



DECLARATION OF CONFORMITY

Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA, 15668-8550
USA
Tel: 800-345-6443

Declares under our sole responsibility that the product:

Product Name	DreamStation CPAP DreamStation CPAP Pro DreamStation Auto CPAP DreamStation BiPAP Pro DreamStation Auto BiPAP	
Product Type	CPAP System, BiPAP System	
Product Part Number	AUX400S15 DreamStation CPAP Pro, AUS AUX500S15 DreamStation Auto CPAP, AUS AUX700S15 DreamStation Auto BiPAP, AUS AUX400H15 DreamStation CPAP Pro w/Humid, AUS AUX500H15 DreamStation Auto CPAP w/Humid, AUS AUX700H15 DreamStation Auto BiPAP w/Humid, AUS AUX400T15 DreamStation CPAP Pro w/Humid/HT, AUS AUX500T15 DreamStation Auto CPAP w/Humid/HT, AUS AUX700T15 DreamStation Auto BiPAP w/Humid/HT, AUS BLX200S15 DreamStation CPAP BL BLX200H15 DreamStation CPAP with Humidifier BL BLX400S15 DreamStation CPAP Pro BL BLX400H15 DreamStation CPAP Pro with Humidifier BL BLX500S15 DreamStation Auto CPAP BL BLX500H15 DreamStation Auto CPAP with Humidifier BL BLX600S15 DreamStation BiPAP Pro BL BLX600H15 DreamStation BiPAP Pro with Humidifier BL BLX700S15 DreamStation Auto BiPAP BL BLX700H15 DreamStation Auto BiPAP with Humidifier BL DEX400S13 DreamStation CPAP Pro GER DEX500S13 DreamStation Auto CPAP GER DEX700S13 DreamStation Auto BiPAP GER EEX200S15 DreamStation CPAP EE EEX200H15 DreamStation CPAP with Humidifier EE EEX400S15 DreamStation CPAP Pro EE EEX400H15 DreamStation CPAP Pro with Humidifier EE EEX500S15 DreamStation Auto CPAP EE	

EEX500H15	DreamStation Auto CPAP with Humidifier EE
EEX600S15	DreamStation BiPAP Pro EE
EEX600H15	DreamStation BiPAP Pro with Humidifier EE
EEX700S15	DreamStation Auto BiPAP EE
EEX700H15	DreamStation Auto BiPAP with Humidifier EE
ESX200S15	DreamStation CPAP ES
ESX400S15	DreamStation CPAP Pro ES
ESX500S15	DreamStation Auto CPAP ES
ESX600S15	DreamStation BiPAP Pro ES
ESX700S15	DreamStation Auto BiPAP ES
ESX200H15	DreamStation CPAP with Humidifier ES
ESX400H15	DreamStation CPAP Pro with Humidifier ES
ESX500H15	DreamStation Auto CPAP with Humidifier ES
ESX600H15	DreamStation BiPAP Pro with Humidifier ES
ESX700H15	DreamStation Auto BiPAP with Humidifier ES
EUX200S15	DreamStation CPAP EU
EUX200H15	DreamStation CPAP with Humidifier EU
EUX400S15	DreamStation CPAP Pro EU
EUX400H15	DreamStation CPAP Pro with Humidifier EU
EUX500S15	DreamStation Auto CPAP EU
EUX500H15	DreamStation Auto CPAP with Humidifier EU
EUX600S15	DreamStation BiPAP Pro EU
EUX600H15	DreamStation BiPAP Pro with Humidifier EU
EUX700S15	DreamStation Auto BiPAP EU
EUX700H15	DreamStation Auto BiPAP with Humidifier EU
FRX400S14	DreamStation CPAP Pro with C-Flex+ FR
FRX401S14	DreamStation CPAP Pro with C-Flex FR
FRX500S14	DreamStation Auto CPAP with A-Flex FR
FRX501S14	DreamStation Auto CPAP with P-Flex FR
FRX700S14	DreamStation Auto BiPAP with BiFlex FR
GBX200H15	DreamStation CPAP with Humidifier GB
GBX200S15	DreamStation CPAP GB
GBX400H15	DreamStation CPAP Pro with Humidifier GB
GBX400S15	DreamStation CPAP Pro GB
GBX500H15	DreamStation Auto CPAP with Humidifier GB
GBX500S15	DreamStation Auto CPAP GB
GBX600H15	DreamStation BiPAP Pro with Humidifier GB
GBX600S15	DreamStation BiPAP Pro GB
GBX700H15	DreamStation Auto BiPAP with Humidifier GB
GBX700S15	DreamStation Auto BiPAP GB
INX200H15	DreamStation CPAP w/Humid, INTL
INX200S15	DreamStation CPAP, INTL

