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EC DECLARATION OF CONFORMITY

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

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

Product Name: Expression Model MR400 MRI Patient Monitoring System

Product Model Number or Designator: MR400

Control Indicator: All Products Manufactured from the Date of Issue: 2019-03-12

Device Classification per specified directive:
MDD 93/42/EEC: Class IIb, Rule 10 according to Annex IX (active devices intended for diagnosis where the nature of variations is such that it could result in immediate danger to the patient)
RED 2014/53/EU: Class 1 according to RED 2014/53/EU

Global Medical Device Nomenclature Code (GMDN) and Title: 33586, Single-patient physiologic monitoring system

Product Options:

	Feature						
Option	ECG	SPO2	NiBP	CO2	Agents	IBP	Temp
F01	X	X	X	X			
F02	X	X	X	X		X	
F03	X	X	X	X			X
F04	X	X	X		X		
F05	X	X	X		X	X	
F06	X	X	X		X		X
F07	X	X	X		X	X	X

Accessories: Refer to attached Schedule.

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

- **Council Directive 93/42/EEC, Annex II - Section 3.2 concerning medical devices as amended by 2007/47/EC (LVFS 2003:11 as amended by LVFS 2009:07);**
- **Council Directive 2014/53/EU concerning radio equipment;**
- **Council Directive 2011/65/EU concerning restriction of the use of certain hazardous substances in electrical and electronic equipment.**

EC Certificate information: Quality system certificates are available upon request.

Name, Address, and Identification Numbers of Notified Body (MDD 93/42/EEC): Intertek Semko AB, Box 1103, SE-164 22 Kista, Sweden (Identification number 0413)

The notified body UL Verification Services Inc., 0984, performed an assessment of Article 3.2 and issued the EU-type examination certificate: AN19C11149-1.

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

Additional Information: The product has been tested in a typical configuration as described in the Manufacturer's accompanying documentation. The product is compliant with the relevant harmonized standards as listed in the Manufacturer's accompanying documentation. Additionally the products listed above have been

PHILIPS

designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the device's accompanying documentation.

Identification No.	Title
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 60601-1:2006/A1 :2013	Medical Electrical Equipment Part 1: General Requirements for Safety
EN 62304:2006/AC:2008	Medical Electrical Equipment Part 1: General Requirements for Safety Medical device software - Software life-cycle processes
EN 60601-1-2:2015	Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
EN 60601-1-6:2010/A1:2015	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability
EN 62366:2008/A1:2015	Medical Devices. Application of Usability Engineering to Medical Devices.
EN 60601-1-8:2007/A11:2017	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
EN ISO 14971:2012	Medical Devices — Application of Risk Management to Medical Devices
EN ISO 13485:2016/AC:2016	Medical Devices — Quality Management Systems- Requirements for Regulatory Purposes
EN 62479:2012	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
EN 301 489-1 V1.9.2	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-3 V1.6.1	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 246 GH
EN 300 440 V2.1.1	Short Range Devices (SRD); Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 300 328 V2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

Signature (signed for and on behalf of Philips):

Printed Name: Rusty Kelly

Title: Head of Quality & Regulatory

Date of Issue: 2019-03-12
Date of Expiry: 2023-06-20

Place of Issue: Orlando, FL USA

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Schedule 1

Accessories listed below are not included within the scope of this Declaration, listed for reference only.

