EU Declaration of Conformity

PHILIPS

Revision: J **Number**: A-866120-DOC

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	Expression Model MR200 MRI Patient Monitoring System
Product Type	MR Patient Monitoring System
Intended Purpose	The Expression Model MR200 MRI Patient Monitoring System is intended for use by healthcare professionals to monitor vital signs of patients undergoing MRI procedures and to provide signals for synchronization of the MRI scanner. The MR200 provides monitoring for the following vital sign parameters: ECG, pulse oximetry (SpO2), non-invasive blood pressure (NIBP), and (optional) carbon dioxide (CO2).
Product Part Number(s) and Descriptions	866120 Expression Model MR200 MRI Patient Monitoring System
Product Options/Accessories Part Number(s) and Descriptions	Option F01 (ECG, SPO2, and NIBP) Option F02 (ECG, SPO2, NIBP, and CO2)
Basic UDI-DI	0884838BM467TE
Control Indicator	Date of Issue: 27-APR-2022 MR200 software SW047 version 01 and WPUM02, and firmware FW27 version 131
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 device, 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 I
Conformity Assessment Path	Annex III
Notified Body Name, Address, ID and EU Certificate Number	The Notified Body identified in this section performed Module B: EU Type Examination and issued the certificate. UL Verification Services Inc. 47173 Benicia Street, Fremont, CA 94538 USA NB ID: 0984 RED type examination Certificate Number AN19C11148-1
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 SRN: NL-AR-000001422
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: 27-APR-2022

Place of Issue: Orlando, FL USA

A-866120-DOC

Date of Expiration 20-JUN-2023

3. Attachment A

Standards and/or Common Specifications

Quality System	
EN ISO 13485:2016/ C12:2018	Medical devices – Quality management systems – Requirements for regulatory purposes
General Safety Standard	
EN 60601-1:2006/A12:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Collateral Safety Standards	
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 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 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
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
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
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

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)
EN 300 440 V2.1.1	Short Range Devices (SRO); 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 V2.2.2	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
RoHS Standards	
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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Attachment to Declaration of Conformity Expression MR200 Patient Monitoring System

Declaration of Conformity Document Number/Rev.: A-866120-DOC/ Rev. J

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

Revision	Update	EC	Assessment
A	• Document number change to comply with A-Q2920-01308 Rev. C • Remove withdrawn EN 1041:2008/A1:2013	2975-2022-04-09966	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.
B	• Updated Standards State of the Art compliance to EN ISO 14971:2019/A11:2021 and EN ISO 13485:2016/A11:2021	2975-2022-08-10244	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.
C	• Removed Date of Expiration • Updated manufacturer SRN from NL-AR-000001422 to US-MF-000002177	N/A	• 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. • US-MF-000002177 is the manufacturer SRN listed in EUDAMED

Assessment: See table above

According to EU MDR Article 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: 16-JUN-2023

Printed Name: Krystal Mitchell

Place of Issue: Orlando, FL USA

Title: Regulatory Affairs Manager