EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101392
Revision v23

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:	BiPAP A40 BiPAP A40 Ventilator (A Series, Merlin)
Product Type:	Ventilator
Intended Purpose:	The BiPAP A40 ventilator is intended to provide invasive and non-invasive ventilatory support to treat adult and pediatric patients weighing over 22lbs (10 kg) with Obstructive Sleep Apnea (OSA), Respiratory Insufficiency, or Respiratory Failure. It is intended to be used in home, institutional/hospital, and portable applications such as wheelchairs and gurneys. It is not intended to be used as a transport ventilator, and is not intended for life support.
Product Part Number(s) and Descriptions:	Part Number(s) listed in this section comply with all directives indicated in DoC unless otherwise noted. 1111169 BiPAP A40 Ventilator International (Flow Gen 1109596) 1111171 BiPAP A40 Ventilator Australia (Flow Gen 1109596) 1111173 BiPAP A40 Ventilator Canada (Flow Gen 1109596) 1111170 BiPAP A40 Ventilator International Private Label (Flow Gen 1109597) 1111175 BiPAP A40 Ventilator France (Flow Gen 1109600) 1116156 BiPAP A40 Silver Series (Flow Gen 1116153) 1111177 BiPAP A40 Ventilator System Silver Series Japan (Flow Gen 1109601) 1111172 BiPAP A40 Ventilator Australia with Humidifier (Device Flow Gen 1109596, Humid Flow Gen 1111514) 1111174 BiPAP A40 Ventilator Canada w/ Heated Tube Humidifier (Device Flow Gen 1109596, Humid Flow Gen 1111517) BR1111169 BiPAP A40 Brazil (Flow Gen 1109598) AR1111169 BiPAP A40 International, Argentina (Flow Gen 1109596) IT1111169 BiPAP A40, IT (Flow Gen 1109596) 1111170S BiPAP A40 Sapio Belife 40 (Flow Gen 1109597) R1111177 BiPAP A40 System Silver, JP R1111169 BiPAP A40, International-Rental R1116156 BiPAP A40, Silver Series- RENTAL

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Product Options/Accessories Part Number(s) and Descriptions:	Refer to the following REG DOCs for accessory information: REG 2102335 (InUse Case), REG 2102803 (Detachable Battery Module), REG 2102194 (SpO2), REG 2102753 (Shielded DC Power Cord), REG 2102976 (Universal Battery Pack)
Basic UDI-DI:	N/A
Control Indicator:	Initial Issue Date: / Part Number: October 1, 2013 — 1111169, 1111171, 1111172 November 11, 2013 — 1111173, 1111174, 1111170, 1111175 July 28, 2014 — 1116156 February 6, 2015 — 1111177 August 14, 2015 — CN1111169 December 7, 2016 — BR1111169 May 4, 2017 — AR1111169 June 20, 2017 — IT1111169, 1111170S June 21, 2018 — Removed CN1111169 March 11, 2021 — R1111177, R1111169, R1116156
Global Medical Device Nomenclature code (GMDN) and Description	47083 Portable electric ventilator

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The object of the Declaration (product part numbers and if applicable the component 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 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 0123
Certificate(s) Issued	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, medical device, according to 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*

2. Mandatory information:

Manufacturer	Respironics, Inc. 1001 Murry Ridge Lane, Murrysville, PA 15668, USA
EU Authorized Representative (AR):	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 Certificate: Q5 015581 0609 MDSAP ISO 13485 Certificate: QS6 015581 0610

Signature (signed for and on behalf of Respironics, Inc): Daria Brown

Date of Issue: 16 April 2021 16 APR 2021

Printed Name: Daria Brown

Place of Issue: Monroeville, PA

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 Standard	
EN 60601-1:2006/A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
Collateral Safety Standards	
EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility. 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	
EN ISO 10651-6:2009	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 6: Home care ventilatory support devices
EN ISO 80601-2-61:2011	Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 80601-2-74:2017	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
Biocompatibility	
ISO 10993-1:2018	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
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
Software	
EN 62304:2006/A1:2015	Medical device software – Software lifecycle 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
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	
EN ISO 17664:2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices