RESPIRONICS®

DECLARATION OF CONFORMITY

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

Declares under our sole responsibility that the product:

Product Name	DreamWear Nasal Mask with Under the Nose Cushion
Product Type	Nasal Mask
Product Part Number	1138389 DreamWear SC UTN Fitpack AUS/USA
Control Designator	Initial Issue Date: Part Number: See Signature Below 1138389
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: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
Particular Safety Standards	
Patient Interface	
EN ISO 17510-2: 2009	Sleep apnea breathing therapy – Part 2: Masks and application accessories
ISO 17510: 2015	Sleep apnea breathing therapy – Masks and application accessories
Biocompatibility	
EN ISO 10993-1: 2009/AC: 2010	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process
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 10993-6: 2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
EN ISO 10993-10:2013	Biological Evaluation of Medical Devices – Part 5: 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
ISO 18562-1: 2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
ISO 18562-2: 2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
ISO 18562-3: 2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)
ISO 18562-4: 2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate
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, 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	
EN ISO 5356-1: 2015	Anesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets
Usability	
IEC 62366-1: 2015	Medical devices – Application of usability engineering to medical devices
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

Name	Andy Zeltwanger
Title	Senior Regulatory Affairs Manager, PI
Signature	
Date (MM/DD/YYYY)	08/15/2018
Place of Issue	Monroeville