

EU DECLARATION OF CONFORMITY



Doc Number REG 2101942
Revision v26

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 ST DreamStation BiPAP AVAPS														
Product Type:	BiPAP														
Intended Purpose:	<p>BiPAP ST Intended Use Statement:</p> <p>The BiPAP S/T device is intended to provide non-invasive ventilatory support to Obstructive Sleep Apnea (OSA) and Respiratory Impairment patients weighing over 18 kg. This device may be used in the hospital or home.</p> <p>BiPAP AVAPS Intended Use Statement:</p> <p>The BiPAP AVAPS device is intended to provide non-invasive ventilatory support to Obstructive Sleep Apnea (OSA) and Respiratory Impairment patients weighing over 18 kg. This device may be used in the hospital or home.</p>														
Product Part Number(s) and Descriptions:	<p>Part Number(s) listed in this section comply with all regulation(s)/directive(s) indicated in DoC unless otherwise noted.</p> <p>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):</p> <table border="1"> <thead> <tr> <th>Part Number</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td colspan="2">BiPAP AVAPS:</td> </tr> <tr> <td>AUX1131S15</td> <td>DreamStation AVAPS30AE AAM AU</td> </tr> <tr> <td>AUX1131H15</td> <td>DreamStation AVAPS30AE AAM w/Humidifier, AU</td> </tr> <tr> <td>AUX1131T15</td> <td>DreamStation AVAPS30AE AAM H/Humid/Heated Tube, AU</td> </tr> <tr> <td>AUX1131S15C</td> <td>DreamStation BiPAP AVAPS AVAPS30AE AAM, Cell, AU</td> </tr> <tr> <td>AUX1131H15C</td> <td>DreamStation BiPAP AVAPS AVAPS30AE AAM w/Humidifier/Cell, AU</td> </tr> </tbody> </table>	Part Number	Description	BiPAP AVAPS:		AUX1131S15	DreamStation AVAPS30AE AAM AU	AUX1131H15	DreamStation AVAPS30AE AAM w/Humidifier, AU	AUX1131T15	DreamStation AVAPS30AE AAM H/Humid/Heated Tube, AU	AUX1131S15C	DreamStation BiPAP AVAPS AVAPS30AE AAM, Cell, AU	AUX1131H15C	DreamStation BiPAP AVAPS AVAPS30AE AAM w/Humidifier/Cell, AU
Part Number	Description														
BiPAP AVAPS:															
AUX1131S15	DreamStation AVAPS30AE AAM AU														
AUX1131H15	DreamStation AVAPS30AE AAM w/Humidifier, AU														
AUX1131T15	DreamStation AVAPS30AE AAM H/Humid/Heated Tube, AU														
AUX1131S15C	DreamStation BiPAP AVAPS AVAPS30AE AAM, Cell, AU														
AUX1131H15C	DreamStation BiPAP AVAPS AVAPS30AE AAM w/Humidifier/Cell, AU														

