EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101606
Revision v09

This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device(s)/accessories covered by this Declaration are in conformity with all regulations or directives below.

1. Object of the declaration:

Product Name:	DreamWear Nasal Mask with Under the Nose Cushion
Product Type:	Nasal Mask
Intended Purpose:	This nasal 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 (>66 lbs/30 kg) for whom CPAP or bi-level therapy has been prescribed.
Product Part Number(s) and Descriptions:	Part Number(s) listed in this section comply with all directives indicated in DoC unless otherwise noted. The following part numbers are compliant with 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC:

Part Number	Device Name/Description
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
1142376	S/M DreamWear Nasal Mask Kit w/HGR, GBL
1116696UA	DreamWear Under the Nose Nasal, FitPack, Ukraine
1144112	S DreamWear Combopack (UTN and Full)
1144113	M DreamWear Combopack (UTN and Full)
1144114	L DreamWear Combopack (UTN and Full)

	1148932	DreamWear Under the Nose/Silicone Pillows Frame Kit Small
	1148933	DreamWear Under the Nose/Silicone Pillows Frame Kit Medium
	1148934	DreamWear Under the Nose/Silicone Pillows Frame Kit Large
Product Options/Accessories Part Number(s) and Descriptions:	Refer to REG 22849 for mask and circuit accessories.	
Basic UDI-DI:	N/A	
Control Indicator:	Initial Issue Date:	REF (Part Number):
	02-Jul-15	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
	15-Oct-15	1116696, 1116720
	04-Dec-19	1142376
	26-Mar-20	1116696UA
	03-Jun-20	1144112, 1144113, 1144114
	10-Dec-20	1148932, 1148933, 1148934
Global Medical Device Nomenclature code (GMDN) and Description	57814 CPAP/BiPAP Face Mask Reusable	

The object of the Declaration (product part numbers and if applicable the component part numbers) that are described above as included in this DoC is / are in conformity with the following regulations / directives. If optional accessories that are used in combination with the product (medical device), but are CE marked on their own are referenced in this DoC, they are excluded further on as these optional accessories have their own DoC.

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)
Risk Classification	Class IIa based on Annex IX and Rule 2
Conformity Assessment Route	Annex II excluding (4)
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany 0123
Certificate(s) Issued	TÜV SÜD EC Certificate Number: G1 015581 0611
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.

2. Mandatory information:

Manufacturer	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 USA
EU Authorized Representative (AR):	Respironics Deutschland GmbH & Co. KG Gewerbestrasse 17 82211 Herrsching, Germany Tel: +49 8152 93060
ISO Quality Certificates Issued:	The Manufacturer is certified by TÜV SÜD to the following: TÜV SÜD EN ISO 13485:2016 Certificate Number: Q5 015581 0609 TÜV SÜD MDSAP Certificate Number: QS6 112601 0001

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Signature (signed for and on behalf of):
Respironics, Inc.

Date of Issue: 27 August 2021

Printed Name: Jennifer Richardson

Place of Issue: Murrysville, PA, USA

Title: Senior Manager, Regulatory Affairs

3. Attachment A Standards and/or Common Specifications

Standard	Standard Title
Quality System	
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
Particular Safety Standards	
Patient Interface	
EN ISO 17510:2020	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 10993-1:2020	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
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	
ISO 15223-1: 2017	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN 1041: 2008/A1:2013	Information supplied by the manufacturer of medical devices
Risk Management	
ISO 14971:2019	Medical devices – Application of risk management to medical devices
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
Tubing and Connections	
EN ISO 5356-1:2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets