RESPIRONICS®

EU DECLARATION OF CONFORMITY

Manufacturer name/address
Respironics Inc.
1001 Murry Ridge Lane Murrysville, PA 15668

This declaration of conformity is issued under the sole responsibility of the manufacturer. The device covered by the present declaration is in conformity with all regulations or directives below, including compliance with related Essential Requirements and Safety and Performance Requirements.

Object of the declaration:

Product Name:	DreamWear Under the Nose Nasal Mask	
Product Type:	Nasal Mask	
Intended Purpose:	This mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.	
Product Part Number(s) and Descriptions:	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

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	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
	1142376	S/M DreamWear Nasal Mask Kit w/HGR, GBL
Product Options/Accessories Part Number(s) and Descriptions:	None	
Control Indicator:	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
	12/04/2019	1142376
Global Medical Device Nomenclature Code (GMDN) and Description	57815 CPAP/BiPAP Nasal Mask Reusable	

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The object of the declaration described above is in conformity with the following regulations:

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)**
Device Risk Classification	Class IIa based on Annex IX and Rule 2
Conformity Assessment Path	Annex II-Section 3.2
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany Notified Body Number: 0123
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. Refer to Attachment A.

Additional information:

EU Authorized Representative:	Respironics Deutschland GmbH & Co. KG Gewerbestrasse 17 82211 Herrsching, Germany Tel: +49 8152 93060
Quality Certificates Issued:	The Manufacturer is certified by TÜV SÜD to the following: TÜV SÜD Product Service GmbH Certificate Number: G1 015581 0605 TÜV SÜD MDSAP Certificate Number: QS6 17 10 15581 058 Copies of the Quality System certificates are available upon request.

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Signature (signed for and on behalf of Philips):

Date of Issue: 04 December, 2019

Printed Name: Andy Zeltwanger

Place of Issue: Monroeville, PA

Title: Sr. Manager, Regulatory Affairs

REG 2101606 Version 04

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Attachment A
Standards and/or Common Specifications

Quality System	
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
Particular Safety Standards	
Patient Interface	
ISO 17510:2015	Medical devices - Sleep apnoea breathing therapy - Masks and application accessories
EN ISO 17510-2:2009	Sleep apnoea breathing therapy - Part 2: 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 10: Tests for irritation and skin sensitization
Other Standards	
Accompany Documents and Labeling	
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 1041:2008/A1:2013	Information supplied by the manufacturer of medical devices
Risk Management	
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices

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Usability	
IEC 62366-1:2015	Medical devices – Part 1: 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
Tubing and Connections	
EN ISO 5356-1:2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets