# EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number 2100066
Revision 28

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:

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|---|---|
| **Product Name:** | EverFlo |
| **Product Type:** | Oxygen Concentrator |
| **Intended Purpose:** | The EverFlo Oxygen Concentrator is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining. The EverFlo Oxygen Concentrator is intended for use in the home or hospital/institutional environment. |
| **Product Part Number(s) and Descriptions:** | Part Number(s) listed in this section comply with all directives indicated in DoC unless otherwise noted.<br><br>1020006 EVERFLO INTL OPI 230V EU<br>1020007 EVERFLO INTL OPI 230V IKK<br>R1020007 EVERFLO INTL OPI 230V IKK Rental<br>1020008 EVERFLO INTL OPI 230V U.K./IRELAND<br>R1020008 EverFlo INTL OPI 230V U.K./IRELAND Rental<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>1020010 EVERFLO INTL OPI 230V AUSTRALIA |
| **Product Options/Accessories Part Number(s) and Descriptions**: | Refer to the following REG DOC for accessory information: REG 2102332 |
| **Basic UDI-DI:** | N/A |
| **Control Indicator:** | Initial Issue Date: / Part Number:<br>Nov. 13, 2006 — 1020006, 1020007, 1020008, 1020011<br>Aug. 8, 2008 — 1020017<br>Jan. 6, 2011 — 1039368<br>May 5, 2011 — 1039366, 1039367<br>July 9, 2013 — 1104000<br>Dec. 18, 2015 — 1102443<br>Sept. 27, 2016 — R1020007<br>Oct. 22, 2008 — R1020008 |
| **Global Medical Device Nomenclature code (GMDN) and Description** | 12873 Stationary oxygen concentrator |

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 11 |
| **Conformity Assessment Route** | Annex II Excluding 4 |
| **Notified Body Name, Address, and ID** | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65<br>80339 München, Germany<br>Identification Number: 0123 |
| **Certificate(s) Issued** | EC certificate: 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.<br><br>Refer to Attachment A. |

| **EU Directive** | **Directive 2015/863 of the European Parliament and of the Council of 8 June 2011 on the restrictions of the use of certain hazardous substances in electrical and electronic equipment, amended up to and inclusive of Directive (EU) 2017/2102** |
|---|---|
| **Risk Classification** | Category 8, medical device, according Annex I. |
| **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.<br><br>*Refer to Attachment A* |

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## 2. Mandatory information:

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| **Manufacturer** | Respironics, Inc.<br>1001 Murry Ridge Lane,<br>Murrysville, PA 15668, USA<br>SRN: US-MF-000002301 |
| **EU Authorized Representative (AR)**: | Respironics Deutschland GmbH & Co. KG<br>Gewerbestrasse 17<br>82211 Herrsching, Germany<br>Tel: +49 8152 93060 |
| **ISO Quality Certificates Issued**: | The Manufacturer is certified by TÜV SÜD Product Service GmbH to the following:<br>EN ISO 13485:2016 certificate number: Q5 015581 0609 |

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

R. James

Date of Issue: 28 MAR 2022

Printed Name:
Ruth James

Place of Issue:
Pittsburgh, PA,
USA

Title:
Senior Manager, Regulatory Affairs

This declaration is valid until: 26 MAY 2024

## 3. Attachment A Standards and/or Common Specifications

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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 80601-2-69:2014** | Medical electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment |
| **Biocompatibility** | |
| **EN ISO 10993-1:2018** | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| **EN ISO 18562-1:2017** | Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter |
| **EN ISO 18562-2:2017** | Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications- Part 2: Tests for Emissions of Particulate Matter |
| **EN ISO 18562-3:2017** | Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications- Part 3: Tests for Emissions of Volatile Organic Compounds |
| **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 14971:2019** | 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** | |

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|---|---|
| **EN IEC 63000** | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |
| **Cleaning and Disinfection** | |
| **ISO 17664:2017** | Processing of health care products - Information to be provided by the medical device |