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AUX1131T15C	DreamStation BiPAP AVAPS AVAPS30AE AAM w/Humidifier/Heated Tube/Cell, AU
AUX1131S15W	DreamStation BiPAP AVAPS AVAPS30AE AAM, WiFi, AU
AUX1131H15W	DreamStation BiPAP AVAPS AVAPS30AE AAM w/ Humidifier/WiFi, AU
AUX1131T15W	DreamStation BiPAP AVAPS AVAPS30AE AAM w/Humidifier/Heated Tube/WiFi, AU
BLX1130S15	DreamStation BiPAP AVAPS30 AAM BL
BLX1130H15	DreamStation BiPAP AVAPS30 AAM w/Humidifier, BL
EEX1130S22	DreamStation BiPAP AVAPS30 AAM EE
EEX1130H22	DreamStation BiPAP AVAPS30 AAM w/Humidifier, EE
ESX1130S15	DreamStation BiPAP AVAPS AVAPS30 AAM, ES
ESX1130H15	DreamStation BiPAP AVAPS AVAPS30, AAM w/ Humidifier, ES
EUX1125S15	DreamStation BiPAP AVAPS AVAPS25, EU
EUX1125H15	DreamStation BiPAP AVAPS AVAPS25, w/Humidifier, EU
EUX1130S15	DreamStation BiPAP AVAPS AVAPS30, AAM, EU
EUX1130H15	DreamStation BiPAP AVAPS AVAPS30, AAM, w/ Humidifier, EU
FRX1130S14	DreamStation BiPAP AVAPS30 AAM FR
FRX1130H14	DreamStation BiPAP AVAPS30 AAM w/Humidifier, FR
GBX1130S20	DreamStation BiPAP AVAPS AVAPS30, GB
RGBX1130S20	DreamStation BiPAP AVAPS30, GB Rental
GBX1130H20	DreamStation BiPAP AVAPS AVAPS30 w/Humidifier, GB
ITX1125S21	DreamStation BiPAP AVAPS25 IT
ITX1130S21	DreamStation BiPAP AVAPS30 IT
LDX1130S23	DreamStation BiPAP AVAPS AVAPS30 AAM, Linde EOLUS 30 DS
LDX1130H23	DreamStation BiPAP AVAPS AVAPS30 AAM, w/ Humidifier Linde EOLUS 30 DS
MDX1130S25	DreamStation BiPAP AVAPS AVAPS30 AAM, MedicAir, Respi Comfort AVAPS DS
MDX1130H25	DreamStation BiPAP AVAPS AVAPS30 AAM, w/ Humidifier MedicAir, Respi Comfort AVAPS DS
NDX1130S15	DreamStation BiPAP AVAPS30 AAM ND
NDX1130H15	DreamStation BiPAP AVAPS30 AAM w/Humidifier, ND
NDX1130S20	DreamStation BiPAP AVAPS30 ND
NDX1130H20	DreamStation BiPAP AVAPS30 w/Humidifier, ND
SAX1130H27	DreamStation BiPAP Synchrony AVAPS AAM, with Humidifier
SAX1130S27	DreamStation BiPAP Synchrony AVAPS AAM
TRX1130S15	DreamStation BiPAP AVAPS30 AAM TR
TRX1130H15	DreamStation BiPAP AVAPS30 AAM w/Humidifier, TR
VTX1130S24	DreamStation BiPAP AVAPS AVAPS30 AAM, VitalAire, Vitalvent DS

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VTX1130H24	DreamStation BiPAP AVAPS AVAPS30 AAM, w/ Humidifier VitalAire, Vitalvent DS
SPX1130H21	DreamStation AVAPS30H – Sapio Belife DS
SPX1130S21	DreamStation AVAPS30S – Sapio Belife DS
BiPAP ST	
BLX1030S15	DreamStation BiPAP ST30 AAM BL
BLX1030H15	DreamStation BiPAP ST30 AAM w/Humidifier, BL
DEX1025S13	DreamStation BiPAP ST25 DE
DEX1130S13	DreamStation BiPAP ST30 AAM DE
DEX1130H13	DreamStation BiPAP ST30 AAM w/Humidifier, DE
DEX1030S13	DreamStation BiPAP ST30 AAM, DE
DEX1030H13	DreamStation BiPAP ST30 AAM w/Humidifier, DE
EEX1030S22	DreamStation BiPAP ST30 EE
EEX1030H22	DreamStation BiPAP ST30 w/Humidifier, EE
ESX1030S15	DreamStation BiPAP S/T ST30 AAM, ES
ESX1030H15	DreamStation BiPAP S/T ST30, AAM w/ Humidifier, ES
ESX1030S20	DreamStation BiPAP S/T ST30, ES
ESX1030H20	DreamStation BiPAP S/T ST30 w/ Humidifier, ES
EUX1025S15	DreamStation BiPAP S/T ST25, EU
EUX1025H15	DreamStation BiPAP S/T ST25, w/ Humidifier, EU
EUX1030S15	DreamStation BiPAP S/T ST30, AAM, EU
EUX1030H15	DreamStation BiPAP S/T ST30, AAM w/ Humidifier, EU
FRX1030S14	DreamStation BiPAP ST30 FR
GBX1030S20	DreamStation BiPAP ST30 GB
RGBX1030S20	Rental, DreamStation ST30, GB
GBX1030H20	DreamStation BiPAP ST30 w/Humidifier, G
ITX1030S20	DreamStation BiPAP S/T ST30, IT
ITX1030H20	DreamStation BiPAP S/T ST30, w/Humidifier, IT
NDX1030S15	DreamStation BiPAP ST30 AAM ND
NDX1030H15	DreamStation BiPAP ST30 AAM w/Humidifier, ND
NDX1030S20	DreamStation BiPAP ST30 ND
NDX1030H20	DreamStation BiPAP ST30 w/Humidifier, ND
TRX1030S15	DreamStation BiPAP ST30 AAM TR
TRX1030H15	DreamStation BiPAP ST30 AAM w/Humidifier, TR

