EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number 2102576
Revision v18

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 below.

1. Object of the declaration:

Product Name:	Trilogy Evo
Product Type:	Ventilator
Intended Purpose:	Trilogy Evo: The Trilogy Evo ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo is intended for pediatric through adult patients weighing at least 2.5 kg. 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. It may be used for both invasive and non-invasive ventilation. 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. Trilogy EV300: The Trilogy EV300 ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy EV300 is intended for pediatric through adult patients weighing at least 2.5 kg. 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 and hospital settings and non-emergency transport settings; for example, wheelchair. It may be used for both invasive and noninvasive ventilation. 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, Intl 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)
TR2110X15B	Trilogy Evo, Turkey
AU2110X15B	Trilogy Evo, Australia

IN2100X15B	Trilogy Evo Ventilator w/OBM, Intl
IN2100X19	Trilogy Evo, O2, 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, EVO2
LA2100X15B	Trilogy Evo, O2, Latin America
BL2100X15B	Trilogy Evo O2, Benelux
EE2100X15B	Trilogy Evo O2, Eastern Europe
GB2100X15B	Trilogy Evo O2, Great Britain
ND2100X15B	Trilogy Evo O2, Nordics
FR2100X14B	Trilogy Evo O2, France
EU2100X19	Trilogy Evo O2, EU (Non-BT)
TR2100X15B	Trilogy Evo, O2, Turkey

IN2200X15B	Trilogy EV300, International
FX2100X15B	Trilogy Evo, O2, Int
FX2110X15B	Trilogy Evo, Int
FX2200X15B	Trilogy EV300, Int

BL2200X15B	Trilogy EV300, Benelux
DE2200X13B	Trilogy EV300, Germany
EE2200X15B	Trilogy EV300, Eastern Europe
ES2200X15B	Trilogy EV300, Spain
EU2200X15B	Trilogy EV300, EU
EU2200X19	Trilogy EV300, EU (Non-BT)
FR2200X14B	Trilogy EV300, France
GB2200X15B	Trilogy EV300, Great Britain
IT2200X21B	Trilogy EV300, Italy
ND2200X15B	Trilogy EV300, Nordics
TR2200X15B	Trilogy EV300, Turkey
VT2110X24B	Aeris Evo

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:	N/A
Control Indicator:	

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
October 17, 2019	TR2110X15B
	TR2100X15B
April 09, 2020	IN2200X15B
July 16, 2020	FX2100X15B
	FX2110X15B
	FX2200X15B
December 4, 2020	BL2200X15B

	DE2200X13B
	EE2200X15B
	ES2200X15B
	EU2200X15B
	EU2200X19
	FR2200X14B
	GB2200X15B
	IT2200X21B
	ND2200X15B
	TR2200X15B
December 15, 2020	AU2110X15B
February 18th, 2021	VT2110X24B

For RED Directive:

Serial Range	Software Version	PN Prefix
M30042641B089 or higher	1.05.01.00	All
M311168202A8D or higher	1.06.02.00	Only for AU, BL, DE, EE, ES, EU, FP, FR, FX, GB, IA, IT, LA, LD, MD, ND, PP, SP, TR, VT, IN

Global Medical Device Nomenclature code (GMDN) and Description	47083 Portable Electric Ventilator

The object of the declaration described above is in conformity with the following directives and/or 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)**
Risk Classification	Class IIb based on Annex IX and Rule 9
Conformity Assessment Route	Annex II (excluding 4)
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany

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	CE0123
Certificate(s) Issued	EC Certificate: G1 015581 0611
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)**
Risk Classification	Category 8, according to 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)***
Risk Classification	Class 1
Conformity Assessment Route	Annex III
Notified Body Name, Address, ID and EU Certificate Number	The Notified Body identified in this section performed EU Type Examination and issued the certificate: 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

2. Additional information:

Manufacturer	Respironics, Inc. 1001 Murry Ridge Lane, Murrysville, PA 15668, USA
EU Authorized Representative:	Respironics Deutschland GmbH & Co. KG Gewerbestrasse 17 82211 Herrsching, Germany Tel: +49 8152 93060
ISO Quality Certificates Issued:	The Manufacturer is certified by TÜV SÜD Product Service GmbH to the following: • EN ISO 13485: 2016 Certificate Number: Q5 015581 0609 • ISO 13485:2016 MDSAP certificate number QS6 015581 0610 *Copies of the Quality System certificates are available upon request.*

Signature (signed for and on behalf of Philips)

Daria Brown

Date of Issue: 15 APR 2021

15 APR 2021

Printed Name: Daria Brown

Place of Issue: Monroeville, PA, USA

Title: Senior Manager, Regulatory Affairs

3. Attachment A
Standards and/or Common Specifications

Standard	Standard Title
Quality System	
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
General Safety Standard	
EN 60601-1:2006/A1:2013	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/A1:2015	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability
EN 60601-1-8:2007/A1:2013	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 10993-1:2018	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 10993-10:2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 18562-2:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Test for emissions of particulate matter
ISO 18562-3:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)

Other Standards	
Accompany Documents and Labeling	
EN 1041:2008/A1:2013	Information supplied by the manufacturer of medical devices
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	
EN 62304:2006/A1:2015	Medical device software – Software life cycle processes
Risk Management	
EN ISO 14971:2019	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 IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances