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:	Profile Lite Nasal Gel Mask	
Product Part Number:	1002851, 1002852, 1002375	Profile Lite Mask (P, S, M/S)
	1002376, 1002377, 1002378, 1002379	Profile Lite Mask (M, M/W, L, L/N)
	1004113, 1004114, 1004115	Profile Lite Mask w/Headgear (P, S, M/S)
	1004116, 1004117, 1004118, 1004119	Profile Lite Mask w/Headgear (M, M/W, L, L/N)
	1006314, 1006315, 1006316	Profile Lite Mask w/Headgear, w/o Exh (P, S, M/S)
	1006317, 1006318, 1006319, 1006320	Profile Lite Mask w/Headgear, w/o Exh (M, M/W, L, L/N)
	1006321, 1006322, 1006323	Profile Lite Mask w/o Exh (P, S, M/S)
	1006326, 1006327, 1006328, 1006329	Profile Lite Mask w/o Exh (M, M/W, L, L/N)

Control Designator:	Initial Issue Date:	Part Numbers:
	July 30, 1999	1002851, 1002852, 1002375, 1002376, 1002377, 1002378, 1002379
	August 21, 2000	1004113, 1004114, 1004115, 1004116, 1004117, 1004118, 1004119
	December 20, 2000	1006314, 1006315, 1006316, 1006317, 1006318, 1006319, 1006320
		1006321, 1006322, 1006323, 1006326, 1006327, 1006328, 1006329

Device Classification and Rule: Class IIa, Rule 2

Global Medical Device Nomenclature Code (GMDN): 12447 Masks

Product Options/Accessories: None

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 62366	Medical Devices - Application of Usability Engineering to Medical Devices

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Signature: [signature]

Date: 2/24/2010

Printed Name: David A. Scala

Place of Issue: Monroeville

Title: Director, Quality Systems
Sleep and Home Respiratory Group