This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device covered by the present Declaration is in conformity with all regulations or directives below, including compliance with related Essential Requirements and General Safety and Performance Requirements.

1. Object of the declaration

<table>
<tr><td>Product Name</td><td>MR Patient Care Portal 5000</td></tr>
<tr><td>Product Type</td><td>MRI Patient Monitoring System</td></tr>
<tr><td>Intended Purpose</td><td>The MR Patient Care Portal 5000 is intended to be used outside the MR Scanner room (i.e. Control Room, Induction Room, or Recovery Room) by healthcare professionals to monitor vital signs of a patient undergoing a MRI procedure. The device remotely monitors a patient’s vital signs by wirelessly communicating with a patient monitoring system.</td></tr>
<tr><td>Product Part Number(s) and Descriptions</td><td>866162: MR Patient Care Portal 5000</td></tr>
<tr><td>Product Options/Accessories Part Number(s) and Descriptions</td><td>Product Options within scope of this declaration
<table>
<tr><th>Option No.</th><th>Option Description</th><th>Part number; Description</th></tr>
<tr><td rowspan="3">A01</td><td rowspan="3">Standard Accessories</td><td>453564880031; Cable Management, Desktop, RoHS</td></tr>
<tr><td>989803205741; Power Adapter, Portal 453564875441; Power Adapter Portal (service part number)</td></tr>
<tr><td>Localized documentation, part numbers are country-specific.</td></tr>
<tr><td>A02</td><td>No Accessories</td><td>453564792561, MRPC; Portal 5000 Desktop Unit (service replacement)</td></tr>
<tr><td>A06</td><td>Flex Antenna</td><td>989803176511; Control Room Flex Antenna (non R.E.D. countries)</td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td>
<table>
<tr><td></td><td></td><td>989803206531; Control Room Flex Antenna, R.E.D.</td></tr>
<tr><td rowspan="2">S01</td><td rowspan="2">MR200 or MR400 communication option</td><td>989803205001; Radio Kit, USB</td></tr>
<tr><td>989803204881; Cradle, Radio</td></tr>
<tr><td>H01</td><td>MR Patient Care Portal 5000 Desktop Unit</td><td>453564792561; MRPC; Portal 5000 Desktop Unit</td></tr>
<tr><td>H02</td><td>Portal Display, 18.5 inch</td><td>989803204941; Portal Display, 18.5 inch (No Line Cord)</td></tr>
</table>

Radio components that ensure conformity to the Radio Equipment Directive:
989803206531, Control Room Flex Antenna, R.E.D.
989803176521, Advanced Communication Option
453564931661; Antenna, Modified HE61 NH, RoHS (Mast Antenna) (service)
989803204881; Cradle, Radio</td></tr>
<tr><td>Basic UDI-DI</td><td>0884838BM469TJ</td></tr>
<tr><td>Control Indicator</td><td>Hardware: Serial Number with production as of the Date of Issue
Software: Version 01.03.00</td></tr>
<tr><td>Global Medical Device Nomenclature Code (GMDN) and Description or CND Code and Description</td><td>33586, General-purpose multi-parameter bedside monitor</td></tr>
</table>

The object of the Declaration described above is in conformity with the following regulations:

EU Directive	**Council Directive 93/42/EEC of 14 June 1993 concerning medical devices amended up to and inclusive of Council Directive 2007/47/EC (MDD) (LVFS 2003:11 as amended by LVFS 2009:07)**
Device Risk Classification	Class IIb based on Annex IX and Rule 10
Conformity Assessment Path	Annex II excluding (4)
Notified Body Name, Address, and ID	Intertek Semko AB Box 1103, SE-164 22 Kista, Sweden (Identification number 0413)
Certificate(s) issued	EC Certificate Number: 41311197-02
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. Refer to Attachment A.

EU Directive	**Directive 2011/65/EU of the European Parliament and of the Council of 08 June 2011 on the restrictions of the use of certain hazardous substances in electrical and electronic equipment, amended up to and inclusive of Directive (EU) 2017/2102 (RoHS)**
Device Classification	Category 8, medical devices according to Annex I
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. Refer to Attachment A

EU Directive	**Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the**

	laws of the Member States relating to the making available on the market of radio equipment (RED)
Device Classification	Class 1
Conformity Assessment Path	Annex II
Notified Body Name, Address, ID and EU Certificate Number	Not Applicable (Conformity Assessment Path Module A)
Standards	The radio equipment was tested to the following standards or technical specifications: Refer to Attachment A

2. Additional information:

Manufacturer	Invivo, a division of Philips Medical Systems 12151 Research Parkway Orlando, FL 32826 USA
EU Authorized Representative	Philips Medizin Systeme Böblingen GmbH, Hewlett-Packard Str. 2, 71034 Böblingen, Germany
Quality Certificates Issued	The Manufacturer is certified by Intertek Testing Services NA, Inc. to the following: ISO 13485:2016 as evidenced by certificate number 0072552-04.

