EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101735
Revision 08

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:	DreamWisp Nasal Mask with Over the Nose Cushion
Product Type:	Nasal Mask
Intended Purpose:	This nasal mask is intended to provide an interface for application of Continuous Positive Airway Pressure (CPAP) or bi-level therapy to patients. The mask is intended 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/30kg) for whom CPAP or bi-level therapy has been prescribed.
Product Part Number(s) and Descriptions:	1137916 FitPack, DreamWisp Nsl, Med Con w/Hgr GBL 1137918 FitPack, DreamWisp Nsl, Med Con w/o Hgr GBL 1137922 P, DreamWisp Nsl, Med Con w/o Hgr GBL 1137923 S, DreamWisp Nsl, Med Con w/o Hgr GBL 1137924 M, DreamWisp Nsl, Med Con w/o Hgr GBL 1137925 L, DreamWisp Nsl, Med Con w/o Hgr GBL 1137926 XL, DreamWisp Nsl, Med Con w/o Hgr GBL 1137932 P, DreamWisp Nsl, Med Con w/Hgr, GBL 1137933 S, DreamWisp Nsl, Med Con w/Hgr, GBL 1137934 M, DreamWisp Nsl, Med Con w/Hgr, GBL 1137935 L, DreamWisp Nsl, Med Con w/Hgr, GBL 1137936 XL, DreamWisp Nsl, Med Con w/Hgr, GBL 1137953 LABPACK, DREAMWISP, ALL CON, S/M/L CUSH W/HGR 1137954 P/XL LABPK, DREAMWISP LAB PACK, S/L CON 1137955 COMBO LAB PACK, DREAMWISP 1137921 FitPack, DreamWisp Nsl, Med Con w/Hgr INTL 1137942 P, DreamWisp Nsl, Med Con w/Hgr, INTL 1137943 S, DreamWisp Nsl, Med Con w/Hgr, INTL 1137944 M, DreamWisp Nsl, Med Con w/Hgr, INTL 1137945 L, DreamWisp Nsl, Med Con w/Hgr, INTL 1137946 XL, DREAMWISP NSL, MED CON W/HGR, INT 1137942AP P, DreamWisp Nsl, Med Con, W/HGR, AP 1137943AP S, DreamWisp Nsl, Med Con, W/HGR, AP 1137944AP M, DreamWisp Nsl, Med Con, W/HGR, AP

	1137945AP L, DreamWisp Nsl, Med Con, W/HGR,AP 1137946AP XL, DreamWisp Nsl, Med Con, W/HGR, AP 1137942CE P, DreamWisp Nsl, Med Con, W/HGR, CE 1137943CE S, DreamWisp Nsl, Med Con, W/HGR, CE 1137944CE M, DreamWisp Nsl, Med Con, W/HGR, CE 1137945CE L, DreamWisp Nsl, Med Con, W/HGR,CE 1137946CE XL, DreamWisp Nsl, Med Con, W/HGR, CE 1137942RC P, DreamWisp Nsl, Med Con, W/HGR, RC 1137943RC S, DreamWisp Nsl, Med Con, W/HGR, RC 1137944RC M, DreamWisp Nsl, Med Con, W/HGR, RC 1137945RC L, DreamWisp Nsl, Med Con, W/HGR,RC 1137946RC XL, DreamWisp Nsl, Med Con, W/HGR, RC 1144502 Fitpack, DreamWisp, USA
Product Options/Accessories Part Number(s) and Descriptions:	Refer to REG 22849 for headgear and chinstrap accessories
Basic UDI-DI:	N/A
Control Indicator:	Initial Issue Date: / Part Number: 16 January, 2019 — 1137916, 1137918, 1137922, 1137923, 1137924, 1137925, 1137926, 1137932, 1137933, 1137934, 1137935, 1137936 27 March, 2019 — 1137953, 1137954 2 April, 2019 — 1137955, 1137921, 1137942, 1137943, 1137944, 1137945, 1137946 12 June, 2019 — 1137942AP, 1137943AP, 1137944AP, 1137945AP, 1137946AP, 1137942CE, 1137943CE, 1137944CE, 1137945CE, 1137946CE, 1137942RC, 1137943RC, 1137944RC, 1137945RC, 1137946RC 02 June, 2020 — 1144502
Global Medical Device Nomenclature code (GMDN) and Description	57815 CPAP/BiPAP Nasal 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 Notified Body Number: 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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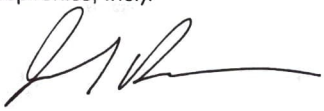
Signature (signed for and on behalf of Respironics, Inc.):



Date of Issue: 27 August 2021

Printed Name: Jennifer Richardson

Place of Issue: Murrysville, PA

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 17510-2:2009	Sleep apnoea breathing therapy - Part 2: Masks and application accessories
EN ISO 17510:2020	Medical devices - Sleep apnoea breathing therapy - 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
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18:2009	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
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	

Standard	Standard Title
Quality System	
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	
ISO 14971:2019	Medical devices - Application of risk management to medical devices
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