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: 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

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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: Joseph E. Olsavsky

Date: 8/2/2012

Printed Name: Joseph E. Olsavsky

Place of Issue: Monroeville

Title: Senior Manager, Regulatory Affairs
Home Respiratory Care