Signature (signed for and on behalf of Invivo, a division of Philips Medical Systems):

Krystal Mitchell

Printed Name: Krystal Mitchell

Title: Regulatory Affairs Manager

Date of Issue: 14-MAR-2022

Place of Issue: Orlando, FL USA

A-866162-90383-DOC

Date of Expiration: 20 June 2023

3. Attachment A

Standards and/or Common Specifications

Quality System	
EN ISO 13485:2016/ AC:2018	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)
General Safety Standard	
EN 60601-1:2006/A12:2014	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A1:2012/C1:2014)
Collateral Safety Standards	
EN ISO 20417:2021	Medical Devices - Information supplied by the manufacturer (ISO 20417:2021)
EN ISO 14971:2019	Application of risk management to medical devices
EN ISO 15223-1:2016, Corrected version 2017-04	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
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 (IEC 60601-1-2:2014)
EN 60601-1-6:2010/ A1:2015	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collateral standard: Usability (IEC 60601-1-6:2010/A1:2013)
EN 60601-1-8:2007/ A11:2017	Medical electrical equipment -- Part 1-8: General requirements for basic safter and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006/A1:2012)
EN IEC 62304:2006/A1:2015	Medical device software - Software life-cycle processes (IEC 62304:2006/A1:2015)
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices (IEC 62366:2015)

Particular Safety Standards	
EN 60601-2-27:2014/C1:2017	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment (IEC 60601-2-27:2011/C1:2012)
EN 60601-2-34:2014	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment (IEC 60601-2-34:2011)
IEC 80601-2-49:2018	Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
EN IEC 80601-2-30:2019	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (IEC 80601-2-30:2018)
EN ISO 80601-2-55:2018	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2018)
EN ISO 80601-2-56:2017/ A1:2020	Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2017/Al:2018)
EN ISO 80601-2-61:2019	Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2017/Cl:2018)
Radio Standards	
EN 62479:2010	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) (IEC 62479:2010)
EN 300 328 V2.2.2	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

EN 301 489-1 v2.2.3	Electromagnetic compatibility and Radio spectrum Matters (ERM). Electromagnetic Compatibility (EMC) standard for radio equipment and services. Part 1: Common technical requirements
RoHS Standard	
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances (IEC 63000:2016)

PHILIPS

Attachment to Declaration of Conformity MR Patient Care Portal 5000

Declaration of Conformity Document Number/Rev.: A-866162-90383-DOC/E

Description of the change The updates to the Declaration of Conformity are detailed in the table below

Revision	Update	EC	Assessment
A	Updated Standards State of the Art compliance to EN ISO 14971:2019/A11:2021 and EN ISO 13485:2016/A11:2021	2975-2022-10-06228	There is no change to the device's software, labeling, or material. There is no change to the intended purpose and no change to the sterilization and packaging. Attachment revision A corresponds to Revision E.01 in eDMR.
B	• Removed Date of Expiration. • Added manufacturer SRN US-MF-000002177.	2975-2023-07-10874	• There is no change to the device's software, labeling, or material. There is no change to the intended purpose and no change to the sterilization and packaging. • The grace period under EU MDD has been extended per Regulation (EU) 2023/607; Date of Expiration (of the EC Certificate per the Medical Device Directive 93/42/EEC) no longer applies. • Manufacturer SRN was inadvertently omitted from Declaration of Conformity. Attachment revision B corresponds to Revision E.02 in eDMR.
C	• Update ISO 13485 Certificate Number 0072552-05 • Update Date of Issue: 19-FEB-2024	2975-2024-02-06780	There is no change to the device's software, labeling, or material. There is no change to the intended purpose and no change to the sterilization and packaging. Attachment revision C corresponds to Revision E.03 in eDMR.
D	Update Date of Issue: 21-NOV-2024 Added Date of Expiration: 31-DEC-2028 Updated Standards State of the Art compliance to: • EN ISO 15223-1:2021 • EN 60601-1:2006/A1:2013/A2:2021 • EN 60601-1-2:2015/A1:2021 • EN 60601-1-6:2010/A1:2015/A2:2021 • EN 62366-1:2015/A1: 2020 • EN 60601-1-8:2007/ A1:2013/A2:2021 • EN 60601-1-9:2008/A1:2013/A2:2020 EN IEC 80601-2-49:2019Updated RoHS EU Directive section:	2975-2024-10-07249	There is no change to the device's software, labeling, or material. There is no change to the intended purpose and no change to the sterilization and packaging. The grace period under EU MDD has been extended per Regulation (EU) 2023/607. Attachment revision D corresponds to Revision E.04 in eDMR.

	• Directive 2011/65/EU of the European Parliament and of the Council of 08 June 2011 on the restrictions of the use of certain hazardous substances in electrical and electronic equipment, amended up to and inclusive of Directive (EU) 2017/2102 (RoHS) and Commission Delegated Directive EU 2015/863		

Assessment: See table above

According to EU MDR Art 120(3), the change is considered non-significant.

Additional comment: N/A

Signature (signed for and on behalf of INVIVO, a division of Philips Medical Systems):

Krystal Mitchell

Date of Issue: 21-NOV-2024

Printed Name: Krystal Mitchell

Place of Issue: Orlando, FL USA

Title: Regulatory Affairs Manager

Date of Expiration: 31-DEC-2028

Document Properties

Property	Value
Template Used/Rev.	A-Q2920-01308-T2-Rev. A
Document Class	see system managing this document
Tier	see system managing this document
Element	see system managing this document