EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number 2102332
Revision 03

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 Accessories
Product Type:	Oxygen Concentrator Accessories
Intended Purpose:	*The following accessories are intended to be used with the EverFlo Oxygen Concentrator which 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.:* Medical Gas Flowmeter, Thorpe Tube (GMDN 61365): A device intended to measure and regulate the flow of a medical gas [e.g., oxygen (O2), carbon dioxide (CO2), nitrous oxide (N2O), helium/oxygen gas mixture (heliox), medical air] during various procedures (e.g., therapeutic administration, anaesthesia, insufflation during surgery). It consists of an upright tube containing a float, which rises and falls in relation to gas flow, and a distal valve (compensated flowmeter) to control gas flow rate; some types include a pressure gauge/regulator. It will be calibrated to a specific medical gas and have a dedicated flow rate range, therefore some types may be dedicated to a specific patient group (e.g., neonate, infant, adult) or clinical use. Tube/mask breathing circuit connector, non-sterile, single-use (GMDN 61346): A non-sterile device intended to connect a breathing circuit breathing tube to an endotracheal (ET) tube, anaesthesia face mask, or other non-sampling breathing circuit component. It is constructed with standardized connecting dimensions and may be designed to connect breathing tubes from paediatric to adult sizes. It is typically made of plastic materials and can have a straight or elbow-shaped design (excluding Y-piece connectors). Some designs may allow for partial rotation at the point of connection (a swivel) and may include a suction port or gas sampling port. This is a single-use device.

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Product Part Number(s) and Descriptions:	Part Numbers listed in this section comply with all directives indicated in DoC unless otherwise noted. H644 1039642	 Kit, Low Range Cabinet Flow Meter Humidifier Connector Tube Kit, EverFlo
Product Options/Accessories Part Number(s) and Descriptions:	None.	
Basic UDI-DI:	H644 1039642	00606959416284 00606959415225
Control Indicator:	H644 1039642	Initial Issue Date: March 14, 2014 Initial Issue Date: October 11, 2017
Global Medical Device Nomenclature code (GMDN) and Description	H644 1039642	61365 Medical gas flowmeter, Thorpe tube 61346 Tube/mask breathing circuit connector, non-sterile, single-use

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.

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 II 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 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. Refer to Attachment A.

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2. Mandatory information:

Manufacturer	Respironics, Inc. 1001 Murry Ridge Lane, Murrysville, PA 15668, USA SRN: US-MF-000002301
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 Product Service GmbH to the following: EN ISO 13485:2016 certificate number: Q5 015581 0609

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

R. James

Date of Issue: 30 MAR 2022

Printed Name: Ruth James
Title: Senior Manager, Regulatory Affairs

Place of Issue: Pittsburgh, PA, USA

This declaration is valid until: 26 MAY 2024

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
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 60601-1-11:2015	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	
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 (VOCs)
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
Risk Management	
EN ISO 14971:2019	Medical devices – Application of risk management 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