# DECLARATION OF CONFORMITY

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

Declares under our sole responsibility that the product:

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| Product Name | EverFlo |
| Product Type | Oxygen Concentrator |
| Product Part Number | 1020006 EVERFLO INTL OPI 230V EU<br>1020007 EVERFLO INTL OPI 230V IKK<br>1020008 EVERFLO INTL OPI 230V U.K./IRELAND<br>1020011 EVERFLO INTL OPI 230V ITALY/CHILE<br>1020017 EverFlo Intl OPI 230V SWTZ<br>1039366 EverFlo 230V OPI, CEE7/7, EUR, UltraFill<br>1039367 EverFlo 230V OPI, CEE7/7, IKK, UltraFill<br>1039368 EVERFLO 230V OPI,UK,ULTRAFILL<br>1102443 EVERFLO, OPI, 230V/60HZ, SAUDI ARABIA<br>1104000 EVERFLO 230V OPI,SWTZ,ULTRAFILL<br><br>Note: Each Part Number may have a U or R prefix, indicating Recertified or Rental, depending on the requirements of the Product Manager. |
| Control Designator | Initial Issue Date: / Part Number:<br>November 13, 2006 — 1020006, 1020007, 1020008, 1020011<br>August 8, 2008 — 1020017<br>January 6, 2011 — 1039368<br>May 5, 2011 — 1039366, 1039367<br>July 9, 2013 — 1104000<br>December 18, 2015 — 1102443 |
| Device Classification, Annex and Rule | Class IIa, Annex IX, Rule 11 |
| Global Medical Device Nomenclature Code (GMDN) | 12873 Stationary oxygen concentrator |
| Product Options/ Accessories | N/A |

| **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 |
| 2. 2011/65/EU Restriction of the use of certain Hazardous Substances (RoHS) in Electric and Electronic Equipment (EEE) |

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| 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. | |
| 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 13485:2016** | Medical devices – Quality management systems – Requirements for regulatory purposes |
| **General Safety Standard** | |
| **EN 60601-1:2006/A1:2013** | Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance |
| **Collateral Safety Standards** | |
| **EN 60601-1-2:2015** | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility. Requirements and tests |
| **EN 60601-1-6:2010/A1:2015** | Medical electrical equipment – Part 1-6: General requirements for safety and essential performance – Collateral standard: Usability |
| **EN 60601-1-8:2007/A1:2013** | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| **EN 60601-1-11:2015** | Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment |
| **Particular Safety Standards** | |
| **Oxygen Concentrators** | |
| **EN ISO 8359:2009** | Oxygen concentrators for medical use – Safety requirements |
| **EN ISO 80601-2-69:2014** | Medical electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment |
| **Biocompatibility** | |

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| **EN ISO 10993-1:2009** | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| **Other Standards** | |
| **Accompany Documents and Labeling** | |
| **EN 1041:2008** | 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 |
| **Software** | |
| **EN 62304:2006/A1:2015** | Medical device software – Software lifecycle processes |
| **Risk Management** | |
| **EN ISO 14971:2012** | 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 |
| **RoHS** | |
| **EN 50581:2012** | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |

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| Name | Colleen Witt |
| Title | Senior Manager, Regulatory Affairs, SRC |
| Signature | Colleen Witt |
| Date (MM/DD/YYYY) | 4/11/2018 |
| Place of Issue | Monroeville, PA, USA |