Product Name	Model Number
CANNULA, DISP, ADULT	9012
CANNULA, DISP, ADULT	9016
CANNULA,DISP,INT INF,(DIVIDED)	9016B
CANNULA,DISP,PED,(DIVIDED)	9016C
CANNULA,DISP,INFANT,(DIVIDED)	9016A
CANNULA, DISP, INT INFANT	9015
CANNULA, DISP, PED	9013
CANNULA, DISP, INFANT	9014
ANESTHETIC OXYGEN (O2) SENSOR	989803162051
KIT,DISPOSABLE WATER TRAP,3160	94012
KIT,SAMPLE,AGENTS,3160	94018
LOFLO SAMPLE LINE, ADULT CANNULA, BOX 20	989803183241
LOFLO SAMPLE LINE, PED. CANNULA, BOX 20	989803183251
LOFLO SAMPLE LINE, NEO. CANNULA, BOX 20	989803183261
LOFLO LINE, ADU DVD CANNULA,BOX 20	989803183271
LOFLO LINE, PED DVD CANNULA, BOX 20	989803183281
LOFLO LINE, ADU AIRWAY ADPT, BOX 20	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 LINE, ADU DVD CANNULA, BOX 100	989803185361
LOFLO LINE, PED DVD CANNULA, BOX 100	989803185371
LOFLO LINE ADU AIRWAY ADPT, BOX 100	989803185381
GEL, ECG/EEG, SKIN PREP, TUBE, 3-PACK	9009
EXPRESSION MR ECG LEADS, AAMI, CV	989803193721
EXPRESSION MR ECG LEADS, AAMI, STANDARD	989803193731
EXPRESSION MR ECG LEADS, AAMI, NEONATAL	989803193741
EXPRESSION MR ECG LEADS, IEC, CV	989803193751
EXPRESSION MR ECG LEADS, IEC, STANDARD	989803193761
EXPRESSION MR ECG LEADS, IEC, NEONATAL	989803193771
QUADTRODE MRI ECG PAD, 25/BOX	989803179031
ELCTRD, MRI ECG, QUTRD.CV, 25/BOX	989803179041
ELCTRD, MRI, NEO.QUDTRD, 25/BOX	989803179051
WIRELESS ECG PATIENT MODULE (GEN 3) 1-5	989803192761
WIRELESS ECG PATIENT MODULE (GEN 3) 6-10	989803194341
CAB, DIGITAL GATING, GE, 3160	9292
CAB, GATING, SIEMENS, 3160	9291
UNIVERSAL GATING INTERFACE	989803195521
CAB, DIG.GATING, HIT/TOSH, 3160	9293
EXPRESSION MR IBP TRANSDUCER CABLE, 5FT	989803194601
EXPRESSION MR IBP DPT KIT, A/P, BOX 20	989803194631
EXPRESSION MR IBP DPT KIT, I/N, BOX 20	989803194641
NIBP CUFF, SINGLE LUMEN, INFANT	989803182611
NIBP CUFF, SINGLE LUMEN, PEDIATRIC	989803182621
NIBP CUFF, SINGLE LUMEN, SMALL ADULT	989803182631
NIBP CUFF, SINGLE LUMEN, ADULT	989803182641
NIBP CUFF, SINGLE LUMEN, ADULT-L	989803182651
NIBP CUFF, SINGLE LUMEN, LRG ADULT	989803182661
NIBP CUFF, SINGLE LUMEN, LRG ADULT-L	989803182671
NIBP CUFF, SINGLE LUMEN, THIGH	989803182681
NIBP CUFF, SINGLE LUMEN, INFANT, DISP	989803182511
NIBP CUFF, SINGLE LUMEN, PEDIATRIC, DISP	989803182521

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Product Name	Model Number
NIBP CUFF, SINGLE LUMEN,SMALL ADULT,DISP	989803182531
NIBP CUFF, SINGLE LUMEN, ADULT, DISP	989803182541
NIBP CUFF, SINGLE LUMEN, ADULT-L, DISP	989803182551
NIBP CUFF, SINGLE LUMEN, LRG ADULT, DISP	989803182561
NIBP CUFF, SINGLE LUMEN,LRG ADULT-L,DISP	989803182571
NIBP CUFF, SINGLE LUMEN, THIGH, DISP	989803182581
NIBP CUFF, SINGLE LUMEN, NEO #1, DISP	989803183171
NIBP CUFF, SINGLE LUMEN, NEO #2, DISP	989803183181
NIBP CUFF, SINGLE LUMEN, NEO #3, DISP	989803183191
NIBP CUFF, SINGLE LUMEN, NEO #4, DISP	989803183201
NIBP CUFF, SINGLE LUMEN, INFANT #5, DISP	989803183211
ADULT PRESSURE INTERCONNECT HOSE	989803183221
NEONATAL PRESSURE INTERCONNECT HOSE	989803183231
PNEUMOGRAPH,CHEST,NM,3160	94023
QUICK CONNECT SPO2 PROBE, 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, PED, 20/BOX	989803166561
QUICK CONNECT SPO2 GRIP, INFANT, 20/BOX	989803166571
QUICK CONNECT SPO2 GRIP, NEO, 20/BOX	989803166581
WIRELESS SPO2 PATIENT MODULE (GEN 3) 1-5	989803192771
WIRELESS SPO2 PATIENT MODULE (GEN 3) 6-10	989803194331
BATTERY, MODULE (GEN 3)	989803191341
BATTERY, MRI, 14.8V, 5.08 AH, UL	989803169491
EXPRESSION INFORMATION PORTAL (IP5)	IP5
ADVANCED COMMUNICATIONS OPTION	989803176521
EUROPEAN LINE CORD	453564177501
NORTH AMERICAN LINE CORD	989803168211
CORD, JUMPER, 25 FEET	989803168221
BRAZILIAN POWER CORD, 3 METER	989803173901
UK LINE CORD, 3 METER	989803174171
POWER CORD, AUS/NZL, 3 METER	989803181291
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
FLEXTEMP II SENSOR (ESOPHAGEAL/RECTAL/AXILLARY, DIRECT MODE)	989803194511
SURGICAL LUBRICANT, 12 PACK	989803168891
FLEXTEMP SYSTEM, JACKET (BOX 10)	989803178181
CHARGING STATION	989803191021
MODULE CHARGER	989803191031