



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: OptiLife Nasal Mask
Product Part Number: 1036832 OptiLife Nasal Mask w/Headgear, P, S, M, L Pillows, Int.
1036833 OptiLife Nasal Mask w/Headgear, P, S, M Pillows and S, M Cradle Cushion, Int.
1036834 OptiLife Nasal Mask w/Headgear, M, L Pillows and M, L, LN Cradle Cushion, Int.
Control Designator: Initial Issue Date: February 8, 2007
June 27, 2008 Part Number: 1036832
1036833 and 1036834
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
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.

Harmonized Standard: EN ISO 13485 Title: 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

Signature:

Date: 2/24/2010

Printed Name: David A. Scala

Place of Issue: Monroeville

Title: Director, Quality Systems
Sleep and Home Respiratory Group