

Doc Number REG 2101599 Revision v16

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 Heated Humidifier		
Product Type:	Humidifier		
Intended Purpose:	The DreamStation Heated Humidifier is an accessory for the Philips Respironics DreamStation therapy devices to provide moisture to the patient circuit. It is intended for use in spontaneously breathing patients weighing over 30 kg (66 lbs), in the home or hospital/institutional environment, who use mask-applied positive pressure ventilation therapy.  The humidifier disinfection aid is intended to allow disinfection of the DreamStation heated humidifier air outlet port. It is used in combination with a high level disinfectant.		
Product Part Number(s) and Descriptions:	Part Number(s) listed in this section comply with all regulations/directives indicated in DoC unless otherwise noted.		
	EUXH Drear	nStation Humidifier, EU	
		mStation Humidifier BL	
		nStation Humidifier GER	
	EEXH DreamStation Humidifier EE		
	ESXH DreamStation Humidifier Spain FRXH DreamStation Humidifier FR		
	GBXH DreamStation Humidifier FR		
	INXH DreamStation Humidifier, INTL		
	ITXH DreamStation Humidifier IT		
	NDXH DreamStation Humidifier ND		
	TRXH DreamStation Humidifier TR		
	RGBXH DreamStation Humidifier, GB, Rental		
	RDEXH DreamStation REMstar Humidifier GER, Rental		
	RINXH DreamStation Humidifier, Rental		
	UAXH DreamStation Humidifier, Ukraine		
Product Options/Accessories Part Number(s) and	This declaration also includes the following product options and accessories:		
Descriptions:	Part Number Description		
	1127627 Humidifier Air Outlet Port Disinfection Aid		
	HT15	15MM Heated Tube	
Basic UDI-DI:	N/A		

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Control Indicator:	Initial Issue Date: May 28, 2015 June 26, 2015 July 15, 2015 July 17, 2015 Sept. 11, 2015 Nov. 05, 2015 February 3, 2017 April 22, 2020 April 19, 2016 March 30, 2017 July 7, 2020	Part Number: EUXH HT15 DEXH ESXH FRXH, GBXH BLXH, EEXH, ITXH, NDXH, TRXH 1127627 INXH RGBXH RDEXH, RINXH UAXH
Global Medical Device Nomenclature Code (GMDN) and Description:	12050 Heated respir	atory humidifier

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 2 and 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	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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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 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

### 2. Mandatory information:

Manufacturer	Respironics, Inc.
	1001 Murry Ridge Lane
	Murrysville, PA 15668
	USA
EU Authorized	Respironics Deutschland GmbH & Co. KG
Representative (AR):	Gewerbestrasse 17
	82211 Herrsching, Germany
	Tel: +49 8152 93060
ISO Quality	The Manufacturer is certified by TUV to the following:
Certificates Issued:	
	EN ISO 13485 and Annex II-Section 3.2 of the MDD as
	evidenced by certificate numbers:
	EN ISO 13485:2016: Q5 015581 0607
	MDSAP ISO 13485:2016: QS6 17 10 15581 058

Signature (signed for and on behalf of)

Respironics, Inc:

Date of Issue: 31 March 2022

Printed Name: Katelyn Manning

Place of Issue: Monroeville, PA

Title: Sr. Manager, Regulatory Affairs

This declaration is valid until: 26 May 2024

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### 3. Attachment A Standards and/or Common Specifications

EN ISO 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 electrical performance  EN 60601-1-(2005/A1-2015) Medical electrical equipment – Part 1-2: General requirements for basic safety and electrical performance – Collateral standard: Electromagnetic compatibility – Requirements and tests  EN 60601-1-(6:2010/A1:2015) Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability – Requirements and tests  EN 60601-1-(6:2010/A1:2015) Medical electrical equipment – Part 1-1: General requirements for basic safety and essential performance – Collateral standard: Usability  EN 60601-1-11:2015 Medical electrical equipment – Part 1-1: General requirements for basic safety and essential performance – Collateral standard: Stability  EN 150 10993-1:2018 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment  Biological evaluation of medical devices – Part 1: Evaluation and testing  EN 150 10993- 10:2019 Biological evaluation of medical devices – Part 1: Evaluation and testing  EN 150 10993- 10:2013 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization  EN 150 10993- 10:2013 Biological evaluation of Medical Devices – Part 11: Establishment of Allowable Limits for Leachable Substances  EN 150 10993- 18:2020 Biological Evaluation of Breathing Gas Pathways in Healthcare Applications, Test for Emissions of Particulate Matter  ISO 18562-2:2017 Biological Evaluation of Breathing Gas Pathways in Healthcare Applications, Test for Emission of Particulate Matter  ISO 18562-3:2017 Medical Devices – Application of Breathing Gas Pathways in Healthcare Applications, Test for Emission of Particulate Matter  ISO 1850 15223- 1650 15223- 1650 15223- 1650 15223- 1650 15223	Standard	Standard Title			
Medical electrical equipment – Part 1: General requirements for basic safety and electrical performance   Part 1: General requirements for basic safety and electrical performance	Quality System	Quality System			
General Safety Standard	EN ISO	Medical devices – Quality management systems – Requirements for regulatory			
EN 60601-1   Medical electrical equipment – Part 1: General requirements for basic safety and electrical pseformance	13485:2016	purposes			
Collateral Safety Standards	General Safety Stan	idard			
Collateral Safety Standards	EN 60601-	Medical electrical equipment – Part 1: General requirements for basic safety and			
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  EN 60601-1-11:2015  Medical electrical equipment - Part 1-6: General requirements for safety and essential performance - Collateral standard: Usability  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  Biocompatibility  ISO 10993-1:2018  Biological evaluation of medical devices - Part 1: Evaluation and testing  EN ISO 10993-  Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity  EN ISO 10993- Biological evaluation of medical devices - Part 10: Tests for in vitro cytotoxicity  EN ISO 10993- Biological evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization  EN ISO 10993- Biological Evaluation of Medical Devices - Part 17: Establishment of Allowable Limits for Leachable Substances  EN ISO 10993- Biological Evaluation of Medical Devices - Part 18: Chemical Characterization of Medical Device Materials within Risk Management Process  ISO 18562-2:2017 Biological Evaluation of Breathing Gas Pathways in Healthcare Applications, Test for Emissions of Particulate Matter  Biological Evaluation of Preathing Gas Pathways in Healthcare Applications, Test for Emissions of Particulate Matter  Biological Evaluation of Breathing Gas Pathways in Healthcare Applications, Test for Emissions of Particulate Matter  Biological Evaluation of Breathing Gas Pathways in Healthcare Applications, Test for Emission of Volati	1:2006/A1:2013	electrical performance			
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	Risk Management				
Usability	ISO 14971:2019	Medical devices – Application of risk management to medical devices			
	Usability				

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IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices	
RoHS		
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances	
Cleaning and Disinfection		
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	

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