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 and 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):

Part Number	Description
BiPAP S/T:	
EUX1025S19	DreamStation BiPAP ST25, no Bluetooth®, EU
EUX1025H19	DreamStation BiPAP ST25 w/ Humidifier, no Bluetooth® EU
EUX1030S19	DreamStation BiPAP ST30 AAM no Bluetooth®, EU

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EUX1030H19	DreamStation BiPAP ST30 AAM w/ Humidifier, no Bluetooth® EU
INX1025S19	DreamStation BiPAP ST25 no Bluetooth®, INTL
INX1025H19	DreamStation BiPAP ST25 w/Humid, no Bluetooth® INTL
INX1025T19	DreamStation BiPAP ST25 w/Humid/Heated Tube, no Bluetooth® INTL
INX1030S19	DreamStation BiPAP ST30 AAM no Bluetooth®, INTL
INX1030H19	DreamStation BiPAP ST30 AAM w/Humid, no Bluetooth® INTL
INX1030T19	DreamStation BiPAP ST30 AAM w/Humid/Heated Tube, no Bluetooth® INTL
UAX1030S19	DreamStation BiPAP ST30 AAM, no Bluetooth®, UA
UAX1030H19	DreamStation BiPAP ST30 AAM w/Humid, No Bluetooth®, UA
ZAX1030S19	DreamStation BiPAP ST30 AAM no Bluetooth®, ZA
ZAX1030H19	DreamStation BiPAP ST30 AAM w/Humidifier, no Bluetooth® ZA
BiPAP AVAPS:	
EUX1125S19	DreamStation BiPAP AVAPS25 no Bluetooth®, EU
EUX1125H19	DreamStation BiPAP AVAPS25, w/ Humidifier, no Bluetooth® EU
EUX1130S19	DreamStation BiPAP AVAPS30 AAM, no Bluetooth®, EU
EUX1130H19	DreamStation BiPAP AVAPS30, AAM, w/ Humidifier, no Bluetooth®, EU
INX1125S19	DreamStation BiPAP AVAPS25 no Bluetooth®, INTL
INX1125H19	DreamStation BiPAP AVAPS25 w/Humid, no Bluetooth® INTL
INX1125T19	DreamStation BiPAP AVAPS25 w/Humid/Heated Tube, no Bluetooth® INTL
INX1130S19	DreamStation BiPAP AVAPS30 AAM no Bluetooth®, INTL
INX1130H19	DreamStation BiPAP AVAPS30 AAM w/Humid, no Bluetooth® INTL
INX1130T19	DreamStation BiPAP AVAPS30 AAM w/Humid/Heated Tube, no Bluetooth® INTL
INX1131S19	DreamStation BiPAP AVAPS30AE AAM no Bluetooth®, INTL
INX1131H19	DreamStation BiPAP AVAPS30AE AAM w/Humid, no Bluetooth® INTL
INX1131T19	DreamStation BiPAP AVAPS30AE AAM w/Humid/Heated Tube, no Bluetooth® INTL
UAX1130S19	DreamStation BiPAP AVAPS30 AAM, no Bluetooth®, UA
UAX1130H19	DreamStation BiPAP AVAPS30 AAM w/HUMID, no Bluetooth®, UA
ZAX1130S19	DreamStation BiPAP AVAPS30 AAM no Bluetooth®, ZA

