# DECLARATION OF CONFORMITY

Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550
USA
800-345-6443

Declares under our sole responsibility that the product:

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| Product Name | Wisp Pediatric Nasal Mask |
| Product Type | Nasal Mask |
| Product Part Number | 1104961 Wisp Ped Fit Pack w/Headgear – EE INT<br>1104976 Wisp Ped SE Elbow Accessory |
| Control Designator | Initial Issue Date: 05/23/2016 Part Number: 1104961, 1104976 |
| Device Classification, Annex and Rule | Class IIa, Annex IX, Rule 2 |
| Global Medical Device Nomenclature Code (GMDN) | 57815 CPAP/BiPAP Nasal Mask Reusable |
| Product Options/ Accessories | None |

| **To which this Declaration relates is in conformity with the provisions of Council Directive:** |
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| 1. 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC |

| 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. | |
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| Notified Body | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65<br>80339 München, Germany<br>0123 |

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| Authorized EU Representative | Respironics Deutschland GmbH & Co. KG<br>Gewerbestrasse 17<br>82211 Herrsching, Germany<br>Tel: +49 8152 93060 |

## Supplementary Information:

The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation. Additionally the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying documentation.

### Standards:

The products listed above are fully compliant with the harmonized standards listed below.

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| **Quality System** | |
| EN ISO 13485:2012 | 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 10993-3:2009 | 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 |
| EN ISO 10993-18:2009 | Biological evaluation of medical devices – Part 18: Chemical characterization of materials |
| **Accompany Documents and Labeling** | |
| EN 980:2008 | Symbols for use in the labeling of medical devices |
| EN 1041: 2008 | Information supplied by the manufacturer of medical devices |
| EN ISO 15223-1:2012 | Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements |
| **Risk Management** | |
| EN ISO 14971:2012 | Medical devices – Application of risk management to medical devices |
| **Tubing and Connections** | |
| ISO 5356-1:2004 | Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets |
| **Usability** | |
| IEC 62366-1:2015 | Medical devices – Part 1: Application of usability engineering to medical devices |

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|---|---|
| Name | Frank Kadi |
| Title | Regulatory Affairs Manager, Patient Interface |
| Signature |  |
| Date (MM/DD/YYYY) | 1/13/2017 |
| Place of Issue | Monroeville |