EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number 2102332
Revision 02

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:	GMDN 61365 Medical Gas Flowmeter, Thorpe Tube 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. GMDN 61346 Tube/mask breathing circuit connector, non-sterile, single-use 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.
Product Part Number(s) and Descriptions:	H644 Kit, Low Range Cabinet Flow Meter 1039642 Humidifier Connector Tube Kit, EverFlo
Product Options/Accessories Part Number(s) and Descriptions:	*None*
Basic UDI-DI:	H644 00606959416284 1039642 00606959415225
Control Indicator:	Initial Issue Date: / Part Number: March 14, 2014 / 1039642 October 11, 2017 / H644
Global Medical Device Nomenclature code (GMDN) and Description:	61365 Medical gas flowmeter, Thorpe tube (H644) 61346 Tube/mask breathing circuit connector, non-sterile, single-use (1039642)

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The object of the declaration described above is in conformity with the following directives and/or 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)**
Risk Classification	Class IIa, 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 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.

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
ISO 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

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

Daria Brown

Date of Issue: May 30, 2021

30 MAY 2021

Printed Name: Daria Brown

Place of Issue: Pittsburgh, PA, USA

Title: Sr. Manager, Regulatory Affairs

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
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