RESPIRONICS'

EU DECLARATION OF CONFORMITY

Respironics, Inc.
1001 Murry Ridge Lane, Murrysville, PA 15668, USA

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 Safety and Performance Requirements.

Object of the declaration:

Product Name:	Trilogy Evo	
Product Type:	Ventilator	
Intended Purpose:	The Trilogy Evo ventilator provides invasive and non-invasive positive pressure ventilation for the care of patients >2.5 kg through adults. The ventilator can measure, display, record, and alarm SpO2, FiO2, CO2, and Pulse Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional, home, and nonemergency transport settings for example wheelchair, or personal vehicle. The AVAPS-AE mode is intended for noninvasive use in adult and pediatric patients weighing over 10kg with Obstructive Sleep Apnea (OSA), Respiratory Insufficiency and Respiratory Failure	
Product Part Number(s) and Descriptions:	IN2110X15B	Trilogy Evo Ventilator, Inti
	IN2110X19	Trilogy Evo, International (non-BT)
	IT2110X21B	Trilogy Evo Ventilator, Italy
	ES2110X15B	Trilogy Evo Ventilator, Iberia
	DE2110X13B	Trilogy Evo Ventilator, Germany
	EU2110X15B	Trilogy Evo Ventilator, EU
	LD2110X23B	Garbin Evo, Linde
	LA2110X15B	Trilogy Evo, Latin America
	BL2110X15B	Trilogy Evo, Benelux
	EE2110X15B	Trilogy Evo, Eastern Europe
	GB2110X15B	Trilogy Evo, Great Britain
	ND2110X15B	Trilogy Evo, Nordics
	FR2110X14B	Trilogy Evo, France
	EU2110X19	Trilogy Evo, EU (Non-BT)
	IN2100X15B	Trilogy Evo Ventilator w/OBM, Inti
	IN2100X19	Trilogy Evo, 02, International (non-BT)
	IT2100X21B	Trilogy Evo Ventilator w/OBM, Italy
	ES2100X15B	Trilogy Evo Ventilator w/OBM, Iberia
	DE2100X13B	Trilogy Evo Ventilator w/OBM, Germany
	EU2100X15B	Trilogy Evo Ventilator w/OBM, EU
	SP2100X26B	LifeVent EV02, Sapio
	LA2100X15B	Trilogy Evo, 02, Latin America
	BL2100X15B	Trilogy Evo 02, Benelux

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EE2100X15B	Trilogy Evo 02, Eastern Europe
GB2100X15B	Trilogy Evo 02, Great Britain
ND2100X15B	Trilogy Evo 02, Nordics Trilogy
FR2100X14B	Evo 02, France Trilogy Evo 02,
EU2100X19	EU (Non-BT)

Product Options/Accessories Part Number(s) and Descriptions: _____

All options/accessories are listed on secondary DoCs:
Class I: REG 2102679
Class II: REG 2102680
XPOD: REG 2102730

<Basic UDI-DI> Control Indicator:

N/A

Initial Issue Date:	Part Number:
March 07, 2019	IN2110X15B
	IT2110X21B
	ES2110X15B
	DE2110X13B
	EU2110X15B
	IN2100X15B
	IT2100X15B
	ES2100X15B
	DE2100X13B
	EU2100X15B
July 29, 2019	LD2110X23B
	SP2100X26B
August 05, 2019	IN2110X19
	IN2100X19
	LA2100X15B
	LA2100X15B
August 16, 2019	BL2110X15B
	BL2100X15B
	EE2110X15B
	EE2100X15B
	GB2110X15B
	GB2100X15B
	ND2110X15B
	ND2100X15B
	FR2110X14B
	FR2100X14B
	EU2110X19
	EU2100X19

For RED Directive:	
Serial Range	Software Version
H23485179 or higher	1.01.09.00

Global Medical Device Nomenclature Code (GMDN) and Description

47083 Portable Electric Ventilator

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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)**
Device Risk Classification	Class lib based on Annex IX and Rule
Conformity Assessment Path	The Manufacturer is certified by TÚV SLID Product Service GmbH to EN ISO 13485 and Annex VII of the Medical Device Directive 93/42/EEC. Copies of the Quality System certificates are available upon request.
Notified Body Name, Address, and ID	TÚV SLID Product Service GmbH Ridlerstrasse 65 80339 Munchen, Germany
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 8 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) 2017/1202 (RoHS)**
Device Risk Classification	Category 8, medical device, according Annex I". Note: The Classification is found in 2011/65/EU.
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 III

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Notified Body Name, Address, ID and EU Certificate Number	Intertek Testing; Certification LTD Intertek House, Cleeve Road Leatherhead, Surry KT22 7SB United Kingdom Notified Body Number: 0359 EU Type Examination Certificate: 0004084
Standards	The radio equipment was tested to the following standards or technical specifications: Refer to *Attachment A*

Additional information:

EU Authorized Representative:	Respironics Deutschland GmbH & Co. KG Gewerbestrasse 17 82211 Herrsching, Germany Tel:+49 8152 93060
Quality Certificates Issued:	The Manufacturer is certified by TUV SLID Product Service GmbH to the following: EN ISO 13485 and Annex ll-Section 3.2 of the MDD as evidenced by certificate number G117 09 15581 057

Signature (signed for and on behalf of *Philips Respironics, Inc.* -	Date of Issue: *08/16/2019*
Printed Name: xxxxxxxxxxxxxxxxxxxx	Place of Issue: xxxxxxxxxxxxxxxxxxxxx
Title: Senior Regulatory Manager	*REG 2102576 v. 04*

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Attachment A
Standards and/or Common Specifications

Quality System	
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
General Safety Standard	
EN 60601- l:2006/Al:2013	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
Collateral Safety Standards	
EN 60601-1-2:2014	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/Al:2015	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability
EN 60601-1-8:2007/Al:2013	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 60601-1-11:2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Particular Safety Standards	
Critical Care Ventilators	
EN ISO 80601-2-12:2011	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
Home Care Ventilators	
EN ISO 80601-2-72:2015	Medical electrical equipment -- Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
Gas Monitors	
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
Pulse Oximetry	
ISO 80601-2-61:2017	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
Biocompatibility	
ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2009	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
Other Standards	
Accompany Documents and Labeling	
EN 1041:2008/Al:2013	Information supplied by the manufacturer of medical devices

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EN ISO 15223-1:2017	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements
ISO 17664:2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

Software

EIM 62304:2006/AI:2015	Medical device software - Software life cycle processes

Risk Management

EN ISO 14971:2012	Medical devices - Application of risk management to medical devices

Usability

IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices

Radio

EN 62311:2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
ETSI EN 300 328 V2.1.1 (2016)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
ETSI EN 300 330 V2.1.1 (2017)	Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
ETSI EN 301 489-1 V2.1.1 (2016)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
ETSI EN 301 489-3 V2.1.1 (2017)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
ETSI EN 301 489-17 V3.1.1 (2016-11)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

RoHS

EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances