	EC Declaration of Conformity <i>EG Konformitätserklärung</i>	Date / Datum 2017-12-07
	European Directive 93/42/EEC European Directive 2011/65/EC <i>Europäische Richtlinie 93/42/EWG</i> <i>Europäische Richtlinie 2011/65/EG</i>	Document ID / Dokument Nr. MD207-027-1712-027-0

Draeger Medical Systems, Inc.
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USA

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

hereby declares that / *erklärt hiermit, dass*

Product Name / <i>Produktbezeichnung</i>	Medical Device / <i>Medizinprodukt</i>	Device Class	UMDNS Code/ GMDN Code
Intermediate Cables	Cables/leads / Medical device electrical cable, reusable	I	16312 / 47487
NMT Thermistor	Leads, Electrical Stimulator, Neuromuscular / General Purpose patient temperature probe, reusable	I	35339 / 37340
NMT Cable	Thermometers, Electronic, Thermistor/ Thermocouple / Transcutaneous electrical stimulation lead	I	18299 / 35751

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.

VP of R&D Monitoring Systems


Mary Gaffy

Director of Regulatory Affairs


Beth Zis

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	Appendix to EC Declaration of Conformity <i>Anlage zur EG Konformitätserklärung</i>	Date / Datum 2017-12-07
	European Directive 93/42/EEC European Directive 2011/65/EC <i>Europäische Richtlinie 93/42/EWG</i> <i>Europäische Richtlinie 2011/65/EG</i>	Document ID / Dokument Nr. MD207-027-1712-027-0-00

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Product name / Produktbezeichnung		Medical device / Medizinprodukt
Intermediate Cables		Cables/leads / Medical device electrical cable, reusable
NMT Thermistor		Leads, Electrical Stimulator, Neuromuscular / General Purpose patient temperature probe, reusable
NMT Cable		Thermometers, Electronic, Thermistor/ Thermocouple / Transcutaneous electrical stimulation lead
Applied standards in full or in part / Vollständig oder teilweise angewendete Normen:		
EN ISO 14971 (ISO 14971)	2012 (2007)	Medical devices – Application of risk management to medical devices
EN 1041	2008+A1:2013	Information supplied by the manufacturer with medical devices
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 Graphical symbols for use in the labeling of medical devices
EN 60601-1 IEC60601-1	2006/A1:2013 2005+A1:2012	Medical electrical equipment – General requirements for safety
EN 60601-1-2 IEC60601-1-2	2007 / AC:2010 (2007)	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility – requirements and tests
EN62366 IEC62366	2008/A1:2015 (2007/A1:2014)	Medical devices - Application of usability engineering to medical device
EN ISO 80601-2-61 (ISO60601-2-61)	2011 (2011)	Medical electrical equipment – Particular requirements for the basic safety, including essential performance of pulse oximeter equipment for medical use
EN 60601-2-34 IEC 60601-2-34	2014 (2011)	Medical electrical equipment – Part 2-34: Particular requirements for the safety, including essential performance of invasive blood pressure monitoring equipment
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 2017-12-07
	European Directive 93/42/EEC European Directive 2011/65/EC <i>Europäische Richtlinie 93/42/EWG</i> <i>Europäische Richtlinie 2011/65/EG</i>	Document ID / Dokument Nr. MD207-027-1712-027-0-ECA

