



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 Under the Nose Nasal Mask
Product Type	Nasal Mask
Product Part Number	1116680 S DreamWear Under the Nose Nasal, Med Frame W/HGR, GBL 1116681 M DreamWear Under the Nose Nasal, Med Frame W/HGR, GBL 1116682 L DreamWear Under the Nose Nasal, Med Frame W/HGR, GBL 1116683 MW DreamWear Under the Nose Nasal, Med Frame W/HGR, GBL 1116685 S DreamWear Under the Nose Nasal, Sm Frame W/HGR, GBL 1116686 M DreamWear Under the Nose Nasal, Sm Frame W/HGR, GBL 1116687 L DreamWear Under the Nose Nasal, Sm Frame W/HGR, GBL 1116688 MW DreamWear Under the Nose Nasal, Sm Frame W/HGR, GBL 1116690 S DreamWear Under the Nose Nasal, Lg Frame W/HGR, GBL 1116691 M DreamWear Under the Nose Nasal, Lg Frame W/HGR, GBL 1116692 L DreamWear Under the Nose Nasal, Lg Frame W/HGR, GBL 1116693 MW DreamWear Under the Nose Nasal, Lg Frame W/HGR, GBL 1116695 DreamWear Under the Nose Nasal, FitPack 1116700 DreamWear Under the Nose Nasal, Med Frame W/HGR, GBL 1116701 DreamWear Under the Nose Nasal, Med Frame W/O HGR, GBL 1116705 S DreamWear Under the Nose Nasal, Med Frame W/O HGR, GBL 1116706 M DreamWear Under the Nose Nasal, Med Frame W/O HGR, GBL 1116707 L DreamWear Under the Nose Nasal, Med Frame W/O HGR, GBL 1116708 MW DreamWear Under the Nose Nasal, Med Frame W/O HGR, GBL 1116710 S DreamWear Under the Nose Nasal, Sm Frame W/O HGR, GBL 1116711 M DreamWear Under the Nose Nasal, Sm Frame W/O HGR, GBL 1116712 L DreamWear Under the Nose Nasal, Sm Frame W/O HGR, GBL 1116713 MW DreamWear Under the Nose Nasal, Sm Frame W/O HGR, GBL 1116715 S DreamWear Under the Nose Nasal, Lg Frame W/O HGR, GBL 1116716 M DreamWear Under the Nose Nasal, Lg Frame W/O HGR, GBL 1116717 L DreamWear Under the Nose Nasal, Lg Frame W/O HGR, GBL 1116718 MW DreamWear Under the Nose Nasal, Lg Frame W/O HGR, GBL 1116696 DreamWear Under the Nose Nasal, FitPack, Intl 1116720 DreamWear Under the Nose Nasal, Medium Frame W/HGR, Intl
Control Designator	Initial Issue Date: Part Number: 07/02/2015 1116680, 1116681, 1116682, 1116683, 1116685,

	1116686, 1116687, 1116688, 1116690, 1116691, 1116692, 1116693, 1116695, 1116700, 1116701, 1116705, 1116706, 1116707, 1116708, 1116710, 1116711, 1116712, 1116713, 1116715, 1116716, 1116717, 1116718 10/15/2015 1116696, 1116720
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 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	Medical devices – Quality management systems – Requirements for regulatory purposes
Particular Standards	
Patient Interface	
EN ISO 17510-2:2009	Sleep apnoea breathing therapy – Part 2: Masks and application accessories
Biocompatibility	
EN ISO 10993-1:2009	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 15223-1:2012	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 5356-1:2004	Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets
ISO 5367:2014	Breathing tubes intended for use with anesthetic apparatus and ventilators
Usability	
EN 62366:2008	Medical devices – Application of usability engineering to medical devices

Name	Frank Kadi
Title	Regulatory Affairs Manager, Patient Interface
Signature	
Date (MM/DD/YYYY)	10/16/2015
Place of Issue	Monroeville

