

EU DECLARATION OF CONFORMITY



Doc Number REG 2101205
Revision 10

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:	Wisp Nasal Mask Wisp Youth Nasal Mask
Product Type:	Nasal Mask
Intended Purpose:	<p>The Wisp 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 (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.</p> <p>The Wisp 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 (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.</p> <p>Important Note: An exhalation port is not built into the Wisp SE Nasal Mask. This mask requires a separate exhalation device.</p> <p>The Wisp Youth 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 7 years or older (>40lbs/18 kg) for whom CPAP or bi-level therapy is prescribed.</p>
Product Part Number(s) and Descriptions:	<p>1094060 Wisp Mask, Clear Frame w/HDGR, INTL</p> <p>1094061 Wisp Mask, Fabric Frame w/HDGR, INTL</p> <p>1094062 Wisp SE Mask, Clear Frame w/HDGR, INTL</p> <p>1093923 P, Wisp Mask, Clear Frame, w/HDGR, INTL</p> <p>1093924 S/M, Wisp Mask, Clear Frame, w/HDGR, INTL</p> <p>1093925 L, Wisp Mask, Clear Frame, w/HDGR, INTL</p> <p>1093926 XL, Wisp Mask, Clear Frame, w/HDGR, INTL</p> <p>1093927 P, Wisp Mask, Fabric Frame, w/HDGR, INTL</p> <p>1094048 S/M, Wisp Mask, Fabric Frame, w/HDGR, INTL</p> <p>1094049 L, Wisp Mask, Fabric Frame, w/HDGR, INTL</p> <p>1113959 XL, Wisp Mask, Fabric Frame w/HDGR, INTL</p> <p>1109308 Wisp Youth Nasal Mask, Fabric Frame, w/HDGR, INTL</p>

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	ES1094060 Wisp Mask, Clear Frame w/HDGR, INTL ES1094061 Wisp Mask, Fabric Frame w/HDGR, INTL ES1094062 Wisp SE Mask, Clear Frame w/HDGR, INTL												
Product Options/Accessories Part Number(s) and Descriptions:	Refer to REG 22849 for mask and circuit accessories.												
Basic UDI-DI:	N/A												
Control Indicator:	<table> <tr> <td>Initial Issue Date:</td> <td>Part Number:</td> </tr> <tr> <td>01/22/2013</td> <td>1094060, 1094061</td> </tr> <tr> <td>05/03/2013</td> <td>1094062</td> </tr> <tr> <td>01/15/2014</td> <td>1093923, 1093924, 1093925, 1093926, 1093927, 1094048, 1094049, 1093959</td> </tr> <tr> <td>05/19/2014</td> <td>1109308</td> </tr> <tr> <td>04/17/2017</td> <td>ES1094060, ES1094061, ES1094062</td> </tr> </table>	Initial Issue Date:	Part Number:	01/22/2013	1094060, 1094061	05/03/2013	1094062	01/15/2014	1093923, 1093924, 1093925, 1093926, 1093927, 1094048, 1094049, 1093959	05/19/2014	1109308	04/17/2017	ES1094060, ES1094061, ES1094062
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05/19/2014	1109308												
04/17/2017	ES1094060, ES1094061, ES1094062												
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 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.

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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

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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 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 within a risk management process
EN ISO 10993-3:2009	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 10993-6:2009	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
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
Tubing and Connections	
EN ISO 5356-1:2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
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

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