	**040486752306012VK19Z000B5**