EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2102796
Revision v13

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 Pro
Product Type:	BiPAP
Intended Purpose:	The BiPAP A40 Pro ventilator is intended to provide invasive and non-invasive ventilatory support to treat adult and pediatric patients weighing over 10 kg (22 lbs) with Obstructive Sleep Apnea (OSA), respiratory insufficiency, or respiratory failure. This device is not intended for life support. It is not intended to be used as a transport ventilator. It is intended to be used both in the home and clinical settings such as hospitals, sleep laboratories, sub-acute care institutions, and portable applications such as wheelchairs and gurneys.
Product Part Number(s) and Descriptions:	Part Number(s) listed in this section comply with all directives indicated in DoC unless otherwise noted. INX3100S19 BiPAP A40 Pro, International BLX3100S19 BiPAP A40 Pro, BL FRX3100S14 BiPAP A40 Pro, FR GBX3100S19 BiPAP A40 Pro, UK ITX3100S21 BiPAP A40 Pro, IT CAX3100S12 BiPAP A40 Pro, CA CAX3100T12 BiPAP A40 Pro, CA w/Heated Tube Humidifier AUX3100S19 BiPAP A40 Pro, AU DEX3100S13 BiPAP A40 Pro, DE INX3100T19 BiPAP A40 Pro International w/ Heated Tube Humidifier INX3100H19 BiPAP A40 Pro International w/ Heated Humidifier EEX3100S19 BiPAP A40 Pro, EE ESX3100S19 BiPAP A40 Pro, ES ESX3100H19 BiPAP A40 Pro, ES w/Heated Humidifier ESX3100T19 BiPAP A40 Pro, ES w/Heated Tube Humidifier FRX3100H14 BiPAP A40 Pro, FR w/Heated Humidifier FRX3100T14 BiPAP A40 Pro, FR w/Heated Tube Humidifier GBX3100H19 BiPAP A40 Pro, UK w/Heated Humidifier GBX3100T19 BiPAP A40 Pro, UK w/Heated Tube Humidifier ITX3100H21 BiPAP A40 Pro, IT w/Heated Humidifier ITX3100T21 BiPAP A40 Pro, IT w/Heated Tube Humidifier NDX3100S19 BiPAP A40 Pro, ND IAX3100S19 BiPAP A40 Pro, IA IAX3100H19 BiPAP A40 Pro, IA w/ Heated Humidifier IAX3100T19 BiPAP A40 Pro, w/Heated Tube Humidifier BRX3100S18 BiPAP A40 Pro, BR ARX3100S19 BiPAP A40 Pro, AR SPX3100S19 BeLife 40 Pro RINX3100S19 BiPAP A40 Pro Titration Rental Program IN RAUX3100S19 BiPAP A40 Pro Titration Rental Program AU

	RBLX3100S19 BiPAP A40 Pro Titration Rental Program BL RBRX3100S19 BiPAP A40 Pro Titration Rental Program BR RCAX3100S12 BiPAP A40 Pro Titration Rental Program CA REEX3100S19 BiPAP A40 Pro Titration Rental Program EE RFRX3100S19 BiPAP A40 Pro Titration Rental Program FR RDEX3100S13 BiPAP A40 Pro Titration Rental Program DE RGBX3100S19 BiPAP A40 Pro Titration Rental Program GB RITX3100S21 BiPAP A40 Pro Titration Rental Program IT RNDX3100S19 BiPAP A40 Pro Titration Rental Program ND RESX3100S19 BiPAP A40 Pro Titration Rental Program ES
Product Options/Accessories Part Number(s) and Descriptions:	See DoC Trilogy Accessories (REG 2100716) for compliance information for Detachable Battery Pack, USA/INTL (PN 1043570) See DoC Detachable Battery Module (REG 2102803) for compliance information for Detachable Battery Module, USA/INTL (PN 3000DBM) See DoC In-Use Case MDR (REG 2102335) for compliance information for the In-Use Case. See DoC Shielded DC Power Cord (REG 2102753) for compliance information for the Shielded DC Power Cord See DoC DC Power Cords (REG 2101724) for compliance information for the Dc Battery Adapter Cable See DoC Universal Battery Pack 2 (REG 2102976) for compliance information for the Universal Battery Pack. See DoC BiPAP Hardware Accessories (REG 22851) for compliance information for the BiPAP Hardware Accessories.
Basic UDI-DI:	N/A
Control Indicator:	

Initial Issue Date:	Part Number:
03 DEC 2019	INX3100S19
17 Dec 2019	BLX3100S19
	FRX3100S14
	GBX3100S19
	ITX3100S21
13 Jan 2020	CAX3100S12
	CAX3100T12
	AUX3100S19
20 Jan 2020	DEX3100S13
07 Feb 2020	INX3100T19
	INX3100H19
	EEX3100S19
	ESX3100S19
	ESX3100H19

		ESX3100T19
		FRX3100H14
		FRX3100T14
		GBX3100H19
		GBX3100T19
		ITX3100H21
		ITX3100T21
		NDX3100S19
	10 Mar 2020	IAX3100S19 IAX3100H19 IAX3100T19
	23 Oct 2020	BRX3100S18 ARX3100S19
	10 Nov 2020	SPX3100S19
	Dec 15, 2020	RINX3100S19 RAUX3100S19 RBLX3100S19 RBRX3100S19 RCAX3100S12 REEX3100S19 RFRX3100S19 RDEX3100S13 RGBX3100S19 RITX3100S21 RNDX3100S19 RESX3100S19
Global Medical Device Nomenclature code (GMDN) and Description	47083 Portable electric ventilator	

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.

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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 Ridlerstrase 65 80339 Munich, Germany 0123
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, 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. 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)

Date of Issue: 21 June 2021

Printed Name: Nicole Beale

Place of Issue: Monroeville, PA, USA

Title: Sr. 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 60601-1-2:2015	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 Safety Standards	
ISO 80601-2-80:2018	Medical electrical equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
EN ISO 80601-2-61:2019	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 10993-3:2014	Biological evaluation of medical devices. Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
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
EN ISO 10993-17:2009	Biological evaluation of medical devices. Part 17: Establishment of allowable limits for leachable substances

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Standard	Standard Title
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: Tests 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)
ISO 18562-4:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate
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	
IEC 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