



## 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: EverGo Portable Oxygen Concentrator

Product Part Number: 900-020-02, 900-022-02 EverGo, International (Black Bag, Blue Bag)  
900-030-02, 900-032-02 EverGo, Japanese (Black Bag, Blue Bag)

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: June 15, 2009

Device Classification and Rule: Class IIa, Rule 9

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

Product Accessories: Nasal Cannula and Battery Charger

### 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 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



A handwritten signature in black ink, appearing to read "Robert W. Sherburn", set against a light blue background.

Signature:

Printed Name: Robert W. Sherburn

Title: Senior Quality Assurance Manager

Date: March 5, 2010

Place of Issue: Kennesaw