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Extent of conformity assessment / Umfang der Konformitätsbewertung	
Part No. / Sachnr.	Product name / Produktbezeichnung
MultiMed:	
5950196	MultiMed 5 pod, 1.5 m
3368391	MultiMed 5 pod, 2.5 m
5191221	MultiMed 6 Pod, 2.5 m
MultiMed Plus:	
MS20093	MultiMed Plus
MS20094	MultiMed Plus OR
NeoMed:	
5590539	NeoMed Pod, 2.5 m
CO:	
8419160	CO Catheter to Interm. Cable
3368458	CO Intermediate Cable, 1 m
MS16916	Picco CO Intermediate Cable
MS16918	Picco CO Catheter Cable
8539983	CO Thermister Cbl, Edwards
Pod communication/Intermediate/connection cables:	
3368425	Pod communication cable, 3.0 m
7257988	Pod communication cable, 0.3 m
5195198	Pod communication cable, 5 m
5599076	SHP ACC Cbl Pod Com 1m (Pod communication cable, 1 m (included w/tpCO2 pod))
5195180	IBP Y-Cable Sensor, 3.7m
3375933	IBP Intermediate Cable, Argon 3.7m
5206581	IBP Y-Cable Argon, 3.7m
4321563	IBP Interm Cable SensoNor 3.7m
5591925	HemoMed Cable to Monitor 3M
5591933	HemoMed Cable to Monitor 5m

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Part No. / Sachnr.	Product name / Produktbezeichnung
4530291	SHP Acc Connection cable
3368433	SpO2 Nellcor Interm Cable, 1m (Nellcor/Dräger SpO2 Extension Cables - Shielded (blue latch), 1 m)
3375834	SpO2 Nellcor Interm Cable, 2m (Nellcor/Dräger SpO2 Extension Cables - Shielded (blue latch), 2 m)
MS18683	SpO2 Intermediate Cable, 1.2M (Nellcor/Dräger SpO2 Intermediate Cable - Shielded (blue cable), 1.2m)
MS17330	SpO2 Intermediate Cable, 3M (Nellcor/Dräger SpO2 Intermediate Cable - Shielded (blue cable), 3 m)
MS24539	X8 to X8 Y-Cable
IBP/transducer adapter cables:	
3368383	IBP Adapter Cable 10-7pin
5592147	IBP Y-Cable 16 to 7pin
5731281	IBP Y-Cable 16P to 10pin
5588095	IBP Y-Cable Adapter 10-7 pin
5206607	IBP Y-Cable Baxter 3.7m
3375958	Hemo/Picco Pod Adapter, 10pin
5196998	Pod Adapter (Abbott/Medex)
5196980	Pod Adapter (Edwards)
3375941	Hemo Pod Adapter, Argon
MS23598	Hemo Pod Adapter SensoNor 7-pin
MS22533	Transducer Cable Draeger 7-pin
MS22532	Transducer Cable Draeger 10-pin
MS22535	Transducer Cable Abbott Medex
MS22147	Transducer Adapter Cable, Edwards
MS22148	Transducer Cable Argon
MS22534	Transducer Adapter Cable, Utah Medical
7486876	IBP Trans Ext Cbl MEM/SNOR 3M
SpO2 Cables	
MS18680	SpO2 Cable Masimo LNOP, 1.2 m
MS17041	SpO2 Interm Cbl Masimo LNOP, 3 m
MS24303	SpO2 Masimo Cable LNCS 1.2 m
MS17522	SpO2 Masimo Cable LNCS 3 m
Alarm output Cables	
4314626	Alarm Out Cbl, Intra Plate, 5m
5194928	Alarm Output Cable, 5m
FiO2	
5597898	FiO2 sensor cable, 1.5m

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Part No. / Sachnr.	Product name / Produktbezeichnung
System Cables	
MS20614	System cable, 4.5 m
MS20135	IACS System cable, 1.5 m
MS20345	IACS Y-Cable for PS50
MS18781	SHP ACC Cable Sys up dn 2.8m
MS18782	SHP ACC Cable Sys up dn .7m
MS26203	SHP ACC Cable Sys up str 1.44m
MS26204	SHP ACC Cable Syst up str .34m
MS22761	System Cable for Omega
MS29702	Y-Adapter M500 Docking station
MK04408	System cable high flex up straight
MK08707	IACS system cable 2.5 m
MK08708	IACS system cable 3.5m
MK09186	IT extension cable
Temperature Adapter Cables	
5592154	Temperature Y-Cable
5198333	Temp Probe Adapter Cable
5196485	Temp Adap cable 7-pin to ¼"
NMT Accessories	
MS13218	NMT Cbl Trident, 2-lead, 0.3M
MS15053	NMT Thermistor Trident
7872174	Interm Cbl Trident (NMT), 1.9M
Scio Accessories	
MS33168	Cable Scio/M540 0.8m
MS33167	Cable Scio/M540 2.2m
MS33986	Cable Scio/M500 0.8m
MS33987	Cable Scio/M500 2.2m
Kits	
7265163	Cardiac Output Kit Argon
7265155	Cardiac Output Kit Baxter
7498947	IBP Transducer Kit Sensor 84

The following non-medical parts meet Directive 2011/65/EC:	
Power Supplies	
MS18284	UNIVERSAL POWER SUPPLY IDS
MS18508	INFINITY G/GXL/V POWER SUPPLY
Power Cords	
4321712	Power Cord, Europe CEE7
4321720	Power Cord, N.America, 5-15A

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Part No. / Sachnr.	Product name / Produktbezeichnung
M300 programming cable and kit	
MS20341	SHP ACC M300 Program Clb
MS18628	Infinity M300 Program Kit
Batteries	
3361164	Replacement Battery, Box of 6
5597377	Battery Charger, Delta
Power Cables	
2171767	Grounding Cable, 5M
IDS	
5732388	Interface Docking Station
Output Cables	
4314618	Analog output cable, 5m
4314667	QRS sync output cable, 3m
MS22948	Export Protocol Cable, PS250
5206441	Export Protocol Cable, 5m
MS15045	Export Protocol Cable, KXLT
4714346	Diagnostic UART, RS232 Cbl, 3m
Remote Keypad Cables	
5206193	Coil Cable Remote Keypad, 7.6m
5596288	Connection Cbl Remote Keypad
7864460	Remote VGA Display Y-Cable, 3M
Remote Display Connections	
7490290	SHP ACC Cable Video Switch 3m
5736173	Remote Display Cable, 23m
4726084	Remote Display – IDS to VGA 3m
5194910	IDS/CPS Cable, 25m
MIB CONNECTION CABLES	
Continuous Cardiac Output/SvO2	
5198929	MIB Cbl Baxter Vigilance/ II 3M
5742981	MIB Cable Abbott Oximetrix3
7493344	MIB Cable Abbott Q2/Q2+1M
Ventilators	
5954537	MIB Cbl Servo-i
5198911	MIB Cbl Maquet SV301
5198945	MIB CBL Maquet SV900
5198937	MIB CBL Puritan Bennett 7200
5198952	MIB CBL Evita/SAV/BABYL/FAB
7493336	MIB-Cable Puritan Bennett 840
7493310	MIB-Cable Hamilton Galileo
7493328	MIB-CableTaema Horus

Part No. / Sachnr.	Product name / Produktbezeichnung
MS16476	MIB-Cable ViaSys Bear1000/Cub
5198952	MIB CBL Evita/SAV/BABYL/FAB
7493336	MIB-Cable Puritan Bennett 840
7493310	MIB-Cable Hamilton Galileo
7493328	MIB-CableTaema Horus
MS16476	MIB-Cable ViaSys Bear1000/Cub
Anesthesia Systems	
5736355	MIB Cable Cicero B/EM BW/CATO
5736348	MIB Cbl Julian/Apollo/Cicero C
7493690	MIB Cable Primus/Julian (CO2)
5944082	MIB Cable Ohmeda ModulusCD
5944074	MIB Cable Narkomed 6/6400
MS16186	Cbl MIB FabiusGS (Medibus)&Tiro
5198952	MIB Cbl Evita/SAV/BabyL/FAB
MS24506	SHP ACC Cbl MIB GE Datex OM 3M
MS16991	MIB Cable Zeus
Blood Gas Analysis Systems	
5742999	MIB Cable AVL Opti CCA
5743872	MIB Cable Via V-ABG1
5944595	MIB Cable OSI Optical Cam
7493351	MIB Cable Microgas 7650
Incubator/Baby Warmer	
MS18805	MIB Cbl Caleo/C2000/Babythm 2M
Special Applications	
5950220	MIB Cbl Aspect BIS A2000
MS24505	MIB Cbl Somanetics InvoS 5100C
Scio® MultiGas and Connection Cables	
Scio Cables	
MS13864	Cable Scio 6802 1.5m
MS13503	Cable Scio 6802 14-9 pin
MS13865	Cable Scio / IDS 1.5m
MS13504	Cable Scio 14-9 .3m
Scio Four Gas Modules	
MS15849	SHP ACC USB Single Serial Adap
MS23211	SHP ACC Modem EXT DB9 1.8M
ICS Extension cables	
MS25936	VGA Extension Cable 20m
Innovian WEB Device Interface Cables	
MS18906	DevConn Cbl G 3M
MS18907	DevConn Cbl G 5M
MS18908	DevConn Cbl G 10M
MS18903	DevConn Cbl A 3M
MS18904	DevConn Cbl A 5M

Part No. / Sachnr.	Product name / Produktbezeichnung
MS18905	DevConn Cbl A 10M
MS18897	DevConn Cbl B 3M
MS18899	DevConn Cbl B 5M
MS18898	DevConn Cbl B 10M
MS18902	DevConn Cbl H 3M
MS18901	DevConn Cbl H 5M
MS18900	DevConn Cbl H 10M
MS20559	DevConn Cbl J 3M
MS20560	DevConn Cbl J 5M
MS20544	DevConn Cbl J 10M
MS23285	DevConn Cbl K 3M
MS23284	DevConn Cbl K 5M
MS22005	DevConn Cbl K 10M
MS23282	DevConn Cbl M 3M
MS23281	DevConn Cbl M 5M
MS23280	DevConn Cbl K 10M
MS24524	DevConn Cbl L 3M
MS24525	DevConn Cbl L 5M
MS24523	DevConn Cbl L 10M
MS24554	DevConn Cbl N 3M
MS24555	DevConn Cbl N 5M
MS24522	DevConn Cbl N 10M
MS24556	DevConn Cbl P 3M
MS24557	DevConn Cbl P 5M
MS24558	DevConn Cbl P 10M
MS16890	Cbl Vitalink/GE9500 99
MS16886	Cbl Marquette DASH
Innovian Anesthesia Device Interface Cables	
MS16600	Cbl Vitalink NM3 IF
MS16598	Cbl Draeger Medibus IF
MS16892	Cbl Medibus/Solar8000M
MS16597	Cbl Draeger Kappa
MS16596	Cbl Draeger Gam/Del X3
MS16595	Cbl I/F Innov AspectBis
MS16594	Cbl Baxter Vigilance
MS16593	Cbl Datex AS3/5 IF
MS16893	Cbl Datascope Diap
MS16592	Cbl Datex Cap Series
MS16591	Cbl Novamatrix 515A IF
MS16589	Cbl Ohmeda RGM 5200
MS16605	Cbl Ohmeda 7800/7900
MS16889	Cbl Ohmeda Vent 7800
MS16891	Cbl Ohmda Astevia 5
MS16603	Cbl Philips CMS I/F
MS16604	Cbl Philips Viridia IF

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Part No. / Sachnr.	Product name / Produktbezeichnung
MS16602	Cbl Spacelabs 90387 IF
MS16601	Cbl Spacelabs UCW IF
MS16599	Cbl Vitalink/GE9500 30
MS17206	Cbl Kit RS232-422 Pwr
MS16894	Cbl Intelivue
Network Connection Cables	
5592667	Network Crossover Cable, 6m
5730176	Network Crossover Cbl, 2m
4726373	Ethernet Patch Cable, 1.2m
4726399	Ethernet Patch Cable, 4.9m
4725557	Network Patch Cable, 20m
Recorder Cables	
4721770	Recorder Cables – IDS 1.5m
4726381	Ethernet patch Cable, 2.4m
4318130	R50 Cable (R50-Monitor) 0.5M
4712993	Recorder Cables 0.5mm
Miscellaneous	
4314659	Cable 14P Universal Key
5596502	SHP Acc Cbl ISD Download

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