EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101002
Revision v06

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:	ComfortGel Blue Nasal Mask ComfortGel Blue SE Nasal Mask Profile Lite 2 Profile Lite 2 SE
Product Type:	Nasal Mask
Intended Purpose:	The ComfortGel Blue 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 by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed. The ComfortGel Blue SE 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 (>30 kg) for whom CPAP or bi-level therapy has been prescribed. The Profile Lite 2 and Profile Lite 2 SE 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 (>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 directive(s) indicated in DoC unless otherwise noted. 1070064 L ComfortGel Blue Nasal Mask w/HGR, INTL 1070065 M ComfortGel Blue Nasal Mask w/HGR, INTL 1070066 S ComfortGel Blue Nasal Mask w/HGR, INTL 1070067 P ComfortGel Blue Nasal Mask w/HGR, INTL 1070068 L ComfortGel Blue SE Nasal Mask w/HGR, INTL 1070069 M ComfortGel Blue SE Nasal Mask w/HGR, INTL 1070070 S ComfortGel Blue SE Nasal Mask w/HGR, INTL 1070071 P ComfortGel Blue SE Nasal Mask w/HGR, INTL 1132181 L Profile Lite 2 Mask with Headgear, Italy 1132182 M Profile Lite 2 Mask with Headgear, Italy 1132183 S Profile Lite 2 Mask with Headgear, Italy 1132184 P Profile Lite 2 Mask with Headgear, Italy 1132185 L Profile Lite 2 SE with Headgear, Italy

	1132186 M Profile Lite 2 SE with Headgear, Italy 1132187 S Profile Lite 2 SE with Headgear, Italy 1132188 P Profile Lite 2 SE with Headgear, Italy
Product Options/Accessories Part Number(s) and Descriptions:	Refer to REG 22849 for accessory headgear and chin straps.
Basic UDI-DI:	N/A
Control Indicator:	**Initial Issue Date:** / **REF (Part Number):** May 24, 2010 / 1070064, 1070065, 1070066, 1070067, 1070068, 1070069, 1070070, 1070071 January 17, 2017 / 1132181, 1132182, 1132183, 1132184, 1132185, 1132186, 1132187, 1132188
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 Identification Number: 0123
Certificate(s) Issued	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 Product Service GmbH to the following: EN ISO 13485 Certificate: Q5 015581 0609 MDSAP ISO 13485 Certificate: QS6 112601 0001

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: Sr. 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
Biocompatibility	
EN ISO 10993-1: 2020	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10: 2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
Other Standards	
Accompany Documents and Labeling	
EN 1041:2008/ A1:2013	Information supplied by the manufacturer of medical devices
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 -- 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