CE 0123	**EC Declaration of Conformity** *EG Konformitätserklärung*	Date / *Datum* 2019-12-17
	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.* MD206-001-1912-002-0

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

EC Representative: Drägerwerk A G & Co. KGaA
Moislinger Allee 53-55
23542 Luebeck
Germany

hereby declares that the / *erklärt hiermit, dass*

Product name / *Produktbezeichnung*	Medical device / *Medizinprodukt*	Device Class	UMDNS Code / GMDN Code
Isolette 8000 plus	Incubator, infant	IIb	12113 / 36025

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.3 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/EU 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 the date of issue / the indicated serial numbers. Any modifications of the medical device not authorized by Draeger Medical 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.3 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/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten.
Diese Erklärung ist gültig für ab dem Ausstellungsdatum / den angegebenen Seriennummern in Verkehr gebrachte Produkte. Jede nicht durch Draeger Medical autorisierte Modifikation an dem Medizinprodukt führt zur Ungültigkeit dieser Erklärung.

Vice President
Engineering Excellence - Thermoregulation
Connect & Develop – Hospital Products

Pete Liptrot

Director, Quality Assurance,
Quality & Regulatory Affairs

Bryan Overton

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* 2019-12-17
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3135 Quarry Road
Telford, PA 18969, USA

Product name / Produktbezeichnung	Medical device / Medizinprodukt
Isolette 8000 plus	Incubator, infant
Applied standards in full or in part / *Vollständig oder teilweise angewendete Normen*:	

No.	Reference Label	International Standard	European Union Version	Standard Title
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	IEC60601-1-2	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 60601-2-19	IEC 60601-2-19:2009/AMD1:2016	EN 60601-2-19:2009/AMD1:2016	Medical Electrical Equipment, Part 2-19: Particular Requirements for Basic Safety and Essential Performance of Infant Incubators
4	IEC 60601-1-6	IEC 60601-1-6: 2010/AMD1:2013	EN 60601-1-6:2010/ AMD 1 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 60601-1-8	IEC 60601-1-8: 2006/AMD1:2012	EN 60601-1-8: 2007/A1:2013	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
8	IEC 62304	IEC 62304: 2006/AMD1:2015	EN 62304: 2006/ AMD1:2015	Medical device Software life-cycle processes
9	ISO 14971	ISO 14971:2007	EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
10	ISO 13485	ISO 13485:2016	EN ISO 13485:2016	Medical Devices - Quality management systems – Requirements for regulatory purposes

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3135 Quarry Road
Telford, PA 18969 USA
Tel 215 721 5400
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info@draeger.com
www.draeger.com

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No.	Reference Label	International Standard	European Union Version	Standard Title
11	ISO 10993-1	ISO 10993 series of standards (ISO 10993-1 (2009-10))	ISO 10993 series of standards (ISO 10993-1 (2009-10))	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
12	OIML R76-1	NA	OIML R76-1:2006	Non-automatic weighing instruments Part 1: Metrological and technical requirements - Tests
13	EN 45501	NA	EN 45501:2015	Metrological Aspects of non-automatic weighing instruments
14	ISTA 2B	ISTA 2B:2011	NA	ISTA Procedure 2B: Packaged-Products weighing over 150 lb. (68 kg) Basic Requirements: atmospheric conditioning, compression, fixed displacement or random vibration and shock testing
15	MDDEV	NA	MEDDEV 2.7.1 Rev.4	GUIDELINES ON MEDICAL DEVICES CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
16	ISO 17664	ISO 17664:2017	EN ISO 17664:2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices

Director, Quality Assurance,
Quality, & Regulatory Affairs

Bryan Overton

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

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

Extent of conformity assessment / *Umfang der Konformitätsbewertung*	
Part No. / *Sachnr.*	Product name / *Produktbezeichnung*
MU20602	Isolette 8000 plus
	Software 5.n
MU12955	IV pole assembly
MU26041	Probe, yellow, central skin temperature, disposable, 10
MU26042	Probe, white, peripheral skin temperature, disposable, 10
MU06943	Cover, probe, Care-For-Me, large 100
MU06944	Cover, probe, Care-For-Me, standard 100
MU24903	Oxygen Sensor kit
MU10918	Collection bottle, disposable, box of 20, 800 cc
MU21120	Hose/plug assembly, condensation management
MU12504	Air inlet filter
MU03876	Iris port sleeve, disposable, 100
MU17879	Swivel drawer assembly, large
MU17880	Swivel drawer assembly, small
7256931	MIB2 protocol converter
MS18805	MIB cable, 2 m

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4726373	MIB network cable, 1.2 m
4726381	MIB network cable, 2.4 m
MU12937	Utility shelf assembly, high
MU14688	Straps, utility shelf (2)
MU18660	Breathing hose holder kit
MU12609	Grommet
MU18916	Kit, HFV door with grommets

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