

## DECLARATION OF CONFORMITY

**Respironics Inc.**  
 1001 Murry Ridge Lane  
 Murrysville, PA 15668-8550  
 Tel: 800-345-6443

Declares under our sole responsibility that the product:

Product Name	SimplyGo Mini
Product Part Number	The following Finished Goods are compliant with 2011/65/EU Restriction of the use of certain Hazardous Substances (RoHS) in Electric and Electronic Equipment (EEE) and 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC:  1113603          SimplyGo Mini Device, Intl 1113604          SimplyGo Mini, Standard Battery, Intl 1113605          SimplyGo Mini, Extended Battery, Intl
Control Designator	<u>Initial Issue Date:</u> <u>Part Number:</u> June 25, 2015                  1113603, 1113604, 1113605
Device Classification and Rule	Class IIa, Rule 11
Global Medical Device Nomenclature Code (GMDN)	31321 Portable oxygen concentrator
Product Options/ Accessories	Carry Bag, Accessory Bag, Standard Rechargeable Battery, Extended Rechargeable Battery, AC Power Supply and Cord, DC Power Supply and Cord.

**To which this Declaration relates is in conformity with the provisions of Council Directive:**

1. 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC
2. 2011/65/EU Restriction of the use of certain Hazardous Substances (RoHS) in Electric and Electronic Equipment (EEE)


The Manufacturer is certified by TÜV SÜD Product Service GmbH to EN ISO 13485. Copies of the Quality System certificates are available upon request.

Notified Body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany 0123
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Authorized EU Representative	Respironics Deutschland Gewerbestrasse 17 82211 Herrsching, Germany Tel: +49 8152 93060
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**Supplementary Information:**

The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation. Additionally the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying documentation.

Name	Colleen Witt
Title	Manager, Regulatory Affairs
Signature	
Date (MM/DD/YYYY)	6/26/2015
Place of Issue	Monroeville, PA