



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: EverFlo Oxygen Concentrator

Table with 2 columns: Product Part Number and description of EverFlo models and regions.

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

Table with 3 columns: Control Designator, Initial Issue Date, and Part Number.

Device Classification and Rule: Class IIa, Rule 9

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

Product Accessories: Air Inlet Filter, Humidifier Connector Tube, and Nasal Cannula

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
 Gewerbstrasse 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: May 5, 2011

Printed Name: Robert W. Sherburn

Place of Issue: Kennesaw

Title: Senior Quality Assurance Manager