DECLARATION OF CONFORMITY

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

Declares under our sole responsibility that the product:

Product Name	DreamWear Gel Pillows Mask
Product Type	Nasal Mask
Product Part Number	1124984 DreamWear Gel Plw, Med Frame w/ HGR, GBL 1124985 DreamWear Gel Plw, Med Frame w/o HGR, GBL 1124986 S, DreamWear Plw, Med Frame w/o HGR, GBL 1124987 M, DreamWear Plw, Med Frame w/o HGR, GBL 1125008 L, DreamWear Plw, Med Frame w/o HGR, GBL 1125009 S, DreamWear Plw, Sm Frame w/o HGR, GBL 1125010 M, DreamWear Plw, Sm Frame w/o HGR, GBL 1125011 L, DreamWear Plw, Sm Frame w/o HGR, GBL 1125012 S, DreamWear Plw, Lg Frame w/o HGR, GBL 1125013 M, DreamWear Plw, Lg Frame w/o HGR, GBL 1125014 L, DreamWear Plw, Lg Frame w/o HGR, GBL 1125015 S, DreamWear Plw, Med Frame w/ HGR, GBL 1125016 M, DreamWear Plw, Med Frame w/ HGR, GBL 1125017 L, DreamWear Plw, Med Frame w/ HGR, GBL 1125018 S, DreamWear Plw, Sm Frame w/ HGR, GBL 1125019 M, DreamWear Plw, Sm Frame w/ HGR, GBL 1125020 L, DreamWear Plw, Sm Frame w/ HGR, GBL 1125021 S, DreamWear Plw, Lg Frame w/ HGR, GBL 1125022 M, DreamWear Plw, Lg Frame w/ HGR, GBL 1125023 L, DreamWear Plw, Lg Frame w/ HGR, GBL 1125024 DreamWear Gel Plw, Med Frame w/ HGR, INTL
Control Designator	Initial Issue Date: Part Number: 12/13/2016 1124984, 1124985, 1124986, 1124987, 1125008, 1125009, 1125010, 1125011, 1125012, 1125013, 1125014, 1125015, 1125016, 1125017, 1125018, 1125019, 1125020, 1125021, 1125022, 1125023 04/20/2017 1125024
Device Classification, Annex and Rule	Class IIa, Rule 2, Annex IX
Global Medical Device Nomenclature Code (GMDN)	57815 CPAP/BiPAP Nasal Mask Reusable
Product Options/ Accessories	None

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

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

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.

Standards:

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

Quality System	
EN ISO 13485:2012/AC:2012	Medical devices – Quality management systems – Requirements for regulatory purposes
Particular Standards	
Patient Interface	
EN ISO 17510:2015	Medical devices – Sleep apnoea breathing therapy – Masks and application accessories
Biocompatibility	
EN ISO 10993-1:2009/ AC:2010	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 10993-3:2009	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 10993-6:2009	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

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 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
Risk Management	
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
Tubing and Connections	
ISO 5356-1:2015	Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets
EN ISO 5367:2014	Breathing tubes intended for use with anesthetic apparatus and ventilators
Usability	
EN 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices

Name	Frank Kadi
Title	Regulatory Affairs Manager, Patient Interface
Signature	
Date (MM/DD/YYYY)	4/20/2017
Place of Issue	Monroeville