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 Full Face Mask	
Product Type	Full Face Mask	
Product Part Number	1133380	S, DreamWear Full, Med Frm W/ HGR, GBL
	1133381	M, DreamWear Full, Med Frm W/ HGR, GBL
	1133382	L, DreamWear Full, Med Frm W/ HGR, GBL
	1133383	MW, DreamWear Full, Med Frm W/ HGR, GBL
	1133385	S, DreamWear Full, Sm Frm W/ HGR, GBL
	1133386	M, DreamWear Full, Sm Frm W/ HGR, GBL
	1133387	L, DreamWear Full, Sm Frm W/ HGR, GBL
	1133388	MW, DreamWear Full, Sm Frm W/ HGR, GBL
	1133390	S, DreamWear Full, Lg Frm W/ HGR, GBL
	1133391	M, DreamWear Full, Lg Frm W/ HGR, GBL
	1133392	L, DreamWear Full, Lg Frm W/ HGR, GBL
	1133393	MW, DreamWear Full, Lg Frm W/ HGR, GBL
	1133395	DreamWear Full, Demo Pack
	1133400	FitPack, DreamWear Full, Med Frame, GBL
	1133405	S, DreamWear Full, Med Frm W/O HGR, GBL
	1133406	M, DreamWear Full, Med Frm W/O HGR, GBL
	1133407	L, DreamWear Full, Med Frm W/O HGR, GBL
	1133408	MW, DreamWear Full, Med Frm W/O HGR, GBL
	1133410	S, DreamWear Full, Sm Frm W/O HGR, GBL
	1133411	M, DreamWear Full, Sm Frm W/O HGR, GBL
	1133412	L, DreamWear Full, Sm Frm W/O HGR, GBL
	1133413	MW, DreamWear Full, Sm Frm W/O HGR, GBL
	1133415	S, DreamWear Full, Lg Frm W/O HGR, GBL
	1133416	M, DreamWear Full, Lg Frm W/O HGR, GBL
	1133417	L, DreamWear Full, Lg Frm W/O HGR, GBL
	1133418	MW, DreamWear Full, Lg Frm W/O HGR, GBL
	1133375	S, DreamWear Full, Sm & Med Frm, GBL
	1133376	M, DreamWear Full, Sm & Med Frm, GBL

	1133377	L, DreamWear Full, Sm & Med Frm, GBL
	1133378	MW, DreamWear Full, Sm & Med Frm, GBL
	1133370	S, DreamWear Full, Sm & Med Frm, INTL
	1133371	M, DreamWear Full, Sm & Med Frm, INTL
	1133372	L, DreamWear Full, Sm & Med Frm, INTL
	1133373	MW, DreamWear Full, Sm & Med Frm, INTL
Control Designator	December 04,2017	1133380, 1133381, 1133382, 1133383, 1133385, 1133386, 1133387, 1133388, 1133390, 1133391, 1133392, 1133393, 1133395, 1133400, 1133405, 1133406, 1133407, 1133408, 1133410, 1133411, 1133412, 1133413, 1133415, 1133416, 1133417, 1133418, 1133375, 1133376, 1133377, 1133378
	See Signature Below	1133370, 1133371, 1133372, 1133373
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	Medical devices – Sleep apnea breathing therapy – Masks and application accessories
Biocompatibility	
EN ISO 10993-1:2009	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 10993-6:2009	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
Other Standards	
Accompany Documents and Labeling	
EN 1041: 2008	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
EN 15986:2011	Symbols for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates
Risk Management	
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
Usability	
IEC 62366-1:2015	Medical devices – Application of usability engineering to medical devices

Name	Andrew Zeltwanger
Title	Senior Manager, Regulatory Affairs
Signature	
Date (MM/DD/YYYY)	02/28/2018
Place of Issue	Monroeville