EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2103118
Revision 04

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 Silicone Pillows Mask	
Product Type:	Nasal Mask	
Intended Purpose:	The DreamWear Silicone Pillows 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:	1146410	S, DreamWear Silicone Pillows, Small Frame with Headgear, Global
	1146411	M, DreamWear Silicone Pillows, Small Frame with Headgear, Global
	1146412	L, DreamWear Silicone Pillows, Small Frame with Headgear, Global
	1146413	MW, DreamWear Silicone Pillows, Small Frame with Headgear, Global
	1146414	S, DreamWear Silicone Pillows, Medium Frame with Headgear, Global
	1146415	M, DreamWear Silicone Pillows, Medium Frame with Headgear, Global
	1146416	L, DreamWear Silicone Pillows, Medium Frame with Headgear, Global
	1146417	MW, DreamWear Silicone Pillows, Medium Frame with Headgear, Global
	1146448	S, DreamWear Silicone Pillows, Large Frame with Headgear, Global
	1146449	M, DreamWear Silicone Pillows, Large Frame with Headgear, Global
	1146450	L, DreamWear Silicone Pillows, Large Frame with Headgear, Global
	1146451	MW, DreamWear Silicone Pillows, Large Frame with Headgear, Global
	1146453	S, DreamWear Silicone Pillows, Small Frame without Headgear, Global
	1146454	M, DreamWear Silicone Pillows, Small Frame without Headgear, Global
	1146455	L, DreamWear Silicone Pillows, Small Frame without Headgear, Global

	1146456	MW, DreamWear Silicone Pillows, Small Frame without Headgear, Global
	1146457	S, DreamWear Silicone Pillows, Medium Frame without Headgear, Global
	1146458	M, DreamWear Silicone Pillows, Medium Frame without Headgear, Global
	1146459	L, DreamWear Silicone Pillows, Medium Frame without Headgear, Global
	1146460	MW, DreamWear Silicone Pillows, Medium Frame without Headgear, Global
	1146461	Small, DreamWear Silicone Pillows, Large Frame without Headgear, Global
	1146462	M, DreamWear Silicone Pillows, Large Frame without Headgear, Global
	1146463	L, DreamWear Silicone Pillows, Large Frame without Headgear, Global
	1146464	MW, DreamWear Silicone Pillows, Large Frame without Headgear, Global
	1146468	DreamWear Silicone Pillows, FitPack, Global
	1146470	DreamWear Silicone Pillows, Setup Pack
	1146471	DreamWear Silicone Pillows, Demo Pack
	1146469	DreamWear Silicone Pillows, FitPack, International
	1146469AP	DreamWear Silicone Pillows, FitPack, Asian Pacific
	1146469CE	DreamWear Silicone Pillows, FitPack, Central Europe
	1146469RC	DreamWear Silicone Pillows, FitPack, Russian Corridor
	1146410AP	S, DreamWear Silicone Pillows, Small Frame with Headgear, Asian Pacific
	1146415AP	M, DreamWear Silicone Pillows, Medium Frame with Headgear, Asian Pacific
	1146450AP	L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific
Product Options/Accessories Part Number(s) and Descriptions:	Refer to REG 22849 for chinstrap and headgear accessories.	
Basic UDI-DI:	N/A	
Control Indicator:	Initial Issue Date: October 27, 2020	Part Number: 1146410, 1146411, 1146412, 1146413, 1146414, 1146415, 1146416, 1146417, 1146448,

	November 19, 2020	1146449, 1146450, 1146451, 1146453, 1146454, 1146455, 1146456, 1146457, 1146458, 1146459, 1146460, 1146461, 1146462, 1146463, 1146464, 1146468, 1146470, 1146471 1146469, 1146469AP, 1146469CE, 1146469RC, 1146410AP, 1146415AP, 1146450AP
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.

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	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

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

Date of Issue: 20 April, 2022

Printed Name: Jennifer Richardson

Place of Issue: Murrysville, PA, USA

Title: Senior Manager, Regulatory Affairs

This declaration is valid until: 26 May 2024

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	Sleep apnea 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
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 ISO 15223-1:2017	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
Risk Management	
EN 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