

# EU DECLARATION OF CONFORMITY



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:

| <b>Product Name:</b>                                                | SimplyGo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |                        |                |                                    |                |                               |               |                      |               |                             |               |                        |                   |                     |                |                              |          |                       |          |                             |          |                                          |
|---------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|------------------------|----------------|------------------------------------|----------------|-------------------------------|---------------|----------------------|---------------|-----------------------------|---------------|------------------------|-------------------|---------------------|----------------|------------------------------|----------|-----------------------|----------|-----------------------------|----------|------------------------------------------|
| <b>Product Type:</b>                                                | Portable Oxygen Concentrator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                            |                        |                |                                    |                |                               |               |                      |               |                             |               |                        |                   |                     |                |                              |          |                       |          |                             |          |                                          |
| <b>Intended Purpose:</b>                                            | The Respironics SimplyGo is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                            |                        |                |                                    |                |                               |               |                      |               |                             |               |                        |                   |                     |                |                              |          |                       |          |                             |          |                                          |
| <b>Product Part Number(s) and Descriptions:</b>                     | <p>Part Number(s) listed in this section comply with all directives indicated in DoC unless otherwise noted.</p> <table><tr><td>1069058</td><td>SimplyGo International</td></tr><tr><td>U1069058</td><td>SimplyGo International Recertified</td></tr><tr><td>RBR1069058</td><td>SimplyGo International Rental</td></tr><tr><td>1100403</td><td>SimplyGo, France</td></tr><tr><td>IT1069058</td><td>SimplyGo, International, IT</td></tr><tr><td>1126193</td><td>SimplyGo, Saudi Arabia</td></tr><tr><td>1139281</td><td>SimplyGo, Argentina</td></tr><tr><td>1141299</td><td>SimplyGo, Ukraine</td></tr><tr><td>R1069058</td><td>SimplyGo System, Intl</td></tr><tr><td>U1100403</td><td>SimplyGo France Recertified</td></tr><tr><td>U1113604</td><td>SimplyGo Mini, Stnd Battery, Intl-Recert</td></tr></table> <p>*Note: The R before a part number denotes a rental device.<br/>*Note: The U before a part number denotes a refurbished device.</p> | 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 |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |                        |                |                                    |                |                               |               |                      |               |                             |               |                        |                   |                     |                |                              |          |                       |          |                             |          |                                          |
| <b>Product Options/Accessories Part Number(s) and Descriptions:</b> | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                            |                        |                |                                    |                |                               |               |                      |               |                             |               |                        |                   |                     |                |                              |          |                       |          |                             |          |                                          |
| <b>Basic UDI-DI:</b>                                                | N/A.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                            |                        |                |                                    |                |                               |               |                      |               |                             |               |                        |                   |                     |                |                              |          |                       |          |                             |          |                                          |
| <b>Control Indicator:</b>                                           | <table border="1"><thead><tr><th><u>Initial Issue Date:</u></th><th><u>Part Number:</u></th></tr></thead><tbody><tr><td>March 13, 2012</td><td>1069058</td></tr><tr><td>April 10, 2012</td><td>1100403</td></tr><tr><td>Sept 27, 2016</td><td>U1069058, RBR1069058</td></tr><tr><td>July 25, 2017</td><td>IT1069058</td></tr><tr><td>April 5, 2018</td><td>1126193</td></tr><tr><td>February 18, 2021</td><td>1139281, 1141299</td></tr><tr><td>March 28, 2021</td><td>R1069058, U1100403, U1113604</td></tr></tbody></table>                                                                                                                                                                                                                                                                                                                                                                                                                           | <u>Initial Issue Date:</u> | <u>Part Number:</u>    | 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 |          |                       |          |                             |          |                                          |
| <u>Initial Issue Date:</u>                                          | <u>Part Number:</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                            |                        |                |                                    |                |                               |               |                      |               |                             |               |                        |                   |                     |                |                              |          |                       |          |                             |          |                                          |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                            |                        |                |                                    |                |                               |               |                      |               |                             |               |                        |                   |                     |                |                              |          |                       |          |                             |          |                                          |

### CONFIDENTIAL

This document was created using the template information listed below:

**Governing Document:**  
QSP 7.9-064, WI 7.9-808

**Document Number:** FRM 4450

**Version:** 11

**Page 1 of 4**

# EU DECLARATION OF CONFORMITY



Doc Number REG 2101229

Revision v16

|                                                                       |                                    |
|-----------------------------------------------------------------------|------------------------------------|
| <b>Global Medical Device Nomenclature code (GMDN) and Description</b> | 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.

|                                            |                                                                                                                                                                                                                                                                      |
|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>EU Directive</b>                        | <b>Council Directive 93/42/EEC of 14 June 1993 concerning medical devices amended up to and inclusive of Council Directive 2007/47/EC (MDD)</b>                                                                                                                      |
| <b>Risk Classification</b>                 | Class <i>I/a</i> based on Annex IX and Rule 11                                                                                                                                                                                                                       |
| <b>Conformity Assessment Route</b>         | Annex II Excluding 4                                                                                                                                                                                                                                                 |
| <b>Notified Body Name, Address, and ID</b> | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65<br>80339 München, Germany<br>Identification Number: 0123                                                                                                                                                            |
| <b>Certificate(s) Issued</b>               | EC Certificate G1 015581 0611                                                                                                                                                                                                                                        |
| <b>Standards</b>                           | 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.<br><br>Refer to Attachment A. |

## CONFIDENTIAL

This document was created using the template information listed below:

|                                                       |                                  |                    |             |
|-------------------------------------------------------|----------------------------------|--------------------|-------------|
| <b>Governing Document:</b><br>QSP 7.9-064, WI 7.9-808 | <b>Document Number:</b> FRM 4450 | <b>Version:</b> 11 | Page 2 of 4 |
|-------------------------------------------------------|----------------------------------|--------------------|-------------|

# EU DECLARATION OF CONFORMITY



Doc Number REG 2101229

Revision v16

|                            |                                                                                                                                                                                                                                                                            |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>EU Directive</b>        | 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)                    |
| <b>Risk Classification</b> | Category 8, medical device, according Annex I                                                                                                                                                                                                                              |
| <b>Standards</b>           | 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.<br><br><i>Refer to Attachment A</i> |

## Mandatory information:

|                                           |                                                                                                                                                                                     |
|-------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Manufacturer</b>                       | Respironics, Inc.<br>1001 Murry Ridge Lane,<br>Murrysville, PA 15668, USA                                                                                                           |
| <b>EU Authorized Representative (AR):</b> | Respironics Deutschland GmbH & Co. KG<br>Gewerbestrasse 17<br>82211 Herrsching, Germany<br>Tel: +49 8152 93060                                                                      |
| <b>ISO Quality Certificates Issued:</b>   | The Manufacturer is certified by TÜV SÜD Product Service GmbH to the following:<br><br>EN ISO 13485 Certificate: Q5 015581 0609<br><br>MDSAP ISO 13485 Certificate: QS6 015581 0610 |

Signature (signed for and on behalf of Philips)

Date of Issue: 30 MAY 2021

30 MAY 2021

Printed Name: Daria Brown

Place of Issue: Pittsburgh, PA, USA

Title: Sr. Manager, Regulatory Affairs

### CONFIDENTIAL

This document was created using the template information listed below:

|                                                       |                                  |                    |                    |
|-------------------------------------------------------|----------------------------------|--------------------|--------------------|
| <b>Governing Document:</b><br>QSP 7.9-064, WI 7.9-808 | <b>Document Number:</b> FRM 4450 | <b>Version:</b> 11 | <b>Page</b> 3 of 4 |
|-------------------------------------------------------|----------------------------------|--------------------|--------------------|

# EU DECLARATION OF CONFORMITY



Doc Number REG 2101229

Revision v16

## 3. Attachment A Standards and/or Common Specifications

|                                         |                                                                                                                                                                                                                                                                |
|-----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Quality System</b>                   |                                                                                                                                                                                                                                                                |
| EN ISO 13485:2016                       | Medical devices – Quality management systems – Requirements for regulatory purposes                                                                                                                                                                            |
| <b>General Safety Standard</b>          |                                                                                                                                                                                                                                                                |
| EN 60601-1:2006/A1:2013                 | Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance                                                                                                                                                        |
| <b>Collateral Safety Standards</b>      |                                                                                                                                                                                                                                                                |
| 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          |
| <b>Particular Safety Standards</b>      |                                                                                                                                                                                                                                                                |
| <b>Oxygen Concentrators</b>             |                                                                                                                                                                                                                                                                |
| EN ISO 80601-2-69:2014                  | Medical Electrical Equipment — Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment                                                                                                                  |
| <b>Oxygen Conserving Devices</b>        |                                                                                                                                                                                                                                                                |
| ISO 80601-2-67:2014                     | Medical electrical equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment                                                                                                                    |
| <b>Biocompatibility</b>                 |                                                                                                                                                                                                                                                                |
| ISO 10993-1:2018                        | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process                                                                                                                                                     |
| <b>Other Standards</b>                  |                                                                                                                                                                                                                                                                |
| <b>Accompany Documents and Labeling</b> |                                                                                                                                                                                                                                                                |
| 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                                                                                                                        |
| <b>Software</b>                         |                                                                                                                                                                                                                                                                |
| EN 62304:2006/ A1:2015                  | Medical device software – Software lifecycle processes                                                                                                                                                                                                         |
| <b>Risk Management</b>                  |                                                                                                                                                                                                                                                                |
| EN ISO 14971:2019                       | Medical devices – Application of risk management to medical devices                                                                                                                                                                                            |
| <b>Usability</b>                        |                                                                                                                                                                                                                                                                |
| IEC 62366-1:2015                        | Medical devices – Part 1: Application of usability engineering to medical devices                                                                                                                                                                              |
| <b>RoHS Standards</b>                   |                                                                                                                                                                                                                                                                |
| EN IEC 63000: 2018                      | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances                                                                                                                       |
| <b>Cleaning and Disinfection</b>        |                                                                                                                                                                                                                                                                |
| ISO 17664:2017                          | Processing of health care products - Information to be provided by the medical device                                                                                                                                                                          |

### CONFIDENTIAL

This document was created using the template information listed below:

|                                                |                           |             |             |
|------------------------------------------------|---------------------------|-------------|-------------|
| Governing Document:<br>QSP 7.9-064, WI 7.9-808 | Document Number: FRM 4450 | Version: 11 | Page 4 of 4 |
|------------------------------------------------|---------------------------|-------------|-------------|