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	ZAX1130H19	DreamStation BiPAP AVAPS30 AAM w/Humidifier, no Bluetooth® ZA
Product Options/Accessories Part Number(s) and Descriptions:	<p>The below optional accessories are used in combination with the medical device(s) that are on this DoC, but are CE marked on its own and subject to their own DoC. Being CE marked on their own, they are mentioned here for reference only and will not be considered any further in this DoC. Hence, the accessories product name(s) listed below are NOT included in this DoC.</p> <p>Refer to REG 2101599 (humidifiers), REG 2101588 (connectivity), REG 2101640 (SpO2), REG 2101724 (power cords/adaptors)</p>	
Basic UDI-DI:	N/A	
Control Indicator:	Initial Issue Date:	Part Number:
	Nov. 21, 2016	FRX1130S14, AUX1131S15, AUX1131H15, AUX1131T15, INX1025S19, INX1025H19, INX1025T19, INX1030S19, INX1030H19, INX1030T19, INX1125S19, INX1125H19, INX1125T19, INX1130S19, INX1130H19, INX1130T19, INX1131S19, INX1131H19, INX1131T19, GB11100135, IN1120135, EU1120135
	Jan. 12, 2017	BLX1030H15, BLX1030S15, BLX1130H15, BLX1130S15, DEX1025S13, DEX1130H13, DEX1130S13, EEX1030H22, EEX1030S22, EEX1130H22, EEX1130S22, ESX1030H15, ESX1030S15, ESX1130H15, ESX1130S15, EUX1025H15, EUX1025S15, EUX1030H15, EUX1030S15, EUX1125H15, EUX1125S15, EUX1130H15, EUX1130S15, EUX1025H19, EUX1025S19, EUX1030H19, EUX1030S19, EUX1125H19, EUX1125S19, EUX1130H19, EUX1130S19, FRX1030S14, FRX1130H14, GBX1030H20, GBX1030S20, ITX1125S21, ITX1130S21, NDX1030H15, NDX1030H20, NDX1030S15, NDX1030S20, NDX1130H15, NDX1130H20, NDX1130S15, NDX1130S20, TRX1030H15, TRX1030S15, TRX1130H15, TRX1130S15, ZAX1030S19, ZAX1030H19, ZAX1130S19, ZAX1130H19
	Jan. 26, 2017	AUX1131S15C, AUX1131H15C, AUX1131T15C, AUX1131S15W, AUX1131H15W, AUX1131T15W
	Aug. 23, 2017	ESX1030S20, ESX1030H20, GBX1130S20, GBX1130H20
	Dec. 14, 2017	LDX1130S23, LDX1130H23, MDX1130S25, MDX1130H25, SAX1130S27, SAX1130H27, VTX1130S24, VTX1130H24
	Apr. 3, 2018	ITX1030S20, ITX1030H20
	Sep 18, 2019	SPX1130H21, SPX1130S21
	Oct. 24, 2018	RGBX1030S20, RGBX1130S20

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	Jul. 8, 2020	DEX1030S13, DEX1030H13
	Jun. 24, 2020	UAX1030H19, UAX1030S19, UAX1130H19, UAX1130S19
For RED Directive:		
Serial Range		Software Version
J193962212669 and higher		1.0 and higher
<p><i>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.</i></p>		
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.

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 Ridlerstrasse 65 80339 München, Germany Notified Body no. 0123
Certificate(s) Issued	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.

