EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101485
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:	*SimplyGo Accessories*
Product Type:	*Portable Oxygen Concentrator Accessories*
Intended Purpose:	GMDN 34158 Battery, Secondary A device (battery or cell) used as a source of electrical energy that is designed to be electrically recharged. The size, shape, and chemical composition of the battery should be specified in keeping with the requirements of the appropriate IEC standard. GMDN 17115 Battery Charger A device designed to supply an electrical charge to rechargeable batteries, restoring the battery to an appropriate working condition. This device is typically connected to the building's electrical power supply and can be used to either charge the batteries by themselves (removed from the device) or whilst they are still inside the parent device (in situ), e.g. a defibrillator or ophthalmoscope. This device usually has current and voltage controls to meet the charge needs of different types of batteries.
Product Part Number(s) and Descriptions:	1082662 SimplyGo, Battery (Extra/Replacement) 1109643 SimplyGo External Battery Module 900-118 Battery Charger/Recalibr, EU 900-119 Battery Charger/Recalibr, UK
Product Options/Accessories Part Number(s) and Descriptions:	Accessories to the SimplyGo device Note: SimplyGo DoC: REG 2101229
Basic UDI-DI:	1082662 00606959401365 1109643 606959401617 900-118 606959408128 900-119 606959408135
Control Indicator:	Initial Issue Date: Part Number: August 8, 2017 1082662 May 21, 2014 900-118, 900-119, 1109643
EMDN / CND code and Dscription And/or Global Medical Device Nomenclature Code (GMDN) and Description:	34158 - Secondary battery (1082662, 1109643) 17115 – External device battery charger (900-118, 900-119)

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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
Certificates Issued	EC certificate: G1 015581 068
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 0607 • MDSAP ISO 13485 Certificate: QS6 17 10 15581 058

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

Daria Brown

Date of Issue: September 24, 2020

24 SEP 2020

Printed Name: Daria Brown

Place of Issue: Monroeville, 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
Common Specifications	