EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101938
Revision 20

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 BiPAP autoSV
Product Type:	Ventilatory Support System
Intended Purpose:	The DreamStation BiPAP AutoSV device is intended to provide mask-applied non-invasive ventilator support to adult patients (>30 kg) for the primary treatment of obstructive sleep-disordered breathing with secondary Central Sleep Apnea or Cheyne-Stokes Respiration (CSR). The device may be used in the hospital or home.
Product Part Number(s) and Descriptions:	The following part numbers are compliant with 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC, Directive 2015/863 of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electric and electronic equipment, amended up to and inclusive of Directive (EU) 2017/1202 (RoHS) in Electric and Electronic Equipment (EEE) and 2014/53/EU Radio Equipment Directive (RED Directive):

Part Number	Description
AUX900S15	DreamStation BiPAP autoSV AU
AUX900T15	DreamStation BiPAP autoSV w/Humid/Heated Tube, AU
AUX900T15C	DreamStation BiPAP autoSV w/Humid/Heated Tube/Cell, AU
BLX900S15	DreamStation BiPAP autoSV BL
BLX900H15	DreamStation BiPAP autoSV w/Humidifier, BL
DEX900S13	DreamStation BiPAP autoSV DE
DEX900H13	DreamStation BiPAP autoSV w/Humidifier, DE
EEX900S15	DreamStation BiPAP autoSV EE
EEX900H15	DreamStation BiPAP autoSV w/Humidifier, EE
ESX900S15	DreamStation BiPAP autoSV ES
ESX900H15	DreamStation BiPAP autoSV w/Humidifier, ES
EUX900S15	DreamStation BiPAP autoSV EU
EUX900H15	DreamStation BiPAP autoSV w/Humidifier, EU
FRX900S14	DreamStation BiPAP autoSV FR
FRX900H14	DreamStation BiPAP autoSV w/Humidifier, FR
FRX900S14W	DreamStation BiPAP autoSV w/WiFi, FR

	GBX900S15 DreamStation BiPAP autoSV GB GBX900H15 DreamStation BiPAP autoSV w/Humidifier, GB ITX900S15 DreamStation BiPAP autoSV IT ITX900H15 DreamStation BiPAP autoSV w/Humidifier, IT NDX900S15 DreamStation BiPAP autoSV ND NDX900H15 DreamStation BiPAP autoSV w/Humidifier, ND RDEX900S13 RENTAL – DreamStation BiPAP autoSV, DE RGBX900S15 DreamStation BiPAP autoSV, GB Rental RDEX900H13 DreamStation BiPAP autoSV w/Humid, DE Rental RGBX900H15 DreamStation BiPAP autoSV w/Humid, GB Rental TRX900S15 DreamStation BiPAP autoSV TR TRX900H15 DreamStation BiPAP autoSV w/Humidifier, TR UAX900S15 DreamStation AutoSV, Ukraine 2014/53/EU Radio Equipment Directive (RED Directive) is not applicable for the following part numbers: Part Number Description EUX900S19 DreamStation BiPAP autoSV no Bluetooth®, EU EUX900H19 DreamStation BiPAP autoSV w/ Humidifier no Bluetooth® EU INX900S19 DreamStation BiPAP autoSV, no Bluetooth®, INTL INX900H19 DreamStation BiPAP autoSV w/Humid, no Bluetooth® INTL INX900T19 DreamStation BiPAP autoSV w/Humid/Heated Tube, no Bluetooth® INTL LAX900S19 DreamStation BiPAP autoSV, no Bluetooth®, LA LAX900H19 DreamStation BiPAP autoSV w/Humid, no Bluetooth® LA LAX900T19 Dreamstation BiPAP autoSV w/Humid/Heated Tube, No Bluetooth® LA ZAX900S19 DreamStation BiPAP autoSV no Bluetooth®, ZA ZAX900H19 DreamStation BiPAP autoSV w/Humidifier, no Bluetooth® ZA
Product Options/Accessories Part Number(s) and Descriptions:	Part Number Description AU1120135 DreamStation Travel Kit, 65W P/S, AU IN1120135 DreamStation Travel Kit, 65W P/S, IN EU1120135 DreamStation Travel Kit, 65W P/S, EU Refer to REG 2101724 for the DreamStation Power Accessories

<table>
<tr><td></td><td>Refer to REG 2101640 for DreamStation, Nonin SPO2 Cable</td></tr>
<tr><td>Basic UDI-DI:</td><td>N/A</td></tr>
<tr><td>Control Indicator:</td><td>
<table>
<tr><th>Initial Issue Date:</th><th>Part Number:</th></tr>
<tr><td>Nov. 22, 2016</td><td>AUX900S15, AUX900T15, FRX900S14, INX900S19, INX900H19, INX900T19, GB11100135, AU1120135, IN1120135, EU1120135</td></tr>
<tr><td>Dec. 1, 2016</td><td>DEX900S13, DEX900H13</td></tr>
<tr><td>Jan. 12, 2017</td><td>BLX900H15, BLX900S15, EEX900H15, EEX900S15,</td></tr>
<tr><td>Jan. 26, 2017</td><td>AUX900T15C</td></tr>
<tr><td>July 6, 2017</td><td>FRX900S14W</td></tr>
<tr><td>Sept 14, 2018</td><td>LAX900S19, LAX900H19, LAX900T19</td></tr>
<tr><td>Jul. 08, 2020</td><td>UAX900S15</td></tr>
<tr><td>Mar. 28, 2021</td><td>RDEX900S13, RGBX900S15, RDEX900H13, RGBX900H15</td></tr>
</table>
For RED Directive:
<table>
<tr><th>Serial Range</th><th>Software Version</th></tr>
<tr><td>J19396196591A and higher</td><td>1.0 and higher</td></tr>
</table>
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.
</td></tr>
<tr><td>Global Medical Device Nomenclature code (GMDN) and Description</td><td>47083 Portable electric ventilator</td></tr>
</table>

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, Annex IX, 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 Notified Body no. 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 2015/863 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**
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*

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 Intertek House, Cleeve Road Leatherhead, Surrey KT22 7SB United Kingdom Notified Body Number: 0359 EU Certificate Number: 0002321,0002323, 0002324, 0005392
Standards	The radio equipment was tested to the following standards or technical specifications: 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 112601 0001 Copies of the Quality System certificates are available upon request.

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

Date of Issue: 09 September 2021

Printed Name: Katelyn Manning

Place of Issue: Monroeville, PA, USA

Title: Senior Regulatory Manager

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	
Home Care Ventilators	
ISO 80601-2-79:2018	Medical electrical equipment – Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
Respiratory Humidifying Devices	
EN ISO 80601-2-74:2020	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
Anaesthetic and Respiratory Equipment	
EN ISO 5356-1:2015	Anaesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets
Biocompatibility	
EN ISO 10993-1: 2020	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
EN ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 18562-1:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
EN ISO 18562-2:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
EN ISO 18562-3:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds
EN ISO 18562-4:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate
Pulse Oximetry	
EN ISO 80601-2-61:2019	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	
EN 62366-1:2015/ AC: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-part 1: Devices that require cleaning followed by disinfection and/or sterilization