INX200T15	DreamStation CPAP w/Humid/HT, INTL
INX400H15	DreamStation CPAP Pro w/Humid, INTL
INX400S15	DreamStation CPAP Pro, INTL
INX400T15	DreamStation CPAP Pro w/Humid/HT, INTL
INX500H15	DreamStation Auto CPAP w/Humid, INTL
INX500S15	DreamStation Auto CPAP, INTL
INX500T15	DreamStation Auto CPAP w/Humid/HT, INTL
INX600H15	DreamStation BiPAP Pro w/Humid, INTL
INX600S15	DreamStation BiPAP Pro, INTL
INX600T15	DreamStation BiPAP Pro w/Humid/HT, INTL
INX700H15	DreamStation Auto BiPAP w/Humid, INTL
INX700S15	DreamStation Auto BiPAP, INTL
INX700T15	DreamStation Auto BiPAP w/Humid/HT, INTL
ITX200S15	DreamStation CPAP IT
ITX200H15	DreamStation CPAP with Humidifier IT
ITX400S15	DreamStation CPAP Pro IT
ITX400H15	DreamStation CPAP Pro with Humidifier IT
ITX500S15	DreamStation Auto CPAP IT
ITX500H15	DreamStation Auto CPAP with Humidifier IT
ITX600S15	DreamStation BiPAP Pro IT
ITX600H15	DreamStation BiPAP Pro with Humidifier IT
ITX700S15	DreamStation Auto BiPAP IT
ITX700H15	DreamStation Auto BiPAP with Humidifier IT
ITX400H15W	DreamStation CPAP Pro w/Humid/WiFi, IT
ITX500H15W	DreamStation Auto CPAP w/Humid/WiFi, IT
NDX200S15	DreamStation CPAP ND
NDX200H15	DreamStation CPAP with Humidifier ND
NDX400S15	DreamStation CPAP Pro ND
NDX400H15	DreamStation CPAP Pro with Humidifier ND
NDX500S15	DreamStation Auto CPAP with Humidifier ND
NDX500H15	DreamStation Auto CPAP with Humidifier ND
NDX600S15	DreamStation BiPAP Pro ND
NDX600H15	DreamStation BiPAP Pro with Humidifier ND
NDX700S15	DreamStation Auto BiPAP ND
NDX700H15	DreamStation Auto BiPAP with Humidifier ND
TRX200S15	DreamStation CPAP TR
TRX200H15	DreamStation CPAP with Humidifier TR
TRX400S15	DreamStation CPAP Pro TR
TRX400H15	DreamStation CPAP Pro with Humidifier TR
TRX500S15	DreamStation Auto CPAP TR
TRX500H15	DreamStation Auto CPAP with Humidifier TR
TRX600S15	DreamStation BiPAP Pro TR
TRX600H15	DreamStation BiPAP Pro with Humidifier TR
TRX700S15	DreamStation Auto BiPAP TR
TRX700H15	DreamStation Auto BiPAP with Humidifier TR

	ZAX200S15 DreamStation CPAP ZA ZAX200H15 DreamStation CPAP with Humidifier ZA ZAX400S15 DreamStation CPAP Pro ZA ZAX400H15 DreamStation CPAP Pro with Humidifier ZA ZAX500S15 DreamStation Auto CPAP ZA ZAX500H15 DreamStation Auto CPAP with Humidifier ZA ZAX600S15 DreamStation BiPAP Pro ZA ZAX600H15 DreamStation BiPAP Pro with Humidifier ZA ZAX700S15 DreamStation Auto BiPAP ZA ZAX700H15 DreamStation Auto BiPAP with Humidifier ZA
Control Designator	Initial Issue Date: Part Number: July 15, 2015 AUX400S15, AUX500S15, AUX700S15, AUX400H15, AUX500H15, AUX700H15, AUX400T15, AUX500T15, AUX700T15, DEX400S13, DEX500S13, DEX700S13 July 17, 2015 ESX200S15, ESX400S15, ESX500S15, ESX600S15, ESX700S15, ESX200H15, ESX400H15, ESX500H15, ESX600H15, ESX700H15 Sept. 11, 2015 FRX400S14, FRX401S14, FRX500S14, FRX501S14, FRX700S14, GBX200H15, GBX200S15, GBX400H15, GBX400S15, GBX500H15, GBX500S15, GBX600H15, GBX600S15, GBX700H15, GBX700S15 Sept.29, 2015 INX200H15, INX400H15, INX500H15, INX600H15, INX700H15, INX200S15, INX400S15, INX500S15, INX600S15, INX700S15, INX200T15, INX400T15, INX500T15, INX600T15, INX700T15 Nov. 05, 2015 BLX200S15, BLX200H15, BLX400S15, BLX400H15, BLX500S15, BLX500H15, EEX200S15, EEX200H15, EEX400S15, EEX400H15, EEX500S15, EEX500H15, EUX200S15, EUX200H15, EUX400S15, EUX400H15, EUX500S15, EUX500H15, ITX200S15, ITX200H15, ITX400S15, ITX400H15, ITX500S15, ITX500H15, NDX200S15, NDX200H15, NDX400S15, NDX400H15, NDX500S15, NDX500H15, TRX200S15, TRX200H15, TRX400S15, TRX400H15, TRX500S15, TRX500H15, ZAX200S15, ZAX200H15, ZAX400S15, ZAX400H15, ZAX500S15, ZAX500H15 Dec. 21, 2015 BLX600S15, BLX600H15, BLX700S15, BLX700H15, EEX600S15, EEX600H15, EEX700S15, EEX700H15,

	EUX600S15, AUX600H15, AUX700S15, EUX700H15, ITX600S15, ITX600H15, ITX700S15, ITX700H15, TRX600S15, TRX600H15, TRX700S15, TRX700H15, ZAX600S15, ZAX600H15, ZAX700S15, ZAX700H15 March 09, 2016 ITX400H15W, ITX500H15W
Device Classification, Annex and Rule	Class IIa, Annex IX, Rule 9
Global Medical Device Nomenclature Code (GMDN)	60711 Home CPAP Unit 60712 Home BiPAP Unit
Product Options/ Accessories	Cellular Modem, Wi-Fi Device, Link Module, SpO2 Cable, Travel Kit, Nasal and Full Face Masks, Humidifiers, Breathing Circuits, Data Management 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. 1999/5/EC Radio Equipment and Telecommunication Terminal Equipment (R&TTE Directive)

The Manufacturer is certified by TÜV SÜD Product Service GmbH to EN ISO 13485 and is also certified to 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
Authorized EU Representative	Respironics Deutschland 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 radio transmitting equipment listed above was tested in accordance with Article 10, via Annex IV, of the R&TTE Directive, and all essential radio test suites (as defined by the Essential Requirements) have

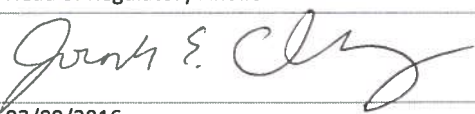
been carried out. Individual countries may apply restrictions on putting this device into service or placing on the market.

Standards:

The products listed above are fully compliant with the harmonized standards listed below.

Quality System	
EN ISO 13485:2012	Medical devices – Quality management systems – Requirements for regulatory purposes
General Standard	
EN 60601-1:2006	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
Collateral Standards	
EN 60601-1-2:2007	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	Medical electrical equipment – Part 1-6: General requirements for safety and essential performance – Collateral standard: Usability
EN 60601-1-11:2010	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	
Humidifiers	
EN ISO 8185:2009	Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems
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
EN ISO 10993-3:2003	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 10993-6:2007	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
Pulse Oximetry	
ISO 80601-2-61:2011	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
Accompany Documents and Labeling	
EN 980:2008	Symbols for use in the labeling of medical devices
EN 1041: 2008	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2012	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements
Software	
EN 62304:2006	Medical device software – Software lifecycle processes
Risk Management	

EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
Usability	
EN 62366:2008	Medical devices – 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)
IEC 61000-4-3: 2006	Electromagnetic Compatibility (EMC) - Part 4: Testing and Measurement Techniques-Section 3: Radiated, Radio-Frequency, Electromagnetic Field Immunity Test
EN 301 908-1 V6.2.1 ETSI EN 301 908-1 V6.2.1:2013	IMT cellular networks Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive; Part 1: introduction and common requirements
EN 300 328:V1.8.1:2012	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
EN 301 489-1 V1.9.2: 2011	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: common technical requirements
EN 301 489-7 V1.4.1:2005	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 7: Specific conditions for mobile and portable radio and ancillary equipment of digital cellular radio telecommunications systems (GSM and DCS)
EN 301 489-17 V2.2:2012	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems
EN 301 489-24 V1.5.1:2010	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 24: Specific conditions for IMT-2000 CDMA Direct Spread (UTRA and E-UTRA) for Mobile and portable (UE) radio and ancillary equipment

Name	Joseph Olsavsky
Title	Head of Regulatory Affairs
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Date	03/09/2016
Place of Issue	Monroeville