EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101845
Revision 06

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 Full Face Mask
Product Type:	Full Face 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 therapy or bi-level therapy has been prescribed.
Product Part Number(s) and Descriptions:	1133380 S, DreamWear Full, Med Frm W/ HGR, GBL 1133381 M, DreamWear Full, Med Frm W/ HGR, GBL 1133382 L, DreamWear Full, Med Frm W/ HGR, GBL 1133383 MW, DreamWear Full, Med Frm W/ HGR, GBL 1133385 S, DreamWear Full, Sm Frm W/ HGR, GBL 1133386 M, DreamWear Full, Sm Frm W/ HGR, GBL 1133387 L, DreamWear Full, Sm Frm W/ HGR, GBL 1133388 MW, DreamWear Full, Sm Frm W/ HGR, GBL 1133390 S, DreamWear Full, Lg Frm W/ HGR, GBL 1133391 M, DreamWear Full, Lg Frm W/ HGR, GBL 1133392 L, DreamWear Full, Lg Frm W/ HGR, GBL 1133393 MW, DreamWear Full, Lg Frm W/ HGR, GBL 1133395 DreamWear Full, Demo Pack 1133400 FitPack, DreamWear Full, Med Frame, GBL 1133405 S, DreamWear Full, Med Frm W/O HGR, GBL 1133406 M, DreamWear Full, Med Frm W/O HGR, GBL 1133407 L, DreamWear Full, Med Frm W/O HGR, GBL 1133408 MW, DreamWear Full, Med Frm W/O HGR, GBL 1133410 S, DreamWear Full, Sm Frm W/O HGR, GBL 1133411 M, DreamWear Full, Sm Frm W/O HGR, GBL 1133412 L, DreamWear Full, Sm Frm W/O HGR, GBL 1133413 MW, DreamWear Full, Sm Frm W/O HGR, GBL 1133415 S, DreamWear Full, Lg Frm W/O HGR, GBL 1133416 M, DreamWear Full, Lg Frm W/O HGR, GBL 1133417 L, DreamWear Full, Lg Frm W/O HGR, GBL 1133418 MW, DreamWear Full, Lg Frm W/O HGR, GBL 1133375 S, DreamWear Full, Sm & Med Frm, GBL 1133376 M, DreamWear Full, Sm & Med Frm, GBL

	1133377	L, DreamWear Full, Sm & Med Frm, GBL
	1133378	MW, DreamWear Full, Sm & Med Frm, GBL
	1133370	S, DreamWear Full, Sm & Med Frm, INTL
	1133371	M, DreamWear Full, Sm & Med Frm, INTL
	1133372	L, DreamWear Full, Sm & Med Frm, INTL
	1133373	MW, DreamWear Full, Sm & Med Frm, INTL
	1133370UA	S, DreamWear Full, Sm & Med Frm, Ukraine
	1133371UA	M, DreamWear Full, Sm & Med Frm, Ukraine
	1133372UA	L, DreamWear Full, Sm & Med Frm, Ukraine
	1133373UA	MW, DreamWear Full, Sm & Med Frm, Ukraine
Product Options/Accessories Part Number(s) and Descriptions:	None	
Basic UDI-DI:	N/A	
Control Indicator:	Initial Issue Date:	Part Number:
	December 04, 2017	1133380, 1133381, 1133382, 1133383, 1133385, 1133386, 1133387, 1133388, 1133390, 1133391, 1133392, 1133393, 1133395, 1133400, 1133405, 1133406, 1133407, 1133408, 1133410, 1133411, 1133412, 1133413, 1133415, 1133416, 1133417, 1133418, 1133375, 1133376, 1133377, 1133378
	March 15, 2018	1133370, 1133371, 1133372, 1133373
	March 26, 2020	1133370UA, 1133371UA, 1133372UA, 1133373UA
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 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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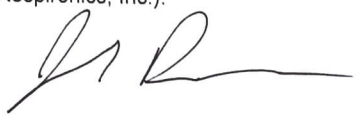
Signature (signed for and on behalf of Respironics, Inc.):



Date of Issue: 08 September, 2021

Printed Name: Jennifer Richardson

Place of Issue: Murrysville, PA

Title: Senior Manager, Regulatory Affairs

3. 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	
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
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	
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