# EU DECLARATION OF CONFORMITY

RESPIRONICS®

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:

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|---|---|
| **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.<br><br>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.<br><br>EUXH DreamStation Humidifier, EU<br>BLXH DreamStation Humidifier BL<br>DEXH DreamStation Humidifier GER<br>EEXH DreamStation Humidifier EE<br>ESXH DreamStation Humidifier Spain<br>FRXH DreamStation Humidifier FR<br>GBXH DreamStation Humidifier GB<br>INXH DreamStation Humidifier, INTL<br>ITXH DreamStation Humidifier IT<br>NDXH DreamStation Humidifier ND<br>TRXH DreamStation Humidifier TR<br>RGBXH DreamStation Humidifier, GB, Rental<br>RDEXH DreamStation REMstar Humidifier GER, Rental<br>RINXH DreamStation Humidifier, Rental<br>UAXH DreamStation Humidifier, Ukraine |
| **Product Options/Accessories Part Number(s) and Descriptions**: | *This declaration also includes the following product options and accessories:*<br><br>*Part Number* / *Description*<br>1127627 — Humidifier Air Outlet Port Disinfection Aid<br>HT15 — 15MM Heated Tube |
| **Basic UDI-DI:** | N/A |

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| **Control Indicator:** | Initial Issue Date:<br>May 28, 2015<br>June 26, 2015<br>July 15, 2015<br>July 17, 2015<br>Sept. 11, 2015<br>Nov. 05, 2015<br>February 3, 2017<br>April 22, 2020<br>April 19, 2016<br>March 30, 2017<br>July 7, 2020 | Part Number:<br>EUXH<br>HT15<br>DEXH<br>ESXH<br>FRXH, GBXH<br>BLXH, EEXH, ITXH, NDXH, TRXH<br>1127627<br>INXH<br>RGBXH<br>RDEXH, RINXH<br>UAXH |
| **Global Medical Device Nomenclature Code (GMDN) and Description:** | 12050 Heated respiratory 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<br>Ridlerstrasse 65<br>80339 München, Germany<br>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.<br><br>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.<br><br>*Refer to Attachment A* |

## 2. Mandatory information:

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

## 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 electrical 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 60601-1-11:2015 | 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** | |
| 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 10993-3:2014 | 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 Risk Management Process |
| ISO 18562-2:2017 | Biological Evaluation of Breathing Gas Pathways in Healthcare Applications, Test for Emissions of Particulate Matter |
| ISO 18562-3:2017 | Biological Evaluation of Breathing Gas Pathways in Healthcare Applications, Test for Emission of Volatile Organic Compounds |
| **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 |
| **Risk Management** | |
| 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 |