CE 0413
CE 0979

DECLARATION OF CONFORMITY

Invivo

PHILIPS

Invivo, a division of Philips Medical Systems
12151 Research Parkway, Suite 200
Orlando, FL 32826
USA

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Name: Expression MR200 MRI Patient Monitoring System

Product Model Number or Designator: Model No. MR200

Control Indicator: Date of Issue: 2013-SEP-16

Device Classification: Class IIb (93/42/EEC, Annex IX, Rule 10)
Class I (1999/5/EEC)

Accessories Classification: Refer to the "Medical Device Accessories Declaration of Conformity", Document Numbers A-Q2975-90083 Revision N2, A-Q2975-90216 Revision A2, and A-Q2975-90217 Revision B2, for classification of the accessories (including rationale) of the medical device accessories CE-marked by Invivo.

Global Medical Device Nomenclature Code (GMDN) and Title: 33586 / Patient monitor, multi-parameter

Product Options (included in the scope of this Declaration):

Option	Description
F01	ECG
	SPO2
	NIBP
F02	ECG
	SPO2
	NIBP
	CO2

Product Accessories (not included in the scope of this Declaration but listed for reference only):

Description	Philips Part No.
LoFlo Sample Line, Adult Cannula (20 per box)	989803183241
LoFlo Sample Line, Pediatric Cannula (20 per box)	989803183251
LoFlo Sample Line, Neonate Cannula (20 per box)	989803183261
LoFlo Sample Line, Adult Cannula, Divided (20 per box)	989803183271
LoFlo Sample Line, Pediatric Cannula, Divided (20 per box)	989803183281
LoFlo Sample Line, Airway Adapt., Adult (20 per box)	989803183291
LoFlo Sample Line, Adult Cannula, Box 100	989803185331
LoFlo Sample Line, Ped Cannula, Box 100	989803185341
LoFlo Sample Line, Neo Cannula, Box 100	989803185351
LoFlo Sample Line, Adult Can, Div, Box 100	989803185361
LoFlo Sample Line, Ped Cannula, Div, Box 100	989803185371
LoFlo Sample Line, Airway Adapt., Box 100	989803185381
Kit, Starter, Standard ECG, 3160	989803152251

Description	Philips Part No.
Kit, Starter, Quadtrode CV,3160	989803152261
Gel, ECG/EEG, Skin Prep, Tube, 3-Pack	989803152291
CAB, 4 LD, MRI ECG (AHA)	989803152301
CAB, 4 LD, NEO.MRI ECG (AHA)	989803152331
CAB, 4 LD, CV MRI ECG (AHA)	989803152351
Kit, Starter, Neonatal, MRI	989803152441
Advanced Apps ECG Cable (AHA)	989803176381
Advanced Filter ECG Cable (AHA)	989803170121
Quadtrode MRI ECG PAD, 25/Box	989803179031
ELCTRD, MRI ECG, QUTRD.CV, 25/Box	989803179041
ELCTRD, MRI, NEO.QUDTRD, 25/Box	989803179051
Wireless ECG Module, ROHS	989803183661
CAB, 4 LD, NEO.MRI ECG, IEC	989803185441
CAB, 4 LD, CV MRI ECG, IEC	989803185451
CAB, 4 LD, MRI ECG, IEC	989803185461
ADVANCED FILTER ECG, IEC	989803185471
Advanced Apps ECG Cable, IEC	989803185481
GE Excite Gating Interface	9292
Hitachi/Toshiba Gating Interface	9293
Siemens Gating Interface	9291
Vector Gating Interface	9294
NiBP, Multi-Use, Infant, 10-15 cm	989803182611
NiBP, Multi-Use, Pediatric, 14-21.5 cm	989803182621
NiBP, Multi-Use, Small Adult, 20.5-28.5 cm	989803182631
NiBP, Multi-Use, Adult, 27.5-36.0 cm	989803182641
NiBP, Multi-Use, Adult X-Lg, 27.5-36.0 cm	989803182651
NiBP, Multi-Use, Lg Adult, 35.0-45.0 cm	989803182661
NiBP, Multi-Use, Lg Adult X-Lg, 35-45 cm	989803182671
NiBP, Multi-Use, Thigh, 44.0-56.0 cm	989803182681
NiBP, Disp, Infant, 10 - 15 cm (Quantity 10)	989803182511
NiBP, Disp, Pediatric, 14 - 21.5 cm (Quantity 10)	989803182521
NiBP, Disp, Small Adult, 20.5 - 28.5 cm (Quantity 10)	989803182531
NiBP, Disp, Adult, 27.5 - 36.0 cm (Quantity 10)	989803182541
NiBP, Disp, Adult Extra Lg, 27.5 - 36.0 cm (Quantity 10)	989803182551
NiBP, Disp, Large Adult, 35.0 - 45.0 cm (Quantity 10)	989803182561
NiBP, Disp, Large Adult X-Lg, 35 - 45 cm (Quantity 10)	989803182571
NiBP, Disp, Thigh, 44.0 - 56.0 cm (Quantity 10)	989803182581
NiBP, Disp, MR, Single Lumen, Sample kit	989803182591
NiBP Cuff, Single-Use, Neo #1 (Quantity 10)	989803183171
NiBP Cuff, Single-Use, Neo #2 (Quantity 10)	989803183181
NiBP Cuff, Single-Use, Neo #3 (Quantity 10)	989803183191
NiBP Cuff, Single-Use, Neo #4 (Quantity 10)	989803183201
NiBP Cuff, Single-Use, Infant #5 (Quantity 10)	989803183211
Adult Pressure Interconnect Hose	989803183221
Neonatal Pressure Interconnect Hose	989803183231
Pneumograph, Chest, NM, 3160	989803152791
European Line Cord	453564177501
ASSY,PWR Cord Set 220V	989803152191
North American Line Cord	989803168211
Power Cable, 25 feet (7.6 meters), AC Jumper, Shielded	989803168221
Brazilian Power Cord, 3 Meter	989803173901
UK Line Cord, 3 Meter	989803174171
Power Cord, AUS/NZL, 3 Meter	989803181291
Power Cord, Italian, 3M, 10A	989803181301
Power Cord, Italian, 3M, 16A	989803181311

