EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101593
Revision v12

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
Product Type:	Portable Oxygen Concentrator
Intended Purpose:	The SimplyGo Mini Portable Oxygen Concentrator is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable, and is capable of continuous use in the home, institutional, and travel/mobile environments
Product Part Number(s) and Descriptions:	Part Number(s) listed in this section comply with all directive(s) indicated in DoC unless otherwise noted. 1113603 SimplyGo Mini Device, International 1113604 SimplyGo Mini with Standard Battery, INTL 1113605 SimplyGo Mini with Extended Battery, INTL U1113604 SimplyGo Mini with Standard Battery, INTL Recertified U1113605 SimplyGo Mini with Extended Battery, INTL Recertified R1113604 SimplyGo Mini with Standard Battery, INTL Rental R1113605 SimplyGo Mini with Extended Battery, INTL Rental IT1113604 SimplyGo Mini with Standard Battery, IT IT1113605 SimplyGo Mini with Extended Battery, IT FR1113604 SimplyGo Mini, Standard Battery, FR FR1113605 SimplyGo Mini, Extended Battery, FR 1135169 SimplyGo Mini Standard Battery, Argentina 1135170 SimplyGo Mini Extended Battery, Argentina 1133943 SimplyGo Mini Standard Battery, Japan 1133944 SimplyGo Mini Extended Battery, Japan 1113606 SimplyGo Mini Device, IKK 1113607 SimplyGo Mini with Standard Battery, IKK 1113608 SimplyGo Mini with Extended Battery, IKK 1126194 SimplyGo Mini, Saudi Arabia 1126195 SimplyGo Mini with Standard Battery, Saudi Arabia 1126196 SimplyGo Mini with Extended Battery, Saudi Arabia *Note: The R before a part number denotes a rental device. *Note: The U before a part number denotes a refurbished device.

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Product Options/Accessories Part Number(s) and Descriptions:	*N/A*
Basic UDI-DI:	*N/A*
Control Indicator:	

Initial Issue Date:	Part Number:
June 25, 2015	1113603, 1113604, 1113605
November 10, 2015	1113606, 1113607, 1113608
June 02, 2016	1126194, 1126195, 1126196
September 22, 2016	U1113604, U1113605, R1113604, R1113605
July 25, 2017	IT1113604, IT1113605
October 10, 2019	FR1113604, FR1113605
February 18, 2021	1135169, 1135170, 1133943, 1133944

Global Medical Device Nomenclature code (GMDN) and Description	31321 Portable oxygen concentrator

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 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* based on Annex IX and Rule *11*
Conformity Assessment Route	Annex II Excluding 4
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany

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	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.

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) 2017/2102 (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 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 Certificate: Q5 015581 0609

Signature (signed for and on behalf of Philips) Date of Issue: 24 March 2022

R. James

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

Place of Issue: Pittsburgh, *PA, USA*

3. Attachment A Standards and/or Common Specifications

Standard	Description
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 disturbances - 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
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
EN ISO 18779:2005	Medical devices for conserving oxygen and oxygen mixtures – Particular requirements
Biocompatibility	
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
Other Standards	
Accompany Documents and Labeling	
EN 1041:2008/ A1:2013	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 Standards	
EN IEC 63000: 2018	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