



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: ComfortGel Blue Nasal Mask
ComfortGel Blue SE Nasal Mask

Product Part Number: 1070064 L ComfortGel Blue Nasal Mask w/Headgear, INTL
1070065 M ComfortGel Blue Nasal Mask w/Headgear, INTL
1070066 S ComfortGel Blue Nasal Mask w/Headgear, INTL
1070067 P ComfortGel Blue Nasal Mask w/Headgear, INTL
1070068 L ComfortGel Blue Nasal Mask SE w/Headgear, INTL
1070069 M ComfortGel Blue Nasal Mask SE w/Headgear, INTL
1070070 S ComfortGel Blue Nasal Mask SE w/Headgear, INTL
1070071 P ComfortGel Blue Nasal Mask SE w/Headgear, INTL
1070072 L ComfortGel Blue Nasal Mask Duopack w/Headgear, INTL
1070073 M ComfortGel Blue Nasal Mask Duopack w/Headgear, INTL
1070074 S ComfortGel Blue Nasal Mask Duopack w/Headgear, INTL
1070075 P ComfortGel Blue Nasal Mask Duopack w/Headgear, INTL
1070076 M/S ComfortGel Blue Nasal Mask Fitpack w/Headgear, INTL
1070081 P-S-M-L ComfortGel Blue Launch Kit w/Headgear, INTL

Control Designator: Initial Issue Date: Part Number:
May 24, 2010 1070064-1070076, 1070081

Device Classification and Rule: Class IIa, Rule 2

Global Medical Device
Nomenclature Code (GMDN): 12447

Product 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 | Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing |
| EN 62366 | Medical Devices – Application of Usability Engineering to Medical Devices |

Signature:

A handwritten signature in blue ink, appearing to read "D. Scala".

Date:

5/24/2010

Printed Name: David A. Scala

Place of Issue: Monroeville

Title: Director, Quality Systems
Sleep and Home Respiratory Group



Revision History

| Version | Brief Description of Change |
|---------|-----------------------------|
| 00 | Initial Release |