Description	Philips Part No.
Power Cord, S Africa, 3 Meter	989803181321
Power Cord, Danish, 3 Meter	989803181331
Power Cord, Israeli, 3 Meter	989803181341
Power Cord, Argentina, 3 Meter	989803181351
Power Cord, Swiss, 3 Meter	989803181361
Quick Connect SPO2 Sensor, MRI	989803161991
Quick Connect SPO2 Clip, Adult	989803166531
Quick Connect SPO2 Clip, Pediatric	989803166541
Quick Connect SPO2 Grip, Adult, 20/box	989803166551
Quick Connect SPO2 Grip, Infant, 20/box	989803166571
Quick Connect SPO2 Grip, Neo, 20/box	989803166581
Quick Connect SPO2 Grip, Ped, 20/box	989803166561
Quick Connect SPO2 Starter Kit	989803167111
Wireless SPO2 Module, ROHS	989803183541
Assy,3.7V Battery Charger, 3160	989803152891
Battery, Wireless Module, 3.7V (each)	989803152881
Expression Information Portal (IP5)	865471
Power Converter, Wireless Module Battery Charger	453564152341
Battery, MRI, 14.8V, 5.08 AH, UL	989803169491
Handle Hook, Hose Management	989803185121
Paper, Thermal Array, Blk, 50mm, Omni	MP05

Accessories Classification: Refer to the "Medical Device Accessories Declaration of Conformity", Document Numbers A-Q2975-90083 Revision N2, A-Q2975-90216 Revision A2, and A-Q2975-90217 Revision B2, for classification of the accessories (including rationale) of the medical device accessories CE-marked by Invivo.

The object of the declaration described above is in conformity with:

- ***Council Directive 93/42/EEC (LVFS 2003:11) concerning medical devices, inclusive of amending Directive 2007/47/EEC (LVFS 2009:07);***

Council Directive 1999/5/EC on radio equipment and telecommunications terminal equipment.

The Manufacturer is certified by the Notified Body (0413) listed below to Annex II-Section 3.2 of the Medical Device Directive. The Manufacturer is certified by the Notified Body (0979) listed below to Annex IX of the Radio & Telecommunications Terminal Equipment Directive. Copies of the Quality System certificate and Notified Body Opinion are available upon request.

Name/Address of Notified Body (0413): Intertek Semko AB, Box 1103, SE-164 22 Kista, Sweden
Name/Address of Notified Body (0979): Intertek Testing Services NA, Inc., 70 Codman Hill Road, Boxborough, MA 01719 USA

Authorized EU Representative: Philips Medizin Systeme Böblingen GmbH, Hewlett-Packard Str. 2, 71034 Böblingen, Germany

Additional Information:

The devices listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation. The products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the device's accompanying documentation.

