



## 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: CoughAssist E70  
Product Part Number: 1098159 CoughAssist E70, International  
Control Designator: Initial Issue Date: August 2, 2012  
Device Classification and Rule: Class IIa, Rule 9  
Global Medical Device Nomenclature Code (GMDN): 36998 Exsufflator  
Product Options/Accessories: Face Masks, Breathing Circuits, Oximetry Interface Kit, Foot Pedal, Power Management (Detachable Battery and Detachable Battery Charger), Data Management and Roll Stand

### 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. 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:

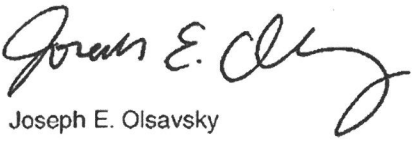
The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are fully compliant with the harmonized standards listed below.

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; Programmable electrical medical systems
EN 60601-1-6	Medical Electrical Equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability

EN 60601-1-11 General Requirements for basic safety and essential performance – Collateral Standard:  
Requirements for medical electrical equipment and medical electrical systems used in home  
healthcare environment

EN ISO 9919:2009 Medical Electrical Equipment – Particular requirements for the basic safety and essential  
performance of pulse oximeter equipment for medical use

Note: EN ISO 9919:2009 only applies to the devices that use the Oximetry Interface Kit

Signature: 

Date: 8/2/2012

Printed Name: Joseph E. Olsavsky

Place of Issue: Monroeville

Title: Senior Manager, Regulatory Affairs  
Home Respiratory Care