	EC Declaration of Conformity <i>EG Konformitätserklärung</i>	Date / Datum 2014-12-02
	European Directive 93/42/EEC, Annex VII European Directive 2011/65/EC <i>Europäische Richtlinie 93/42/EWG, Anhang VII</i> <i>Europäische Richtlinie 2011/65/EG</i>	Document ID / Dokument Nr. MD207-025-1412-025-0

Draeger Medical Systems, Inc.
 3135 Quarry Road
 Telford, PA 18969-1042
 USA

EC Representative: Draeger Medical GmbH
Europäischer Bevollmächtigter: Moislinger Allee 53-55
 23542 Lübeck
 Germany

hereby declares that / *erklärt hiermit, dass*

Product Name / Produktbezeichnung	Medical Device / Medizinprodukt	Device Class	UMDNS / GMDN Code
ECG Leads	Cables/Leads, ECG	I	15-754 / 35562
ESU Block	Adapter, cable, electrosurgical		15-754 / 35041
EEG Lead	Cables/Leads, electroencephalograph		16-313 / 35749

meets the provisions of the following European Directives:

- 93/42/EEC on medical devices. The procedure according to Annex VII of the above mentioned directive has been followed.
- 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 the date of issue. Any modifications of the medical device not authorized by Draeger Medical Systems, Inc. will invalidate this declaration. RoHS compliance is ensured under the sole responsibility of Draeger Medical Systems, Inc.

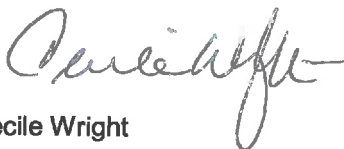
mit den Bestimmungen der folgenden europäischen Richtlinien übereinstimmt:

- 93/42/EWG über Medizinprodukte. Das Verfahren gemäß den Vorgaben in Anhang VII derselben Richtlinie wurde eingehalten.
- 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.

President

Director of Regulatory Affairs



Cecile Wright



Beth Zis

Draeger Medical Systems, Inc.

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	Appendix to EC Declaration of Conformity <i>Anlage zur EG Konformitätserklärung</i>	Date / Datum 2014-12-02
	European Directive 93/42/EEC, Annex VII European Directive 2011/65/EC <i>Europäische Richtlinie 93/42/EWG, Anhang VII</i> <i>Europäische Richtlinie 2011/65/EG</i>	Document ID / Dokument Nr. MD207-025-1412-025-0-00

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Product name / Produktbezeichnung		Medical device / Medizinprodukt
ECG Leads ESU Block EEG Lead		Cables/Leads, ECG Adapter, cable, electrosurgical Cables/Leads, electroencephalograph
Applied standards in full or in part / Vollständig oder teilweise angewendete Normen:		
EN 14971	2012	Medical devices – Application of risk management to medical devices
EN 980	2008	Graphical symbols for use in the labeling of medical devices
EN 1041	2008+A1:2013	Information supplied by the manufacturer with medical devices
EN 60601-1 (IEC 60601-1)	1990/A1:1993/A2:1996 (1988/A1:1991/A2/1995)	Medical electrical equipment general requirements for safety
EN 60601-1-2 (IEC 60601 -1-2)	2001/A1:2006 (2001/A1:2004)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: electromagnetic compatibility - requirements and tests
EN62366 (IEC62366)	2008 (2007)	Medical devices – Application of usability engineering to medical devices
EN 10993-1	2009	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN 10993-5	2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ANSI/AAMI EC12	2000/(R)2005	Disposable ECG electrodes
ANSI/AAMI EC53	1995/(R)2001	ECG cables and lead wires
EN 50581	2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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	Appendix II to EC Declaration of Conformity <i>Anlage II zur EG Konformitätserklärung</i>	Date / Datum 2014-12-02
	European Directive 93/42/EEC, Annex VII European Directive 2011/65/EC <i>Europäische Richtlinie 93/42/EWG, Anhang VII</i> <i>Europäische Richtlinie 2011/65/EG</i>	Document ID / Dokument Nr. MD207-025-1412-025-0-ECA

