EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2103229
Revision 05

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:	DreamStation 2 CPAP/Auto CPAP DreamStation 2 Advanced CPAP/Auto CPAP	
Product Type:	Positive Airway Pressure Units	
Intended Purpose:	For the treatment of Obstructive Sleep Apnea (OSA)	
Product Part Number(s) and Descriptions:	FRX521H14C	DreamStation 2 Auto CPAP Advanced Humid/P Flex/Cell/BT, FR
	BLX410H15C	DS2 CPAP w/Humid cell/BT, BL
	BLX420H15C	DS2 Adv CPAP w/Humid cell/BT, BL
	BLX510H15C	DS2 Auto CPAP w/Humid cell/BT, BL
	BLX520H15C	DS2 Adv Auto CPAP w/Humid cell/BT, BL
	DEX420H13C	DS2 Auto CPAP w/Humid cell/BT, DE
	DEX520H13	DS2Adv Auto CPAP w/Humid BT only, DE
	DEX520H13C	DS2Adv Auto CPAP w/Humid cell/BT, DE
	EEX410H15C	DS2 CPAP w/Humid cell/BT, EE
	EEX420H15C	DS2Adv CPAP w/Humid cell/BT, EE
	EEX510H15C	DS2 Auto CPAP w/Humid cell/BT, EE
	EEX520H15C	DS2Adv Auto CPAP w/Humid cell/BT, EE
	ESX410H15	DS2 CPAP w/Humid BT only, ES
	ESX410H15C	DS2 CPAP w/Humid cell/BT, ES
	ESX420H15C	DS2Adv CPAP w/Humid cell/BT, ES
	ESX520H15C	DS2Adv Auto CPAP w/Humid cell/BT, ES
	EUX410H15	DS2 CPAP w/Humid BT only, EU
	EUX410H15C	DS2 CPAP w/Humid cell/BT, EU
	EUX420H15	DS2Adv CPAP w/Humid BT only, EU
	EUX420H15C	DS2Adv CPAP w/Humid cell/BT, EU
	EUX510H15	DS2 Auto CPAP w/Humid BT only, EU
	EUX510H15C	DS2 Auto CPAP w/Humid cell/BT, EU
	EUX520H15	DS2Adv Auto CPAP w/Humid BT only, EU
	EUX520H15C	DS2Adv Auto CPAP w/Humid cell/BT, EU
	GBX420H15C	DS2Adv CPAP w/Humid cell/BT, GB
	GBX520H15C	DS2Adv Auto CPAP w/Humid cell/BT, GB
	ITX410H15	DS2 CPAP w/Humid BT only, IT
	ITX410H15C	DS2 CPAP w/Humid cell/BT, IT
	ITX420H15C	DS2Adv CPAP w/Humid cell/BT, IT
	ITX510H15	DS2 Auto CPAP w/Humid BT only, IT
	ITX510H15C	DS2 Auto CPAP w/Humid cell/BT, IT
	ITX520H15C	DS2Adv Auto CPAP w/Humid cell/BT, IT

	NDX510H15C DS2 Auto CPAP w/Humid cell/BT, ND NDX520H15C DS2Adv Auto CPAP w/Humid cell/BT, ND NDX520T15C DS2Adv Auto CPAP w/Humid/HT cell/BT, ND
Product Options/Accessories Part Number(s) and Descriptions:	Refer to REG 2102704 for Roll Stand accessory
Basic UDI-DI:	N/A
Control Indicator:	Initial Issue Date: Part Number(s): Feb 26, 2021 FRX521H14C March 26, 2021 BLX410H15C, BLX420H15C, BLX510H15C, BLX520H15C May 24, 2021 DEX420H13C, DEX520H13, DEX520H13C, EEX410H15C, EEX420H15C, EEX510H15C, EEX520H15C, ESX410H15, ESX410H15C, ESX420H15C, ESX520H15C, EUX410H15, EUX410H15C, EUX420H15, EUX420H15C, EUX510H15, EUX510H15C, EUX520H15, EUX520H15C, GBX420H15C, GBX520H15C, ITX410H15, ITX410H15C, ITX420H15C, ITX510H15, ITX510H15C, ITX520H15C, NDX510H15C, NDX520H15C, NDX520T15C ********** For RED Directive: **Serial Range** | **Software Version** J18858389660F and higher | 1.1 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.*
Global Medical Device Nomenclature code	60711 Home CPAP Unit

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(GMDN) and Description	

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 IIa 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	No. 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) 2017/2102 (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*

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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 I
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. Cleve Road, Leatherhead, Surrey, KT22 7SB United Kingdom Notified Body Number: 0359 Certificate Numbers 0002325, 0002326, 0005391
Standards	The radio equipment was tested to the following standards or technical specifications: *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 TUV to the following: EN ISO 13485:2016 and Annex II-Section 3.2 of the MDD as evidenced by certificate numbers: Q5 015581 0609 QS6 015581 0610 (MDSAP)

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

Date of Issue: 26 May 2021

Printed Name: Katelyn Manning

Place of Issue: Monroeville, PA, USA

Title: Sr. Manager, Regulatory Affairs

3. Attachment A Standards and/or Common Specifications

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 60601-1-11:2015	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	
Humidifiers	
ISO 80601-2-74:2017	Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment.
Sleep Apnea Devices	
EN ISO 17510-1:2009	Sleep apnoea breathing therapy -- Part 1: Sleep apnoea breathing therapy equipment
ISO 80601-2-70:2015	Medical Electrical Equipment -- Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
Biocompatibility	
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO10993-3:2014	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 10993-6:2009	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
EN ISO 10993-10:2013	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
Pulse Oximetry	
EN ISO 80601-2-61: 2011	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

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
Radio	
EN 62311:2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
EN 60950-1:2005 A1:2009/ A2:2013	Information technology equipment. Safety. Part 1: General requirements
EN 55032:2015	Electromagnetic compatibility of multimedia equipment - Emission Requirements
EN 301 908 -1 V11.1.1:2016	IMT cellular networks; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU; Part 1: Introduction and common requirements
EN 301 908-2 V11.1.1:2016	IMT cellular networks; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU; Part 2: CDMA Direct Spread (UTRA FDD) User Equipment (UE)
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
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 301 489-52 V1.1.0:2016	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 52: Specific conditions for Cellular Communication Mobile and portable (UE) radio and ancillary equipment; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

EN 301 511 V12.5.1:2016	Global System for Mobile communications (GSM); Mobile Stations (MS) equipment; Harmonised Standard covering the essential requirements of article 3.2 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
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