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From July 22, 2021 onward, product is to be compliant up through Directive 2015/683 (RoHS 3) as amended up to 2017/2102 and the following table is to be used related to RoHS compliance once product has been verified as compliant.

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 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. <i>Refer to Attachment A.</i>

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 1
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. Cleeve Road, Leatherhead, Surrey, KT22 7SB United Kingdom Notified Body Number: 0359 Certificate Number: 0002324, 0005392
Standards	The radio equipment was tested to the following standards or technical specifications: <i>Refer to Attachment A</i>

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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 and Annex II-Section 3.2 of the MDD as evidenced by certificate numbers: EN ISO 13485:2016: Q5 015581 0609 MDSAP ISO 13485:2016: QS6 112601 0001 Copies of the Quality System certificates are available upon request.

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

Date of Issue: 31-Aug-2023

Printed Name: Anne Rossi

Place of Issue: Murrysville, PA, USA

Title: Head of Regulatory Affairs – S&RC

This declaration is valid until: 26 May 2024 per EC Certificate No. G1 015581 0611 Rev. 00

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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 60601-1-2:2014	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	
Humidifiers	
EN ISO 80601-2-74:2020	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
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
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
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

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Standard	Standard Title
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

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Standard	Standard Title
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

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Revision History

*If yes, attach EU Authorized Representative (AR) approval to EU MDR GSPR & Technical Documentation file when routing in SAP. Required for initial MDR release and any significant changes (including but not limited to additional part numbers added for Europe to the EU DoC). Refer to WI 7.9-1093 and QSP 7.9-062 for additional information.

<u>Version #</u>	<u>Description of Changes</u>	<u>EU AR Verification Required (Yes* or No) For MDR Compliant DoCs only. Mark N/A if not MDR Compliant</u>
26	<p>In support of ECR 500043118:</p> <ul style="list-style-type: none"> Form updated to new version (FRM 4450 Version 13). Resigning due to change in leadership. 	N/A
25	<p>In support of ECR 500040428:</p> <ul style="list-style-type: none"> Update the intended use statement to from Respiratory Insufficiency to Respiratory Impairment in accordance with definitions outlined in 80601-2-79. Removed EN ISO 10651-6:2009, due to obsolescence, and replaced with ISO 80601-2-79 Removed EN ISO 10993-6:2016 Biological evaluation of medical devices – Part 6: Tests for local effects after implantation as it is not applicable Update ISO 80601-2-61:2017 to EN ISO 80601-2-61:2019, which is the European Norm Update ISO 10993-1:2018 to EN ISO 10993-1:2020, which is the European Norm Update IEC 62366-1:2015 to EN 62366-1:2015/ AC:2015, which is the European Norm Update ISO 80601-2-74:2017 to EN ISO 80601-2-74:2020, which is the European Norm Add following standards, which the device now complies with: <ul style="list-style-type: none"> EN ISO 18562-1:2020 EN ISO 18562-2:2020 EN ISO 18562-3:2020 EN ISO 18562-4:2020 Add the following additional standards which the device is compliant to: <ul style="list-style-type: none"> EN ISO 10993-17:2009 EN ISO 10993-18:2020 EN ISO 5356-1:2015 Correct EN 63000:2018 to EN IEC 63000:2018 Remove the following PNs from Control Indicator 	N/A

