



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: EasyLife Nasal Mask and EasyLife SE Nasal Mask

Product Part Number:

1050020, 1050021, 1050022, 1050023, 1050024,	EasyLife Nasal Mask w/Headgear, Intl (P, S, M, MW, L)
1050025, 1050026, 1050027, 1050028, 1050029,	EasyLife DuoPack w/Headgear, Intl (P, S, M, MW, L)
1050030, 1050031, 1050032, 1050033, 1050034,	EasyLife SE Nasal Mask w/Headgear, Intl (P, S, M, MW, L)
1050088, 1050089	EasyLife FitPack w/Headgear, Intl (S/M, MW/L)

Control Designator: Initial Issue Date:

1050021, 1050022, 1050023, 1050024, 1050026, 1050027, 1050028, 1050029, 1050031, 1050032, 1050033, 1050034, 1050088, 1050089	December 3, 2009
1050020, 1050025, 1050030	January 24, 2011

Device Classification and Rule: Class IIa, Rule 2

Global Medical Device
Nomenclature Code (GMDN): 12447 Mask

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:	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
EN 62366

Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
Medical Devices -- Application of Usability Engineering to Medical Devices

Signature: 

Date: 1/24/2011

Printed Name: David A. Scala

Place of Issue: Monroeville

Title: Director, Quality Systems
Sleep and Home Respiratory Group