EU Declaration of Conformity

PHILIPS

Document Number 1105023MC7
Revision C

This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device(s)/accessories covered by this Declaration are in conformity with all regulations or directives specified below.

1. Object of the declaration:

Product Name	Capnostat 5 Mainstream CO_2 Sensor		
Product Type	CO_2 Sensor		
Intended Purpose	The Capnostat 5 is a CO_2 sensor used during mainstream monitoring of a patient's exhaled CO_2. The C5 continually measures and transmits a capnogram (real time CO_2 concentration (mmHg) wave form), values for $ETCO_2$, inspired CO_2 and respiration rate that are captured and managed by a physiological monitor.		
Product Part Number(s) and Descriptions	**Part Number**	**Description**	**12NC**
	1015928	Capnostat 5 Mainstream CO2 Sensor (Respironics)	NA
	1036698	Capnostat 5 Mainstream CO2 Sensor (Mindray)	NA
	1050549	Capnostat 5 Mainstream CO2 Sensor (Lutech)	NA
Product Options/ Accessories Part Number(s) and Descriptions	All accessories are separately CE marked. They are included within the scope of other Declaration(s) of Conformity		
Basic UDI-DI	0884838BM633T7		
Control Indicator	**Initial Issue Date**	**Part Number**	
	01Apr2005	1015928	
	20Nov2006	1036698	
	29Jul2008	1050549	
Global Medical Device Nomenclature code (GMDN) and Description	GMDN Code: 36552 - Patient Monitoring Module, Carbon Dioxide CND Code: Z12030204 – Gas Exchange Monitoring Instruments		

The object of the Declaration (product part numbers and if applicable the accessory part numbers) that are described above as included in this DoC is / are in conformity with the following regulations / directives. If optional accessories that are used in combination with the product (medical device), but are CE marked on their own are referenced in this DoC, they are excluded further on as these optional accessories have their own DoC.

EU Regulation	**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (EU MDR)**
Risk Classification	Class IIb based on Annex VIII and Rule 10

EU Declaration of Conformity

PHILIPS

Document Number 1105023MC7
Revision C

Conformity Assessment Path	Annex IX
Notified Body Name, Address, and ID	BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands 2797
Certificate(s) Issued	EU Quality Management System Certificate (MDR) 737191
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
Common Specifications	None

EU Declaration of Conformity

PHILIPS

Document Number 1105023MC7
Revision C

2. Mandatory information:

Manufacturer	Respironics Novametrix, LLC. 3000 Minuteman Road Andover, MA 01810 USA SRN US-MF-000007951
EU Authorized Representative (AR)	Philips Medical Systems Nederland B.V. Veenpluis 6, 5684PC Best, The Netherlands NL-AR-000001422
ISO Quality Certificates Issued	The Manufacturer is certified by BSI to the following: Quality Management System - ISO 13485:2016, FM 72260 ISO 13485:2016 MDSAP Certificate 685566

Signature (signed for and on behalf of Respironics Novametrix, LLC):

Date of Issue:

12-OCT-2023

Printed Name: Brenda Niel

Title: Head of Regulatory Affairs

Place of Issue:
3000 Minuteman Road
Andover, MA 01810

1105023MC7 Rev. C

EU Declaration of Conformity

PHILIPS

Document Number 1105023MC7
Revision C

3. Attachment A
Standards and/or Common Specifications

Standard	Standard Title	Product Applicability
Quality System		
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes	All Products
EN ISO 14971:2019	Medical devices – Application of Risk Management to Medical Devices	All Products
General Safety Standard		
IEC 60601-1:2005/AMD2:2020 EN 60601-1:2006/A1:2013	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance	All Products
IEC 60601-1-2:2014+AMD1:2022 (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	All Products
IEC 62304:2006+A1:2015	Medical device software - Software life-cycle processes	All Products
ISO 20417	Information supplied by the manufacturer of medical devices	All Products
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	All Products
Particular Safety Standards		
Biocompatibility		
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	All Products
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	All Products
ISO 80601-2-55:2018	Medical Electrical Equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors	All Products
IEC 60068-2-27:2008	Environmental testing -- Part 2-27: Tests - Test Ea. and guidance: Shock	All Products
IEC 60068-2-31:2008	Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens	All Products
IEC 60068-2-64: 2008+AM D1: 2019	Environmental testing -- Part 2-64: Test methods - Test Fh: Vibration, broad-band random (digital control) and guidance	All Products
Other Standards		
Accompany Documents and Labeling		
EN 50419:2022	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)	All Products
IEC 60529:2013	Degrees of protection provided by enclosures (IP Code)	All Products
IEC 60417:2002 DB	Graphical symbols for use on equipment	All Products
ISO 7000:2019	Graphical Symbols for use on equipment	All Products

EU Declaration of Conformity

PHILIPS

Document Number 1105023MC7
Revision C

Standard	Standard Title	Product Applicability
ISO 7010:2019	Graphical symbols — Safety colours and safety signs	All Products
IEC 62570:2014	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	All Products
Usability		
IEC 62366-1:2015+AMD1:2020 (EN 62366-1 2015)	Medical Devices – Part 1: Application of Usability Engineering to Medical Devices	All Products