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Part No.	Product name
Infinity®TruST- Telemetry / Infinity M300 Accessories	
7499804	ECG 3-Lead Trust Euro, Telem.
7499812	ECG 3-Lead Trust AHU/US, Telem
7499820	ECG 5-Lead Trust Euro, Telem.
7499838	ECG 5-Lead Trust AHU/US, Telem
7499846	ECG 6-Lead Trust Euro, Telem
7499853	ECG 6-Lead Trust AHA/US, Telem
ECG Leads (Single Pin)	
MS16159	ECG 3-lead single-pin Euro, 1 m
MS16231	ECG 3-lead single-pin AHA, 1 m
MS16158	ECG 5-lead single-pin Euro, 1 m
MS16546	ECG 5-lead single-pin AHA, 1 m
MS16157	ECG 6-lead single-pin Euro, 1 m
MS16547	ECG 6-lead single-pin AHA, 1 m
ECG MonoLeads (Single Pin)	
MS14555	MonoLead 3,Euro, 2 m
MS14556	MonoLead 3, AHA/US, 2 m
MS14559	MonoLead 5, Euro, 2.5 m
MS14560	MonoLead 5, AHA/US, 2.5 m
MS14683	MonoLead 6, Euro, 3 m
MS14682	MonoLead 6, AHA/US, 3 m
MS17185	ECG Cbl MonoLead 6, Euro 5.7 m
MS28557	ECG Cbl MonoLead 3, AHA/US 4.1 m
MS28558	ECG Cbl MonoLead 5, AHA/US 5.3 m
MS28559	ECG Cbl MonoLead 5, Euro 5.3 m
MS28560	ECG Cbl MonoLead 6, AHA/US 5.7 m
MS28561	ECG Cbl MonoLead 3, Euro, 4.1 m
ECG MonoLeads (Dual Pin)	
MS16160	MonoLead 3 Dual-Pin Euro, 2 m

Part No.	Product name
MS16233	MonoLead 3 Dual-Pin AHA/US, 2 m
MS16161	MonoLead 5 Dual Pin Euro, 2.5 m
MS16229	MonoLead 5 Dual-Pin AHA, 2.5 m
ECG Leads (Dual Pin)	
5956433	ECG 3-lead dual-pin Euro, 1 m
5956441	ECG 3-lead dual-pin AHA/US, 1 m
5956466	ECG Cbl 5-lead dual-P Euro, 1 m
5956458	ECG Cbl 5-lead dual- P AHA, 1 m
5956482	ECG 6-lead, dual-P Euro 1 m
5956474	ECG Cbl 6-lead dual-P AHA, 1 m
Chest Leads	
5956508	ECG Cbl 5-lead Chest Euro 1 m
5956490	ECG Cbl 5-lead Chest AHA/US 1 m
MS16232	MonoLead 5 Chest Euro, 1.5 m
MS16230	MonoLead 5 Chest AHA, 1.5 m
MS22365	ECG Cbl 4-Ld Single-Pin EUR 1m
MS22364	ECG Cbl 4-Ld Single-Pin AHA 1m
MS14693	ECG Cbl MonoLead 4, Euro, 1.7 m
MS14694	ECG Cbl MonoLead 4, AHA/US 1.7 m
MS20475	ECG Cbl MonoLead 4, AHA/US 3.7 m
MS20476	ECG Cbl MonoLead 4, Euro, 3.7m
ESU Blocks	
5947226	ECG ESU Block, 5-Lead
7486140	ECG 6-Lead ESU Block
Adapters	
5194779	ECG Neo Adapter Pin, 10 pcs
5592162	ECG Neomed Adapter Cable, 1.5 m
MS14679	MultiMed®5 SinglePin Adapter
MS14680	MultiMed 6 SinglePin Adapter
MS14681	Monolead Telemetry Adapter
MS25951	ECG Neo Adapter Cable MM 2M
Telemetry ECG-Lead Sets	
5956359	Grbr 5 lead IEC2 Tele
5956367	Grbr 5 lead IEC1 Tele
7863710	Grbr 3 lead IEC2 Tele

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Part No.	Product name
Others	
MS16492	ECG Ext. 5-lead Dual-Pin, 2 m (Dual-pin 5-lead extension cable for use with MultiMed®3/5/6/12 pods)
MS31435	4 Lead ECG Extension Cbl 2M
5734418	ECG Limb 5-Lead Radiotransl, 1.5 m (Limb lead set is for both AHA/US and Euro color codes)
MS16256	ECG Extension single-pin, 2 m
5734400	ECG 5-Lead spacer F MM 12
4316621	ECG Analog Cable, Telemetry
4527750	ECG Electrodes, Disposable 50 pcs
5947804	EEG Leads, 0.6m, reusable, 9 pcs

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