



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: FitLife Total Face Mask
Product Part Number: 1060803, 1060804, 1089994 FitLife Mask w/ Headgear, Entrainment Elbow (EE), Intl (Small, Large, & Extra Large)
1061711, 1061712, 1089995 FitLife Mask w/ Headgear, Standard Elbow (SE), Intl (Small, Large, & Extra Large)
Control Designator: Initial Issue Date: Part Number:
See date below 1060803, 1060804, 1089994, 1061711, 1061712, 1089995
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
EN ISO 17510-2 Sleep apnoea breathing therapy - Part 2: Masks and application accessories

Signature: [Handwritten Signature]

Date: 3/16/2012

Printed Name: David A. Scala

Place of Issue: Monroeville

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