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	DreamStation Go CPAP DreamStation Go Auto CPAP
Product Type	CPAP System
Product Part Number	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, 2011/65/EU Restriction of the use of certain Hazardous Substances (RoHS) in Electric and Electronic Equipment (EEE) and 2014/53/EU Radio Equipment Directive (RED Directive): The following devices use Flow Gen 1130788: AUG400S15 DreamStation Go CPAP with Bluetooth, Australia AUG500S15 DreamStation Go Auto CPAP with Bluetooth, Australia DEG502S13 DreamStation Go Auto CPAP with Bluetooth, FSS, Germany DEG500S13 DreamStation Go Auto CPAP with Bluetooth, Germany BLG500S15 DreamStation Go Auto CPAP with Bluetooth, BL BLG502S15 DreamStation Go Auto CPAP with Bluetooth, FSS, BL ESG500S15 DreamStation Go Auto CPAP with Bluetooth, ES ESG502S15 DreamStation Go Auto CPAP with Bluetooth, FSS, ES EUG400S15 DreamStation Go CPAP with Bluetooth, EU EUG500S15 DreamStation Go Auto CPAP with Bluetooth, EU EUG502S15 DreamStation Go Auto CPAP with Bluetooth, FSS, EU FRG501S14 DreamStation Go Auto CPAP with P-Flex & Bluetooth, France FRG503S14 DreamStation Go Auto CPAP with P-Flex & Bluetooth, FSS, France

	GBG500S15 DreamStation Go Auto CPAP with Bluetooth, UK GBG502S15 DreamStation Go Auto CPAP with Bluetooth, FSS, UK NDG500S15 DreamStation Go Auto CPAP with Bluetooth, ND NDG502S15 DreamStation Go Auto CPAP with Bluetooth, FSS, ND IAG502S15 DreamStation Go Auto CPAP with Bluetooth, India CHG502S15 DreamStation Go Auto CPAP with Bluetooth, Switzerland HKG502S15 DreamStation Go Auto CPAP with Bluetooth, Hong Kong SAG502S15 DreamStation Go Auto CPAP with Bluetooth, Saudi Arabia TRG502S15 DreamStation Go Auto CPAP with Bluetooth, Turkey ITG502S15 DreamStation Go Auto CPAP with Bluetooth, Italy TWG502S15 DreamStation Go Auto CPAP with Bluetooth, Taiwan IDG502S15 DreamStation Go Auto CPAP with Bluetooth, Indonesia MYG502S15 DreamStation Go Auto CPAP with Bluetooth, Malaysia PLG502S15 DreamStation Go Auto CPAP with Bluetooth, Poland
Control Designator	July 27, 2017 AUG400S15, AUG500S15, DEG502S13, DEG500S13, 1130788 August 31, 2017 BLG500S15, BLG502S15, ESG500S15, ESG502S15, EUG400S15, EUG500S15, EUG502S15, FRG501S14, FRG503S14, GBG500S15, GBG502S15, NDG500S15, NDG502S15 December 19, 2017 IAG502S15, CHG502S15 May 03, 2018 HKG502S15, SAG502S15, TRG502S15, ITG502S15, TWG502S15, IDG502S15, MYG502S15, PLG502S15 For RED Directive:

Serial Range	Software Version
Serial numbers higher than J19366162F60A	1.1 and higher

Device Classification, Annex and Rule	RED: Class I Radio Equipment MDD: Class IIa, Annex IX, Rule 9

Global Medical Device Nomenclature Code (GMDN)	60711 Home CPAP Unit
Product Options/ Accessories	Wi-Fi Device, Nasal and Full Face Masks, Breathing Circuits, Data Management Software and Lab Titration PC Software

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 by 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 0123
The radio capability is certified by Cetecom GmbH to 2014/53/EU Radio Equipment Directive (RED Directive). Copies of the certificates are available upon request.	
Notified Body	Cetecom ICT Services GmbH Im Teelbruch 116 45219 Essen, Germany 0680

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 60601-1-2:2015	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. General requirements for basic 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 Standards	
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	
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing
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 14971:2012	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
Tubing and connections	
EN ISO 5356-1:2015	Anesthetic and respiratory equipment-conical connectors-Part 1: Cones and Sockets
EN ISO 5359:2014/A1:2017	Low pressure hose assemblies for use with medical gases
EN ISO 5367:2014	Breathing tubes intended for use with anesthetic apparatus and ventilators
Radio	

EN 300 328 V2.1.1	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 Directive 2014/53/EU
EN 301 489-1 V2.1.1	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	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
EN 62479:2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
EN 62209-2:2010	Human exposure to radio frequency fields from hand-held and body mounted wireless communication devices - Human models, instrumentation, and procedures - Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz)
RoHS	
EN 50581:2012	E Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Name	Michelle Brinker
Title	Senior Manager, Regulatory Affairs
Signature	Michelle Brinker
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