CE 0123	**EC Declaration of Conformity** *EG Konformitätserklärung*	Date / *Datum* 2021-05-24
	European Directive 93/42/EEC, Annex II **European Directive 2011/65/EU** *Europäische Richtlinie 93/42/EWG, Anhang II* *Europäische Richtlinie 2011/65/EG*	Document ID / *Dokument Nr.* MD206-081-2105-001-0

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

EC Representative: *Europäischer Bevollmächtigter:*
Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

EC Certificate: G1 061092 0073
Valid Until: 2024-05-26

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

Product name / *Produktbezeichnung*	Medical device / *Medizinprodukt*	Device Class	UMDNS Code / GMDN Code
BiliLux	LED Phototherapy Light	IIa	13037 / 35239

meets the provisions of the following European Directives:
- 93/42/EEC on medical devices. An examination of the quality management system has been carried out following Annex II (excluding 4) of the directive by the notified body TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, EC No. 0123. The quality management system also complies to EN ISO 9001 and EN ISO 13485.
- 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
This declaration is effective for products placed on the market as of date of issue. Any modifications of the medical device not authorized by Draeger Medical Systems Inc. will invalidate this declaration.

mit den Bestimmungen der folgenden europäischen Richtlinien übereinstimmt:
-93/42/EWG über Medizinprodukte Eine Überprüfung des Qualitätsmanagementsystems, nach den Regeln wie in Anhang II (ohne 4) der Richtlinie beschrieben, wurde durch die Benannte Stelle TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, *EU Kennnummer* 0123, *vorgenommen. Das Qualitätsmanagementsystem erfüllt weiterhin die Anforderungen gemäß EN ISO 9001 und EN ISO 13485.*
-2011/65/EG zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten. Diese Erklärung ist gültig für ab dem Ausstellungsdatum in Verkehr gebrachte Produkte. Jede nicht durch Draeger Medical Systems, Inc. autorisierte Modifikation an dem Medizinprodukt führt zur Ungültigkeit dieser Erklärung. Die RoHS-Konformität wird ausschliesslich durch Draeger Medical System, Inc. gewährleistet.

Regulatory Affairs Manager
Karen Otrupchak

Vice President Global Functions – Thermoregulation
Pete Liptrot

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

Dräger

CE 0123	**Appendix I to EC Declaration of Conformity** *Anlage I zur EG Konformitätserklärung*	Date / *Datum* 2021-05-24
	European Directive 93/42/EEC **European Directive 2011/65/EU** *Europäische Richtlinie 93/42/EWG* *Europäische Richtlinie 2011/65/EG*	Document ID / *Dokument Nr.* MD206-081-2105-001-0 Page 1 of 2

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

Product name / Produktbezeichnung	Medical device / Medizinprodukt
BiliLux	LED Phototherapy System
Applied standards in full or in part / *Vollständig oder teilweise angewendete Normen*	

No.	Reference Label	International Standard	European Union Version	Standard Title
1	IEC 60601-1	IEC 60601-1:2005 AMD1:2012	EN 60601-1:2006/A1:2013	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance
2	IEC 60601-1-2	IEC 60601-1-2: 2014	EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3	IEC 60601-2-50	IEC 60601-2-50: 2009/A1:2016	EN 60601-2-50: 2009/A1:2016	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment
4	IEC 60601-1-6	IEC 60601-1-6: 2010/AMD1:2013	EN 60601-1-6:2010/ AMD1:2015	Medical Electrical Equipment, Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
5	IEC 62366	IEC 62366: 2007/AMD1:2014	EN 62366: 2008/ AMD1:2015	Medical devices – Application of usability engineering to medical devices
6	IEC 62304	IEC 62304: 2006	EN 62304: 2006/AC:2008	Medical device Software life-cycle processes
7	ISO 14971	ISO 14971:2007	EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
8	ISO 13485	ISO 13485:2016	EN ISO 13485:2016	Medical Devices - Quality management systems – Requirements for regulatory purposes
9	ISTA 2A	ISTA 2A:2011	-	Procedure 2A: Packaged-Products weighing 150 lb (68 kg) or Less. Basic Requirements: atmospheric conditioning, compression, fixed displacement or random vibration and shock testing.

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

CE 0123	**Appendix I to EC Declaration of Conformity** *Anlage I zur EG Konformitätserklärung*	Date / *Datum* 2021-05-24
	European Directive 93/42/EEC **European Directive 2011/65/EU** *Europäische Richtlinie 93/42/EWG* *Europäische Richtlinie 2011/65/EG*	Document ID / *Dokument Nr.* MD206-081-2105-001-0 Page 2 of 2

10	ISO 17664	ISO 17664:2004	EN ISO 17664:2004	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
11	MEDDEV	-	MEDDEV 2.7.1 Rev.4	GUIDELINES ON MEDICAL DEVICES CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
12	15223-1	ISO 15223-1:2012	EN ISO 15223-1:2012	MEDICAL DEVICES - SYMBOLS TO BE USED WITH MEDICAL DEVICE LABELS, LABELLING AND INFORMATION TO BE SUPPLIED - PART 1: GENERAL REQUIREMENTS (ISO 15223-1:2012)+ EN980 Symbols for use in the labelling of medical devices
13	1041	-	EN 1041:2008 A1:2013	Information supplied by the manufacturer of medical devices
14	ISO 10993-1	ISO 10993-1:2009/AC:2010	EN ISO 10993-1:2009/AC:2010	ISO 10993-1:2009/AC:2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Vice President Global Functions
Thermoregulation

Pete Liptrot

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

CE 0123	**Appendix II to EC Declaration of Conformity** *Anlage II zur EG Konformitätserklärung*	Date / *Datum* 2021-05-24
	European Directive 93/42/EEC **European Directive 2011/65/EU** *Europäische Richtlinie 93/42/EWG* *Europäische Richtlinie 2011/65/EU*	Document ID / *Dokument Nr.* MD206-081-2105-001-0-ECA Page 1 of 1

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

Extent of conformity assessment / *Umfang der Konformitätsbewertung*	
Part No. / *Sachnr.*	Product name / *Produktbezeichnung*
MU20100	BiliLux LED phototherapy system
MU25840	BiliLux LED phototherapy light
MU26076	BiliLux Trolley
MU26077	BiliLux Spring Arm
MU26079	Radiometer

Vice President Global Functions
Thermoregulation

Pete Liptrot

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