EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101660
Revision 08

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 Mini Accessories
Product Type:	Portable Oxygen Concentrator Accessories
Intended Purpose:	The following accessories are intended to be used with the SimplyGo Mini Portable Oxygen concentrator, which is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. The battery kits are available if an extra battery is needed and are comprised of secondary batteries. Secondary Battery - A rechargeable set of electrochemical cells, or a single cell, designed to store chemical energy and release it in the form of electrical energy to provide power for active implantable medical devices or external medical instruments, for backup power for programmable devices that must retain electronic information, or to power portable or other medical devices when it is not possible or convenient to use the line supply.
Product Part Number(s) and Descriptions:	Part Number(s) listed in this section comply with all regulation/directive indicated in DoC unless otherwise noted. Part Number — Description **1116816** — SimplyGo Mini Standard Battery Kit **1116817** — SimplyGo Mini Extended Battery Kit
Product Options/Accessories Part Number(s) and Descriptions:	None
Basic UDI-DI:	0606959BM154LY
Control Indicator:	Initial Issue Date: **October 6, 2015** — Part Number: 1116816, 1116817
EMDN / CND code and Description **And** **Global Medical Device Nomenclature code**	CND: Z12159004 Oxygen Concentrators GMDN: 34158 Secondary Battery

(GMDN) and Description	

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 Regulation	**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (EU MDR)**
Risk Classification	Class I based on Annex VIII and Rule 13
Conformity Assessment Route	N/A
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany NB ID – Not Applicable
Certificate(s) Issued	N/A
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
Common Specifications	None

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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. Mandatory information:

Manufacturer	Respironics, Inc. 1001 Murry Ridge Lane, Murrysville, PA 15668, USA Legal Manufacturer SRN: US-MF-000002301
EU Authorized Representative:	Philips Medical Systems Nederland B.V. Veenpluis 6 5684PC Best, The Netherlands Single Registration Number (SRN): NL-AR-000001422
ISO Quality Certificates Issued:	The Manufacturer is certified by TÜV SÜD Product Service GmbH to the following: EN ISO 13485 as evidenced by Q5 015581 0609 TÜV SÜD MDSAP Certificate Number: QS6 015581 0610 *Copies of the Quality System certificates are available upon request*

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

R James

Date of Issue: 28 March 2022

Printed Name: Ruth James
Title: Sr. Manager, Regulatory Affairs

Place of Issue: Pittsburgh, PA, USA

3. Attachment A Standards and/or Common Specifications

Standard	Standard Title	Product Applicability
Quality System		
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes	All Products
General Safety Standard		
EN 60601-1:2006/ A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance	All Products
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 disturbances - Requirements and tests	All Products
EN 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for safety and essential performance – Collateral standard: Usability	All Products
EN 60601-1-8:2007	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	All Products
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	All Products
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	All Products
Oxygen Conserving Devices		
EN ISO 80601-2-67:2014	Medical electrical equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment	All Products
EN ISO 18779:2005	Medical devices for conserving oxygen and oxygen mixtures – Particular requirements	All Products
Batteries		
IEC 62133:2012	Secondary cells and batteries containing alkaline or other non-acid - electrolytes — Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	All Products
Other Standards		
Accompany Documents and Labeling		
EN 1041:2008/ A1:2013	Information supplied by the manufacturer of medical devices	All Products
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	All Products
Risk Management		

Standard	Standard Title	Product Applicability
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices	All Products
EN ISO 18562-1:2017	EN ISO 18562-1:2017	EN ISO 18562-1:2017
EN ISO 18562-2:2017	EN ISO 18562-1:2017	EN ISO 18562-1:2017
EN ISO 18562-3:2017	EN ISO 18562-1:2017	EN ISO 18562-1:2017
Usability		
IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices	All Products
RoHS		
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances	All Products