EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2102679
Revision v06

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:	The Philips Respironics Cable, 12/24V Battery, with Terminals, is used to connect devices to a 12V or 24V DC deep cycle marine-type (lead acid) battery when AC power is not available. This cable is pre-wired and properly terminated to ensure safe connection of an external battery to the device. The Philips Respironics Cable, 12/24V Battery, with Car Adapter, is used to connect devices to a 12V or 24V DC auxiliary power outlet in an automobile. This adapter is fused, filtered, and designed for safe connection to a standard automotive electrical system and plugs into a standard vehicle power outlet, or cigarette lighter socket. The Philips Respironics USB to RJ45 Connection Cable can be used to interface a ventilator with a hospital monitor such as the Philips intellivue. The Philips Respironics USB to CO2 Monitor Cable connects a CO2 monitor to a ventilator through a USB connection. The Philips Respironics USB to DB9 Connection Cable is used to interface a ventilator with a hospital monitor. The Philips Respironics Detachable Internal Battery Pack is a rechargeable lithium-ion battery intended to supply power to Trilogy Evo-series ventilation devices. The Philips Respironics Detachable Battery Pack is a rechargeable lithium-ion battery intended to supply power to Trilogy Evo-series ventilation devices. The Philips Respironics In-Use Case is intended to carry a Trilogy Evo ventilator while protecting it from scratches and wear during use. This case is for single patient use in the home environment. The Roll Stand is a movable stand intended to hold Philips Respironics ventilators.

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	The Wheelchair Mount is used to attach to the Roll Stand.
Product Part Number(s) and Descriptions:	1127401 Cable, 12/24V Battery, W/Terminals 1127402 Cable, 12/24V battery, W/Car Adaptor 1127403 Cable, Isolated, USB to RJ45 1127404 Cable, USB to CO2 Monitor 1127405 Cable, Isolated, USB to DB9 1127881 Trilogy Evo Internal Battery Pack 1127889 Trilogy Evo Detachable Battery Pack 1133930 Trilogy Evo In-Use Case 1136880 Trilogy Evo Internal Battery Pack, India 1136881 Trilogy Evo Detachable Battery Pack, India 1134429 Trilogy Evo Roll Stand 1134633 Trilogy Evo Wheelchair Mount
Product Options/Accessories Part Number(s) and Descriptions:	*N/A*
Basic UDI-DI:	*N/A*
Control Indicator:	

Initial Issue Date:	Part Number:
March 07, 2019	1127403
	1127404
	1133930
	1134429
April 12, 2019	1134633
April 29, 2019	1127401
	1127881
	1127889
May 31, 2019	1127405
August 05, 2019	1127402
October 2, 2019	1136880
	1136881

Global Medical Device Nomenclature code (GMDN) and Description	Cables - 47487 Electrical-only medical device connection cable, reusable In-Use Case - 37685 Personal device holder, reusable Rolling Stand - 42514 Ventilator Stand Battery - 34158 Secondary Battery Wheelchair bracket - 37744

The object of the declaration described above is in conformity with the following directives

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	Cables - Class I Annex IX, Rule 1 In-Use Case - Class I Annex IX, Rule 1 Roll Stand / Wheelchair Bracket - Class I Annex IX, Rule 1 Battery – Class I Annex IX, Rule 12
Conformity Assessment Route	Annex VII
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany *ID: Not applicable for Class I*
Certificate(s) Issued	N/A
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, medical device, according 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*

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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 607 • MDSAP ISO13485: 2016 Certificate Number: QS6 17 10 15581 058 *Copies of the Quality System certificates are available upon request.*

Signature (signed for and on behalf of Respironics, Inc.)

Daria Brown

Date of Issue: 08 September 2020

08 SEPT 2020

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 60601-1-11:2015	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
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.
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
Risk Management	
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices

Standard	Standard Title
Usability	
IEC 62366-1:2015	Medical devices -- Part 1: Application of usability engineering to medical devices
RoHS	
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
Cleaning and Disinfection	
ISO 17664:2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices