EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2103122
Revision 03

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:	Therapy Mask 3100 NC Therapy Mask 3100 SP
Product Type:	Nasal 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 and multi-patient use in the hospital/institutional environment. The mask is to be used on patients >7 years old (>40 lbs) 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 regulation(s)/directive(s) indicated in DoC unless otherwise noted. 1144608 Therapy Mask 3100 NC, FitPack, w/HGR, GBL Nasal cushion 1144610 Therapy Mask 3100 SP, fitpack, w/HGR, GBL Silicone pillows 1145060 Therapy Mask 3100 NC-SP, demopack, GBL Nasal cushion-silicone pillows 1145459 XS, Therapy Mask 3100 NC, w/HGR, GBL Nasal cushion 1145460 S, Therapy Mask 3100 NC, w/HGR, GBL Nasal cushion 1145461 M, Therapy Mask 3100 NC, w/HGR, GBL 1145462 MW, Therapy Mask 3100 NC, w/HGR, GBL Nasal cushion 1145463 L, Therapy Mask 3100 NC, w/HGR, GBL Nasal cushion 1145464 XS, Therapy Mask 3100 SP, w/HGR, GBL Silicone pillows 1145465 S, Therapy Mask 3100 SP, w/HGR, GBL Silicone pillows 1145466 M, Therapy Mask 3100 SP, w/HGR, GBL Silicone pillows 1145467 MW, Therapy Mask 3100 SP, w/HGR, GBL Silicone pillows 1145478 L, Therapy Mask 3100 SP, w/HGR, GBL Silicone pillows 1145038 Therapy Mask 3100 NC, fitpack, w/HGR, INT Nasal cushion 1145039 Therapy Mask 3100 NC, fitpack, w/HGR, CE Nasal cushion

	1145040 Therapy Mask 3100 NC, fitpack, w/HGR, RC Nasal cushion 1145041 Therapy Mask 3100 NC, fitpack, w/HGR, AP Nasal cushion 1145049 Therapy Mask 3100 SP, fitpack,w/HGR, INT Silicone pillows 1145050 Therapy Mask 3100 SP, fitpack, w/HGR, CE Silicone pillows 1145051 Therapy Mask 3100 SP, fitpack, w/HGR, RC Silicone pillows 1145052 Therapy Mask 3100 SP, fitpack, w/HGR, AP Silicone pillows
Product Options/Accessories Part Number(s) and Descriptions:	See DoC Mask Accessories (REG 22849) for compliance information for Deluxe Chin Strap and Premium Chin Strap.
Basic UDI-DI:	N/A
Control Indicator:	Initial Issue Date: Part Number: April 28, 2021 1144608, 1144610, 1145060, 1145459, 1145460, 1145461, 1145462, 1145463, 1145464, 1145465, 1145466, 1145467, 1145478 May 24, 2021 1145038, 1145039, 1145040, 1145041, 1145049, 1145050, 1145051, 1145052
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

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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

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

Date of Issue: 27 August, 2021

Printed Name: Jennifer Richardson

Place of Issue: Murrysville, PA

Title: Senior 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 17510:2020	Sleep apnea breathing therapy. Masks and application accessories
EN ISO 17510-2:2009	Sleep apnea 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
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 – 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