

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 1146411	S, DreamWear Silicone Pillows, Small Frame with Headgear, Global M, DreamWear Silicone Pillows, Small Frame	
	1146412	with Headgear, Global 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	

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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 1146464 MW, DreamWear Silicone Pillows, Large Frame without Headgear, Global 1146464 DreamWear Silicone Pillows, FitPack, Global 1146470 DreamWear Silicone Pillows, FitPack, Global 1146470 DreamWear Silicone Pillows, Demo Pack 1146470 DreamWear Silicone Pillows, FitPack, International 1146469 DreamWear Silicone Pillows, FitPack, Central Europe 1146469CE DreamWear Silicone Pillows, FitPack, Russian Corridor 1146410AP S, DreamWear Silicone Pillows, Small Frame with Headgear, Asian Pacific 1146410AP S, DreamWear Silicone Pillows, Medium Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillow	·				
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1146460 MW, DreamWear Silicone Pillows, Medium Frame without Headgear, Global 1146461 M, 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, FitPack, Global 1146470 DreamWear Silicone Pillows, FitPack, Global 1146469 DreamWear Silicone Pillows, FitPack, International 1146469 DreamWear Silicone Pillows, FitPack, Asian Pacific 1146469CE DreamWear Silicone Pillows, FitPack, Central Europe 1146469CC DreamWear Silicone Pillows, FitPack, Russian Corridor 1146409CC DreamWear Silicone Pillows, Medium Frame with Headgear, Asian Pacific 1146410AP S, DreamWear Silicone Pillows, Medium Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP Refer to REG 22849 for chinstrap and headgear accessories. Product Options/Accessories Part Number(s) and Descriptions: Basic UDI-DI: Control Indicator: October 27, 2020 1146410, 1146411, 1146412, 1146415, 1146413, 1146414, 1146415,		1146459	L, Dream	Wear Silicone Pillows, Medium Frame	
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, FitPack, Global 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 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific		1146460	MW, Dre	amWear Silicone Pillows, Medium	
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 1146469C DreamWear Silicone Pillows, FitPack, Central Europe 1146469RC DreamWear Silicone Pillows, FitPack, Russian Corridor 1146410AP SpreamWear Silicone Pillows, FitPack, Russian Corridor 1146415AP M, DreamWear Silicone Pillows, Medium Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP Refer to REG 22849 for chinstrap and headgear accessories. Product Options/Accessories Part Number(s) and Descriptions: Basic UDI-DI: N/A Control Indicator: Part Number: October 27, 2020 1146410, 1146411, 1146412, 1146413, 1146414, 1146415,		1146461	Small, D	reamWear Silicone Pillows, Large	
1146463 L, DreamWear Silicone Pillows, Large Frame without Headgear, Global 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, FitPack, Russian Corridor 1146410AP S, DreamWear Silicone Pillows, Medium 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 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific		1146462	M, Drear	mWear Silicone Pillows, Large Frame	
1146464 MW, DreamWear Silicone Pillows, Large Frame without Headgear, Global 1146470 DreamWear Silicone Pillows, Setup Pack 1146471 DreamWear Silicone Pillows, Demo Pack 1146469 DreamWear Silicone Pillows, FitPack, Global 1146469 DreamWear Silicone Pillows, Demo Pack 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 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP Refer to REG 22849 for chinstrap and headgear accessories. Product Options/Accessories Part Number(s) and Descriptions: Basic UDI-DI: N/A Control Indicator: Part Number: October 27, 2020 1146410, 1146411, 1146412, 1146413, 1146414, 1146415,		1146463	L, Dream	Wear Silicone Pillows, Large Frame	
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 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Medium Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, Medium Frame with Headgear, Asian Pacific 1146450AP L, DreamWear Silicone Pillows, TitPack, Russian Pacific 1146450AP S, DreamWear Silicone Pillows, FitPack, Russian Corridor 1146450AP S, DreamWear Silicone Pillows, FitPack, Russian Pacific 1146450AP S, DreamWear Silicone Pillows, FitPack, Russian Pacific 1146415AP M; DreamWear Silicone Pillows, FitPack, Russian Pacific 1146415AP N; DreamWear Silicone Pillows, FitPack, Russian Pacific 1146415AP N; DreamWear Silicone Pillows, FitPack, Russian Pacific 1146415AP N; DreamWear Silicone Pillows, FitPack, Russian Pacific 1146410AP S, DreamWear Silicone Pillows, FitPack, Pack, Pack, Pack, P		1146464	MW, Dre	amWear Silicone Pillows, Large Frame	
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International DreamWear Silicone Pillows, FitPack, Asian Pacific 1146469CE DreamWear Silicone Pillows, FitPack, Central Europe 1146410AP 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: Basic UDI-DI: Control Indicator: N/A Initial Issue Date: October 27, 2020 1146410, 1146411, 1146412, 1146413, 1146414, 1146415,		1146471	DreamW	ear Silicone Pillows, Demo Pack	
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 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific Product Options/Accessories Part Number(s) and Descriptions: Basic UDI-DI: N/A Control Indicator: Part Number: October 27, 2020 1146410, 1146411, 1146412, 1146413, 1146413, 1146414, 1146415,		1146469			
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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: Basic UDI-DI: N/A Control Indicator: N/A Initial Issue Date: Part Number: October 27, 2020 1146410, 1146411, 1146412, 1146413, 1146414, 1146415,		1146469RC	DreamWear Silicone Pillows, FitPack, Russian		
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: Basic UDI-DI: Control Indicator: N/A Initial Issue Date: October 27, 2020 1146410, 1146411, 1146412, 1146413, 1146414, 1146415,		1146410AP	S, Drean		
Product Options/Accessories Part Number(s) and Descriptions: Basic UDI-DI: Control Indicator: 1146450AP L, DreamWear Silicone Pillows, Large Frame with Headgear, Asian Pacific Refer to REG 22849 for chinstrap and headgear accessories. N/A Part Number(s) Initial Issue Date: October 27, 2020 1146410, 1146411, 1146412, 1146413, 1146414, 1146415,		1146415AP	M, Drear	nWear Silicone Pillows, Medium Frame	
Options/Accessories Part Number(s) and Descriptions: Basic UDI-DI: Control Indicator: N/A		1146450AP	L, Dream	NWear Silicone Pillows, Large Frame with	
Basic UDI-DI: N/A Control Indicator: Initial Issue Date: Part Number: October 27, 2020 1146410, 1146411, 1146412, 1146415,	Options/Accessories Part Number(s) and	Refer to REG	22849 for	chinstrap and headgear accessories.	
October 27, 2020 1146410, 1146411, 1146412, 1146413, 1146414, 1146415,	Basic UDI-DI:	N/A			
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	1146468, 1146470, 1146471
November 19, 2020	1146469, 1146469AP, 1146469CE,
	1146469RC, 1146410AP, 1146415AP,
	1146450AP
57815 CPAP/BiPAP N	asal Mask Reusable
	November 19, 2020 57815 CPAP/BiPAP N

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

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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 Standa	ards			
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	S			
EN ISO 5356-1:2015	Anaesthetic and respiratory equipment Conical connectors Part 1: Cones and sockets			

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