CE 0413
CE 0979

## 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 MR400 MRI Patient Monitoring System

**Product Model Number or Designator:** MR400

**Control Indicator:** Serial numbers: USLP400001, USLP400002, USLP400003, USLP400004, USLP400005

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

Refer to the "Accessories RoHS Declaration of Conformity", Document Number A-Q2975-90220, for the medical device accessories CE-marked by Invivo.

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

**Product Options/Accessories:**

| | Features | | | | |
|---|---|---|---|---|---|
| **Option** | ECG | SPO2 | NiBP | Temp | Agents/CO2 |
| LP4 | X | X | X | X | X |

| Accessory | Original Part | Number REF |
|---|---|---|
| CANNULA, DISP, ADULT | 9012 | 989803152561 |
| CANNULA, DISP, ADULT | 9016 | 989803152601 |
| CANNULA,DISP,INT INF,(DIVIDED) | 9016B | 989803152621 |
| CANNULA,DISP,PED,(DIVIDED) | 9016C | 989803152631 |
| CANNULA,DISP,INFANT,(DIVIDED) | 9016A | 989803152611 |
| CANNULA, DISP, INT INFANT | 9015 | 989803152591 |
| CANNULA, DISP, PED | 9013 | 989803152571 |
| CANNULA, DISP, INFANT | 9014 | 989803152581 |
| Anesthetic Oxygen (O2) Sensor | — | 989803162051 |
| KIT,DISPOSABLE WATER TRAP,3160 | 94012 | 989803152671 |
| KIT,SAMPLE,AGENTS,3160 | 94018 | 989803152661 |
| 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 |

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|---|---|---|
| GEL, ECG/EEG, SKIN PREP, TUBE, 3-PACK | 9009 | 989803152291 |
| 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 | 989803152821 |
| CAB, GATING, SIEMENS, 3160 | 9291 | 989803152831 |
| CAB, GATING, PHILIPS ACH, 3160 | 9294 | 989803152841 |
| CAB, DIG.GATING, HIT/TOSH, 3160 | 9293 | 989803152851 |
| 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, 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 | 989803152791 |
| 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) | — | 865471 |
| 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 |
| CAL GAS, AEROSOL, 5% CO2 Balance N2 | — | 989803190141 |
| CAL GAS,AEROSOL CO-2 | — | 989803152641 |

**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;***

**EC Certificate information:** 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/Identification Numbers of Notified Body:**
(0413): Intertek Semko AB, Box 1103, SE-164 22 Kista, Sweden

(0979): Intertek Testing Services NA, Inc., 70 Codman Hill Road,
Boxborough, MA 01719 USA

**Name/Address of 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. Copies of the accompanying documentation are available upon request.

**Signature (signed for and on behalf of Philips):**

**Date of Issue**: 1/22/2015

**Printed Name: Rusty Kelly**

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

**Title**: Sr. Quality and Regulatory Affairs Manager