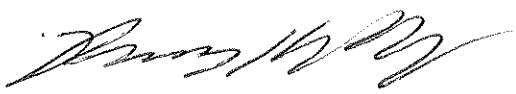
Document #	Title	Revision Date
EN 1041	Information Supplied by the Manufacturer of Medical Devices	2008
EN 62366	Application of Usability Engineering to Medical Devices	2008
IEC 62366	Application of Usability Engineering to Medical Devices	2007
EN 60601-1	Medical Electrical Equipment Part 1: General Requirements for Safety	Second Edition (1990) with Amendments 1 (1993) and 2 (1995)
IEC 60601-1	Medical Electrical Equipment Part 1: General Requirements for Safety	Second Edition (1988) with Amendment 1 (1991) with Amendment 2 (1995)
EN 60601-1-2	Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	2007 (consolidated Second Edition with Amendment 1)
IEC 60601-1-2	Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	2007 (consolidated Second Edition with Amendment 1)
EN 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements for Safety - Collateral Standard: Usability	2007 (Third Edition)
IEC 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements for Safety - Collateral Standard: Usability	2010 (Third Edition)
EN 60601-1-8	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	2004 (First Edition corresponding to 60601-1 Second Edition)
IEC 60601-1-8	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	2003 (First Edition with Amendment 1 (2006) corresponding to 60601-1 Second Edition)
EN 60601-2-27	Medical Electrical Equipment Part 2: Particular Requirements for Safety - Specification for Electrocardiographic Monitoring Equipment	2006 (Second Edition)
IEC 60601-2-27	Medical Electrical Equipment Part 2: Particular Requirements for Safety - Specification for Electrocardiographic Monitoring Equipment	2005 (Third Edition)
EN 60601-2-33	Medical electrical equipment. Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	2010
IEC 60601-2-33	Medical electrical equipment. Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	2010

Document #	Title	Revision Date
EN 60601-2-49	Medical Electrical Equipment - Part 2-49: Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment	2001 (First Edition corresponding to 60601-1 Second Edition)
IEC 60601-2-49	Medical Electrical Equipment - Part 2-49: Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment	2001 (First Edition corresponding to 60601-1 Second Edition)
EN 60601-2-30	Medical Electrical Equipment - Part 2-30: Particular Requirements for the Safety, Including Essential Performance, of Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment	2000 (Second Edition)
IEC 60601-2-30	Medical Electrical Equipment - Part 2-30: Particular Requirements for the Safety, Including Essential Performance, of Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment	1999 (Second Edition corresponding to 60601-1 Second Edition)
EN ISO 21647	Medical Electrical Equipment – Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors	2009
ISO 21647	Medical Electrical Equipment – Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors	2004 with Corrigendum 1 (2005)
EN ISO 9919	Medical Electrical Equipment – Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical Use	2009
ISO 9919	Medical Electrical Equipment – Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical Use	2005
EN ISO 10993-1	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process	2009
ISO 10993-1	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process	2009
EN ISO 10993-5	Biological evaluation of medical devices. Part 5: Tests for in vitro cytotoxicity	1999 2009
ISO 10993-5	Biological evaluation of medical devices. Part 5: Tests for in vitro cytotoxicity	1999 2009
EN ISO 10993-10	Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization	2002 2010
ISO 10993-10	Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization	2002 2010
BS EN ISO 14971	Medical devices - Application of risk management to medical devices	2012
ISO 14971	Medical devices - Application of risk management to medical devices	2007
AS/NZS 3200.1.2	Australian Registry of Therapeutic Goods, Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	2005
IEC 60068-2-1	Environmental Testing – Part 2-1: Test – Test A: Cold	2007
IEC 60068-2-2	Environmental Testing – Part 2-2: Test – Test B: Dry Heat	2007
IEC 60068-2-6	Environmental Testing – Part 2: Tests – Test FE: Vibration (Sinusoidal)	2007

Document #	Title	Revision Date
IEC 60068-2-27	Environmental Testing – Part 2: Tests – Test EA and Guidance: Shock	2008
IEC 60068-2-29	Basic Environmental Testing Procedures – Part 2: Tests – Test EB and Guidance: Bump	1987
IEC 60068-2-64	Environmental Testing Procedures – Part 2-64: Tests – Test FH: Vibration, Broadband Random and Guidance	2008
ISTA Procedure 1A	Fixed Displacement Vibration and Shock Testing for Packaged Products weighing 150 lb (68 kg) or less	2012
IEC 62133	Secondary cells and batteries containing alkaline or other non-acid electrolytes	2002
UL 2054	Standard for Household and Commercial Batteries	2004
ETSI EN 300 328-1	Wideband Transmission systems. Data transmission equipment operating in the 2,4 GHz ISM band and using spread spectrum modulation techniques. Part 1: Technical characteristics and test conditions	2004-11 (V1.6.1)
ETSI EN 300 440-1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range	2001 (V1.3.1)
ETSI EN 300 440-2	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range	2004 (V1.1.2)
ETSI EN 301 489-1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements	2004 (V1.6.1)
ETSI EN 301 489-3	Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 3: Specific Conditions for Short-Range Devices (SRD) Operating on Frequencies between 9 KHz and 40 GHz	2002 (V1.4.1)
RSS-210, Issue 7	Industry Canada, Low-power License-exempt Radio Communication Devices (All Frequency Bands): Category 1 Equipment	September 2005

Signature (signed for and on behalf of Philips):

Date of Issue: 16SEP2013



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Title: Sr. Quality & Regulatory Manager
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