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	<ul style="list-style-type: none"> ○ CNX1025 H17, CNX1025S17, CNX1025T17, CNX1030H17, CNX1030S17, CNX1030T17, CNX1130H17, CNX1130S17, CNX113017, CNX1131H17, CNX1131S17, CNX1131T17 ● Update device descriptions of the following PNs to match descriptions in SAP <ul style="list-style-type: none"> ○ AUX1131T15W – DreamStation BiPAP AVAPS AVAPS30AE AAM w/Humidifier/Heated Tube/WiFi, AU ○ RGBX1130S20 – DreamStation BiPAP AVAPS30, GB Rental ○ DEX1030S13 – DreamStation BiPAP ST30 AAM, DE ○ DEX1030H13 – DreamStation BiPAP ST30 AAM w/Humidifier, DE ○ ESX1030S20 – DreamStation BiPAP S/T ST30, ES ● Updated FRM version from 11 to 12 	
24	<p>In support of ECR 500036641</p> <ul style="list-style-type: none"> ● Updated CE and QMS certificate references ● Updated to template version 11 of FRM 4450 	N/A
23	<p>In support of ECR 500038878:</p> <ul style="list-style-type: none"> ● Added PN RGBX1030S20 to the control indicator section. PN was added to DoC on ver18. <p>In support of ECR 500039388:</p> <ul style="list-style-type: none"> ● Added PNs UAX1030H19, UAX1030S19, UAX1130H19, UAX1130S19 	N/A
22	<p>In support of ECR 500039915</p> <ul style="list-style-type: none"> ● SAX1130S27 is being reactivated due to its inadvertent obsolescence in ECR500039149 ● Updated the following standards to their current compliant version: <ul style="list-style-type: none"> ○ ISO 80601-2-61:2017+C1:2018 ○ EN ISO 10993-6:2016 ● Updated ISO Quality Certificates Issued <ul style="list-style-type: none"> ○ From: MDSAP ISO 13485:2016: QS6 17 10 015581 058 ○ To: MDSAP ISO 13485:2016: QS6 015581 0610 	N/A
21	<p>In support of ECR 500039149:</p>	N/A

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	<ul style="list-style-type: none"> Removed obsolete part number SAX1130S27 <p>In support of ECR 500036512:</p> <ul style="list-style-type: none"> removed obsolete part number AU1120135 															
20	<p>In support of ECR 500038767:</p> <ul style="list-style-type: none"> Remove PNs CNX1025H17, CNX1025S17, CNX1025T17, CNX1030H17, CNX1030S17, CNX1030T17, CNX1130H17, CNX1130S17, CNX1130T17, CNX1131H17, CNX1131S17, and CNX1131T17, which do not have CE marks and were added in error Correct EN 60601-1-2 year from 2015 to 2014 Replace 50581 with 63000 Update template to FRM 4450 v10 	N/A														
19	<p>In support of ECR 500038872:</p> <ul style="list-style-type: none"> Add PNs DEX1030S13 and DEX1030H13 	N/A														
18	<p>In support of ECR 500038778</p> <ul style="list-style-type: none"> Updated into new version of template Added the following PNs: RGBX1030S20, RGBX1130S20 <p>In Support of 500038456, Obsolete the following part numbers</p> <table border="1" data-bbox="453 1199 1005 1810"> <thead> <tr> <th>Part Numbers</th> <th>Product Name</th> </tr> </thead> <tbody> <tr> <td>DEX1025H13</td> <td>DreamStation ST25, H, DE</td> </tr> <tr> <td>FRX1030H14</td> <td>DreamST ST30 H, FR</td> </tr> <tr> <td>FRX400S14W</td> <td>DreamStation Pro w/WiFi, FR</td> </tr> <tr> <td>ITX1025H21</td> <td>DreamST ST25 H, IT</td> </tr> <tr> <td>ITX1025S21</td> <td>DreamST ST25, IT</td> </tr> <tr> <td>ITX1125H21</td> <td>DreamST AVAPS25 H, IT</td> </tr> </tbody> </table>	Part Numbers	Product Name	DEX1025H13	DreamStation ST25, H, DE	FRX1030H14	DreamST ST30 H, FR	FRX400S14W	DreamStation Pro w/WiFi, FR	ITX1025H21	DreamST ST25 H, IT	ITX1025S21	DreamST ST25, IT	ITX1125H21	DreamST AVAPS25 H, IT	N/A
Part Numbers	Product Name															
DEX1025H13	DreamStation ST25, H, DE															
FRX1030H14	DreamST ST30 H, FR															
FRX400S14W	DreamStation Pro w/WiFi, FR															
ITX1025H21	DreamST ST25 H, IT															
ITX1025S21	DreamST ST25, IT															
ITX1125H21	DreamST AVAPS25 H, IT															

