EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101229
Revision v16

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
Product Type:	Portable Oxygen Concentrator
Intended Purpose:	The Respironics SimplyGo is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis.
Product Part Number(s) and Descriptions:	Part Number(s) listed in this section comply with all directives indicated in DoC unless otherwise noted. 1069058 SimplyGo International U1069058 SimplyGo International Recertified RBR1069058 SimplyGo International Rental 1100403 SimplyGo, France IT1069058 SimplyGo, International, IT 1126193 SimplyGo, Saudi Arabia 1139281 SimplyGo, Argentina 1141299 SimplyGo, Ukraine R1069058 SimplyGo System, Intl U1100403 SimplyGo France Recertified U1113604 SimplyGo Mini,Stnd Battery,Intl-Recert *Note: The R before a part number denotes a rental device. *Note: The U before a part number denotes a refurbished device.
Product Options/Accessories Part Number(s) and Descriptions:	*N/A*
Basic UDI-DI:	*N/A.*
Control Indicator:	

Initial Issue Date:	Part Number:
March 13, 2012	1069058
April 10, 2012	1100403
Sept 27,2016	U1069058, RBR1069058
July 25, 2017	IT1069058
April 5, 2018	1126193
February 18, 2021	1139281, 1141299
March 28, 2021	R1069058, U1100403, U1113604

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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 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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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*

Mandatory information:

Manufacturer	Respironics, Inc. 1001 Murry Ridge Lane, Murrysville, PA 15668, USA
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 MDSAP ISO 13485 Certificate: QS6 015581 0610

Signature (signed for and on behalf of Philips) Date of Issue: *30 MAY 2021*

Daria Brown 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

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 compatibility. 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 used 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	
ISO 80601-2-67:2014	Medical electrical equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment
Biocompatibility	
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/ 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