RESPIRONICS®

EU DECLARATION OF CONFORMITY

Manufacturer name/address
Respironics Inc.
1001 Murry Ridge Lane Murrysville, PA 15668

This declaration of conformity is issued under the sole responsibility of the manufacturer. The device covered by the present declaration is in conformity with all regulations below and other relevant Union legislation.

Object of the declaration:

Product Name:	ComfortGel Blue Full
Intended Purpose:	For application of Continuous Positive Airway Pressure (CPAP) or bi-level therapy
Product Designator:	Same as Product Name
Product Part Number(s):	1081820 S ComfortGel Blue Full, International 1081821 M ComfortGel Blue Full, International 1081822 L ComfortGel Blue Full, International 1081823 XL ComfortGel Blue Full, International
Control Indicator:	Initial Issue Date: March 28, 2012 Part Numbers: 1081820, 1081821, 1081822, 1081823
Global Medical Device Nomenclature Code (GMDN) and Description	57814 CPAP/BiPAP Face Mask Reusable
Product Options/Accessories:	None

The object of the declaration described above is in conformity with the following regulations:

EU Directive	**Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD)**
Device Risk Classification	Class IIa based on Annex IX and Rule 2
Conformity Assessment Path	The Manufacturer is certified by TÜV SÜD Product Service GmbH to EN ISO 13485 and is also certified by Annex II-Section 3.2 of the Medical Device Directive 93/42/EEC. Copies of the Quality System certificates are available upon request.
Name/Address/ID of Notified Body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany 0123
Standards	The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are fully compliant with the product standards listed below in Attachment A.

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Additional information:

EU Authorized Representative:	Respironics Deutschland GmbH & Co. KG Gewerbestrasse 17 82211 Herrsching, Germany Tel: +49 8152 93060
Quality Certificates Issued:	TÜV SÜD Product Service GmbH Certificate Number: G1 17 09 15581 057 TÜV SÜD MDSAP Certificate Number: QS6 17 10 15581 058 Copies of the Quality System certificates are available upon request.

Signature (signed for and on behalf of Philips):

Printed Name: Andy Zeltwanger

Title: Sr. Manager, Regulatory Affairs

Date of Issue: 14 May 2019

Place of Issue: Monroeville, PA

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Attachment A
Standards or Common Specifications

Quality System	
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
Particular Standards	
Patient Interface	
EN ISO 17510-2:2009	Sleep apnoea breathing therapy – Part 2: Masks and application accessories
Biocompatibility	
EN ISO 10993-1:2009	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
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 14971:2012	Medical devices – Application of risk management to medical devices
Usability	
EN 62366:2008	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