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	ITX1130H21	DreamST AVAPS30 H, IT	
	TRX1030H20	DreamST ST30 H, TR	
	TRX1030S20	DreamStation ST30, TR	
17	<p>In support of ECR 500038202:</p> <ul style="list-style-type: none"> Removed DreamStation, Nonin SpO2 cable (PN 1121694) and related GMDN code 35477 <p>In support of ECR 500037771</p> <ul style="list-style-type: none"> Removed PN GB1120135 		N/A
16	<p>In support of ECR 500036970:</p> <ul style="list-style-type: none"> Added RED Certification number 0005392 Updated EN ISO 10993-1:2009 to EN ISO 10993-1:2018 Updated EN 1041 to EN 1041/A1:2013 Added EN ISO 17664:2017 		N/A
15	<p>In support of 500037688:</p> <ul style="list-style-type: none"> Added PNs CNX1025 H17, CNX1025S17, CNX1025T17, CNX1030H17, CNX1030S17, CNX1030T17, CNX1130H17, CNX1130S17, CNX1130T17, CNX1131H17, CNX1131S17, CNX1131T17 Updated GMDN code description for 47083 – “Portable electric ventilator” 		N/A
14	<p>In support of 500037757:</p> <ul style="list-style-type: none"> Updated the product names for PNs SPX1130H21 and SPX1130S21 to match the updated HIBC models. Product name update was requested by in country representative 		N/A
13	<p>In support 500036491:</p> <ul style="list-style-type: none"> Add PNS SPX1130H21 and SPX1130S21 Updated template to FR 4450 ver 08 Moved the following PNs to the Product Options/Accessories Part Number(s) section: GB1120135, AU1120135, IN1120135, EU1120135, 1121694 to comply with new template form Updated RoHS reference to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in 		N/A

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	electric and electronic equipment, amended up to and inclusive of Directive (EU) 2017/1202 (RoHS)	
12	In support of 500035711: <ul style="list-style-type: none"> Updated radio standards Updated 60601-1-8 to EN 60601-1-8:2007/A11:2017 	N/A
11	In support of ECR 500035574: <ul style="list-style-type: none"> Added PNs ITX1030S20 and ITX1030H20. Changed the footer to 2018. Removed “-8550” from the Respironics Inc. zip code on page 1. Removed reference to EN 980:2008 from the standards table. Change EN 62366-1:2015 to IEC 62366-1:2015 in standards table. 	N/A
10	In support of ECR 500035197: <ul style="list-style-type: none"> Updated the following standard references: 13485, 60601-1, 60601-1-6, 60601-1-8, 62304, 62366-1, 50581 Removed 8185 Added 80601-2-74 Updated description of VTX1130H24 TO DreamStation BiPAP AVAPS AVAPS30 AAM, w/ Humidifier VitalAire, Vitalvent DS and updated description of VTX1130S24 TO DreamStation BiPAP AVAPS AVAPS30 AAM, VitalAire, Vitalvent DS Updated Description of SAX1130H27 TO DreamStation BiPAP Synchrony AVAPS AAM, with Humidifier and Updated Description of SAX1130S27 TO DreamStation BiPAP Synchrony AVAPS AAM 	N/A
09	In support of ECR 500034517: <ul style="list-style-type: none"> Added PNs LDX1130S23, LDX1130H23, MDX1130S25, MDX1130H25, SAX1130S27, SAX1130H27, VTX1130S24, VTX1130H24 Removed PNs DEX1030H13, DEX1030S13 from the control designator section. Changed the year 2006 to 2013 for EN 60601-1 and 2007 to 2010 for EN 60601-1-8. <p>Note: Version 08 of this document has been superseded. All updates made in version 08 of this document are reflected in version 09.</p>	N/A
08	In support of German IKK registration: <ul style="list-style-type: none"> Removed PNs DEX1030S13 and DEX1030H13 	N/A

