



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: BiPAP autoSV Advanced System One Ventilatory Support System

Product Part Number:	951P	BiPAP AutoSV Adv Sys One, INTL
	AU951S	BiPAP autoSV Advanced System One AUS
	AU951HS	BiPAP autoSV Adv System One w/HUMID AUS
	CA951S	BiPAP autoSV Advanced System One CAN
	CA951HS	BiPAP autoSV Adv System One w/HUMID CAN
	IN951S	BiPAP autoSV Advanced System One INT
	IN951HS	BiPAP autoSV Adv System One w/HUMID INT
	LA951S	BiPAP autoSV Advanced System One LA
	LA951HS	BiPAP autoSV Adv System One w/HUMID LA
	DE952S	BiPAP autoSV Advanced System One GER
	DE952HS	BiPAP autoSV Adv System One w/HUMID GER
	FR955S	BiPAP autoSV Advanced System One FR
	FR955HS	BiPAP autoSV Adv System One w/HUMID FR
	957P	BiPAP AutoSV Adv Sys One, CN
	CN957S	BiPAP autoSV Advanced System One CN
	CN957HS	BiPAP autoSV Adv System One w/HUMID CN

Control Designator:	Initial Issue Date:	Part Number(s)
	See Signature Date Below	951P, AU951S, AU951HS, CA951S, CA951HS, IN951S, IN951HS, LA951S, LA951HS, DE952S, DE952HS, FR955S, FR955HS, 957P, CN957S, CN957HS

Device Classification and Rule: Class IIb, Rule 9

Global Medical Device Nomenclature Code (GMDN): 15613 Ventilator

Product Options/Accessories: Nasal and Full Face Masks, Humidifiers, Breathing Circuits, Data Management and Lab Titration PC Software

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
Gewerbestr. 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. Additionally the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying documentation:

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 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety
EN ISO 10651-6	Lung Ventilators for Medical Use – Particular Requirements for Basic Safety and Essential Performance – Part 6: Home-care Ventilatory Support Devices
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
EN ISO 10993-1	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
EN 62304	Medical Device Software - Software Life-Cycle Processes
EN 62366	Medical devices - Application of usability engineering to medical devices

Signature: 

Date: 3/14/2011

Printed Name: David A. Scala

Place of Issue: Monroeville

Title: Senior Manager, Quality Systems & Compliance
Sleep and Home Respiratory Group