EU Declaration of Conformity

PHILIPS

Revision: A **Number**: A-866162-90383

Based on Template/Revision: A-Q2920-01308-T1/C Record

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

Product Name	MR Patient Care Portal 5000
Product Type	MRI Patient Monitoring System
Intended Purpose	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.
Product Part Number(s) and Descriptions	866162: MR Patient Care Portal 5000
Product Options/Accessories Part Number(s) and Descriptions	Product Options within scope of this declaration

Option No.	Option Description	Description
A01	Standard Accessories	Instructions for Use, Quick Reference Guide, Integration Guide
A02	No Accessories	MR Patient Care Portal 5000 only
A06	Flex Antenna	Optional antenna replacement
S01	MR200 or MR400 communication option	Includes USB radio kit and charging cradle
H01	MR Patient Care Portal 5000 Desktop Unit	Ordered in conjunction with H02 and A01
H02	Portal Display, 18.5 inch (no line cord)	Ordered in conjunction with H01 and A01

	Components that ensure conformity to the Radio Equipment Directive: 989803206531, Control Room Flex Antenna, R.E.D. 989803176521, Advanced Communication Option
Basic UDI-DI	0884838BM469TJ
Control Indicator	Hardware: Serial Number with production as of 07-MAY-2021 Software: Version 01.01.00
Global Medical Device Nomenclature Code (GMDN) and Description or CND Code and Description	33586, General-purpose multi-parameter bedside monitor

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)
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 0072552-03.

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

Krystal Mitchell

Date of Issue: 07 May 2021

Printed Name: Krystal Mitchell

Title: Regulatory Affairs Manager

Place of Issue: Orlando, FL USA

A-866162-90383

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 1041:2008/A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 14971:2019	Application of risk management to medical devices (ISO 14971:2019)
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: 2019	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	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
EN 60601-2-49:2015	Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment (IEC 60601-2-49:2011)
EN 80601-2-30:2010/ A1:2015	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (IEC 80601-2-30:2009/A1:2013)
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
EN ISO 80601-2-61:2019	Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
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 (V2.1.1)	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
EN 301 489-1 v2.2.2	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)