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	<ul style="list-style-type: none"> Renamed PN DEX1130S13 “DreamStation BiPAP ST30 AAM DE” and moved it to the BiPAP ST with radio functionality section. Renamed PN DEX1130H13 “DreamStation BiPAP ST30 AAM w/Humidifier, DE” and moved it to the BiPAP ST with radio functionality section. 	
07	<p>In support of ECR 500034542:</p> <ul style="list-style-type: none"> Added SpO2 cable to list of accessories 	N/A
06	<p>In support of ECR 500034577:</p> <ul style="list-style-type: none"> Added PNs ESX1030S20, ESX1030H20, GBX1130S20, GBX1130H20 	N/A
05	<p>In support of ECR 500034455:</p> <ul style="list-style-type: none"> Updated product part number section to include RED compliance Removed Cetecom reference Added dated references for radio standards Updated 15223-1 reference 	N/A
04	<p>In support of ECR 500034733:</p> <ul style="list-style-type: none"> Replaced R&TTE with RED throughout. Updated product part number to call out only AU PNs as RED compliant. Added EN 301 908-2 that was inadvertently missed on DoC Added table / note for serial number and software version in Control Designator section. Added RED Classification in the Device Classification section. Updated to version 04 of FR 4450. 	N/A
03	<p>In support of ECO 500034240:</p> <ul style="list-style-type: none"> Update Kahootz Control Knob Design for Manufacturability Changed Rule 9 to Rule 10 in this text: “Class IIa, Annex IX, Rule 9 (PN 1121694)” Changed “Device” to “Accessory” in this text: “Wi-Fi Device” Added “Oximetry Sensors” to the Accessories row Changed EN 62366-1: 2015 to EN 62366: 2008 	N/A

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02	<p>In support of ECO 500034151 Release Kahootz Tri-Packs:</p> <ul style="list-style-type: none"> • Added PNs: <ul style="list-style-type: none"> ○ AUX1131S15C, AUX1131H15C, AUX1131T15C AUX1131S15W, AUX1131H15W, AUX1131T15W 	N/A
01	<p>In support of ECO 500033185 Release Kahootz Postponement PNs:</p> <ul style="list-style-type: none"> • Added PNs: <ul style="list-style-type: none"> ○ BLX1030H15, BLX1030S15, BLX1130H15, BLX1130S15, DEX1025H13, DEX1025S13, DEX1030H13, DEX1030S13, DEX1130H13, DEX1130S13, EEX1030H22, EEX1030S22, EEX1130H22, EEX1130S22, ESX1030H15, ESX1030S15, ESX1130H15, ESX1130S15, EUX1025H15, EUX1025S15, EUX1030H15, EUX1030S15, EUX1125H15, EUX1125S15, EUX1130H15, EUX1130S15, EUX1025H19, EUX1025S19, EUX1030H19, EUX1030S19, EUX1125H19, EUX1125S19, EUX1130H19, EUX1130S19, FRX1030H14, FRX1030S14, FRX1130H14, GBX1030H20, GBX1030S20, ITX1025H21, ITX1025S21, ITX1125H21, ITX1125S21, ITX1130H21, ITX1130S21, NDX1030H15, NDX1030H20, NDX1030S15, NDX1030S20, NDX1130H15, NDX1130H20, NDX1130S15, NDX1130S20, TRX1030H20, TRX1030S20, TRX1030H15, TRX1030S15, TRX1130H15, TRX1130S15, TRX900H15, ZAX1030S19, ZAX1130H19, ZAX1130S19, ZAX1030H19 • Changed document number in footer from “REG 2101942 Att 1” to “REG 2101942c” 	N/A
00	Initial Release	N/A

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