EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2100066
Revision v27

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:	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:	1020006 EVERFLO INTL OPI 230V EU 1020007 EVERFLO INTL OPI 230V IKK R1020007 EVERFLO INTL OPI 230V IKK Rental 1020008 EVERFLO INTL OPI 230V U.K./IRELAND R1020008 EverFlo INTL OPI 230V U.K./IRELAND Rental 1020011 EVERFLO INTL OPI 230V ITALY/CHILE 1020017 EverFlo Intl OPI 230V SWTZ 1039366 EverFlo 230V OPI, CEE7/7, EUR, UltraFill 1039367 EverFlo 230V OPI, CEE7/7, IKK, UltraFill 1039368 EVERFLO 230V OPI,UK,ULTRAFILL 1102443 EVERFLO, OPI, 230V/60HZ, SAUDI ARABIA 1104000 EVERFLO 230V OPI,SWTZ,ULTRAFILL 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: November 13, 2006 — 1020006, 1020007, 1020008, 1020011 August 8, 2008 — 1020017 January 6, 2011 — 1039368 May 5, 2011 — 1039366, 1039367 July 9, 2013 — 1104000 December 18, 2015 — 1102443 Sept. 27, 2016 — R1020007 Oct. 22, 2008 — R1020008
Global Medical Device Nomenclature Code (GMDN) and Description:	12873 Stationary oxygen concentrator

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The object of the declaration described above is in conformity with the following regulations:

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)**
Device Risk Classification	Class IIa based on Annex IX and Rule 11
Conformity Assessment Path	Annex II Excluding 4
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany Identification Number: 0123
Certificate 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. Refer to Attachment A.

EU Directive	**Directive 2011/65/EU 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) 2017/1202 (RoHS)**
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. *Refer to Attachment A*

2. Additional information:

Manufacturer	Respironics, Inc. 1001 Murry Ridge Lane, Murrysville, PA 15668, USA
EU Authorized Representative:	Respironics Deutschland GmbH & Co. KG Gewerbestrasse 17 82211 Herrsching, Germany Tel: +49 8152 93060
Quality Certificates Issued:	The Manufacturer is certified by TÜV SÜD Product Service GmbH to the following: EN ISO 13485 Certificate: Q5 015581 0609 MDSAP ISO 13485 Certificate: QS6 015581 0610

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

Daria Brown

Date of Issue: May 30, 2021

May 30, 2021

Printed Name: Daria Brown

Place of Issue: Pittsburgh, PA, USA

Title: Sr. Manager, Regulatory Affairs

3. Attachment A
Standards and/or Common Specifications

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 18562-2:2020	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications-Part 2: Tests for Emissions of Particulate Matter
EN ISO 18562-3:2020	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	
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