## EC DECLARATION OF CONFORMITY

PHILIPS

**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 MR200 MRI Patient Monitoring System

**Product Model Number or Designator:** MR200

**Control Indicator:** All Products Manufactured from the Date of Issue: 2019-02-27

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

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

**Product Options:** F01 (ECG, SPO2, and NIBP); F02 (ECG, SPO2, NIBP, and CO2)

**Accessories:** Refer to attached Annex.

**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; and**
- **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: AN19C11148-1.**

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

| Reference | 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 |

| Reference | Title |
|---|---|
| EN 60601-1:2006/A1:2013 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| EN 62304:2006/AC:2008 | Medical device software - Software life-cycle processes |
| 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 |
| 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 (ISO 14971:2007, Corrected version 2007-10-01) |
| EN ISO 13845:2016/AC:2016 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) |
| 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 55011:2009/A1:2010<br>CISPR 11:2009/A1:2010 | Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement |
| EN 301 489-1 V1.9.2 / 2011-09-29 | Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements |
| 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):**

**Date of Issue**: 2019-02-27
**Expiration Date:** 2023-06-20

**Printed Name:** Rusty Kelly

**Place of Issue:** Orlando, FL USA

**Title**: Head of Quality & Regulatory

## Annex

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

| Product Name | Model Number |
|---|---|
| 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 |
| CAB, 4 LD, MRI ECG | 9224 |
| CAB, 4 LD, NEO.MRI ECG | 9222 |
| CAB, 4 LD, CV MRI ECG | 9223 |
| ADVANCED APPS ECG CABLE | 989803176381 |
| ADVANCED FILTER ECG CABLE | 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 PATIENT MODULE | 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 |
| CAB, DIGITAL GATING, GE, 3160 | 9292 |
| CAB, GATING, SIEMENS, 3160 | 9291 |
| CAB, DIG.GATING, HIT/TOSH, 3160 | 9293 |
| UNIVERSAL GATING INTERFACE | 989803195521 |
| 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 |
| 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, SAMPLE KIT, DISP | 989803182591 |
| 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 |

| Product Name | Model Number |
|---|---|
| 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 | 989803183541 |
| BATT.3.7V,WRLS.PAT.MDLE | 9065 |
| BATTERY, MRI, 14.8V, 5.08 AH, UL | 989803169491 |
| HANDLE HOOK, HOSE MANAGEMENT | 989803185121 |
| EXPRESSION INFORMATION PORTAL (IP5) | IP5 |
| CAL GAS, AEROSOL, 5% $CO_2$ BALANCE N2 | 989803190141 |
| 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 |
| CHARGING STATION | 989803191021 |
| MODULE CHARGER | 989803191031 |