DECLARATION OF CONFORMITY

Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668
USA
Tel: 800-345-6443

Declares under our sole responsibility that the product:

Product Name	Trilogy 100 Garbin	
Product Type	Ventilator	
Product Part Number	1054096	Trilogy100 Ventilator International
	1054097	Trilogy100 Ventilator Germany
	1054655	Trilogy100 Ventilator Japan
	AU1054096	Trilogy100 Ventilator Australia
	BR1054096	Trilogy100 Ventilator Brazil
	LA1054096	Trilogy100 Ventilator Latin America
	1040001	Garbin Ventilator, Germany
	KR1054096	Trilogy100 Ventilator, Korea (Vitalaire)
	KO1054096	Trilogy100 Ventilator, Korea (Philips)
	BT1054096	Trilogy100 Ventilator, INTL Bluetooth
	1054096B	Trilogy100 Ventilator, International, Bluetooth
	1054097B	Trilogy100 Ventilator, Germany, Bluetooth
	CA1054096B	Trilogy100 Ventilator, Canada, Bluetooth
	1040001B	Garbin Ventilator, Germany, Bluetooth
	1058180B	Garbin Ventilator, International, Bluetooth
	AU1054096B	Trilogy100 Ventilator, Australia, Bluetooth
	IT1054096B	Trilogy100 Ventilator, Italy, Bluetooth
	1054655B	Trilogy 100 Ventilator, Japan, Bluetooth

Control Designator	Initial Issue Date:	Part Number:
	December 5, 2008	1054096, 1054097, AU1054096, CA1054096
	April 30, 2009	1058180
	June 18, 2009	LA1054096
	December 11, 2009	1054655
	November 7, 2011	1040001
	May 24, 2012	BR1054096
	September 12, 2012	CN1054096
	April 29, 2015	BT1054096
	December 15, 2015	1054096B, 1054097B, CA1054096B, 1040001B, 1058180B
	April 04, 2016	AU1054096B

	October 10, 2016 — KR1054096, IT1054096B November 10, 2016 — 1058180, CA1054096 June 14, 2017 — KO1054096 September 12, 2018 — 1054655B For RED Directive: Serial Range: TV117091900 and higher — Software Version: 14.2 and higher *Note: Devices manufactured in compliance with R&TTE are outside of the serial number range but are deemed RED compliant as no hardware or software changes were required to demonstrate compliance to the Radio Equipment Directive.*
Device Classification, Annex and Rule	Class IIb, Annex IX, Rule 9 Class 1 Radio Equipment
Global Medical Device Nomenclature Code (GMDN)	47083 Portable electric ventilator
Product Options/ Accessories	Nasal and Full Face Masks, Humidifiers, Breathing Circuits, In-Use Bag, Data Management PC Software, Oximetry, Detachable Battery and MPV Support System

To which this Declaration relates is in conformity with the provisions of Council Directive:
1. 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC
2. 2011/65/EU Restriction of the use of certain Hazardous Substances (RoHS) in Electric and Electronic Equipment (EEE)
3. 2014/53/EU Radio Equipment Directive (RED Directive)

The Manufacturer is certified by TÜV SÜD Product Service GmbH to EN ISO 13485 and is also certified to Annex II-Section 3.2 of the Medical Device Directive 93/42/EEC. Copies of the Quality System certificates are available upon request.	
Notified Body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany Identification Number: 0123
The radio capability is certified by INTERTEK TESTING; CERTIFICATION LTD to 2014/53/EU Radio Equipment Directive (RED). Copies of the certificates are available upon request.	
Notified Body	INTERTEK TESTING; CERTIFICATION LTD Intertek House, Cleeve Road Leatherhead, Surrey KT22 7SB United Kingdom Notified Body Number: 0359

Authorized EU Representative	Respironics Deutschland GmbH & Co. KG Gewerbestrasse 17 82211 Herrsching, Germany

Tel: +49 8152 93060

Supplementary Information:

The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation. Additionally the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying documentation.

The products listed above have been designed and manufactured in accordance with the essential requirements set out in Article 3 of the Radio Equipment Directive (2014/53/EU). These products have been constructed to operate using the radio spectrum effectively and follow the relevant conformity assessment procedure referred to in Article 17 of the Directive. This product is intended to connect to the Publicly Available Interfaces (PAI) and used throughout the EEA. Individual countries may apply restrictions on putting this device into service or placing on the market.

Standards:

The products listed above are fully compliant with the harmonized standards listed below.

Quality System	
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
General Standard	
EN 60601-1:2006/A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
Collateral Standards	
EN 60601-1-2:2007	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 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 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 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;
Oximetry	

ISO 80601-2-61:2017	Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
Labeling	
EN 1041: 2008+A1	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
Biocompatibility	
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
Software	
EN 62304:2006/A1:2015	Medical device software – Software lifecycle 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 301 489-1 V2.1.1:2017	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
EN 301 489-17 V3.1.1:2017	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 EMC for broadband data transmission systems
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 HS Wideband transmission systems 2,4 GHz
EN 62311: 2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
RoHS	
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
Cleaning and Disinfection	
EN ISO 17664:2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

Name	Colleen Witt
Title	Sr. Manager, Regulatory Affairs
Signature	Colleen Witt
Date (MM/DD/YYYY)	9/13/18
Place of Issue	Monroeville