RESPIRONICS®

CE 0123

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 Portable Oxygen Concentrator

Product Part Number:		
	1068987	SimplyGo System
	1069058	SimplyGo, International
	1100403	SimplyGo, France

Note: Each PN may have a U or R prefix, indicating Recertified or Rental, depending on the requirements of the Product Manager.

Control Designator:	Initial Issue Date:	Part Number
	March 13, 2012	1068987
	March 13, 2012	1069058
	April 10, 2012	1100403

Device Classification and Rule: Class IIa, Rule 9

Global Medical Device Nomenclature Code (GMDN): 12873 Oxygen Concentrator

Product Accessories: Nasal Cannula, Battery Charger, AC Power Supply, DC Car Charger, DC Airline Cord, Humidifier Pouch, Accessory Bag, Mobile cart.

To which this Declaration relates is in conformity with the provisions of Council Directive: 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC.

The Manufacturer is certified by the Notified Body listed below to EN ISO 13485 and Annex II-Section 3.2 of the Medical Device Directive 93/42/EEC. Copies of the Quality System certificates are available upon request.

Notified Body: TÜV SÜD Product Service GmbH

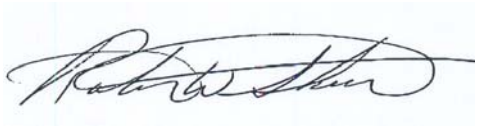
Authorized EU Representative: Respironics Deutschland
Gewerbestrasse 17
82211 Herrsching, Germany
Tel: +49 8152 93060

Supplementary Information:

The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are fully compliant with the harmonized standards listed below.

Harmonized Standard:	Title:
EN ISO 13485	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14971	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing

EN 62304	Medical Device Software - Software Life-Cycle Processes
EN ISO 8359	Oxygen Concentrators for Medical Use - Safety Requirements
EN 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety
EN 60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-4	Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems
EN 60601-1-6	Medical Electrical Equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability

Signature: 

Date: April 10, 2012

Printed Name: Robert W. Sherburn

Place of Issue: Kennesaw

Title: Senior Quality Assurance Manager