

**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: Nuance Gel Pillows Mask  
Nuance Pro Gel Pillows Mask

Product Part Number: 1105161 Nuance Gel Pillows Mask with Headgear, International  
1105168 Nuance Pro Gel Pillows Mask with Headgear, International

Control Designator: Initial Issue Date: Part Number:  
11/08/2013 1105161, 1105168

Device Classification and Rule: Class IIa, Rule 2

Global Medical Device  
Nomenclature Code (GMDN): 57815 CPAP/BIPAP Nasal Mask Reusable

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  
Ridlerstrasse 65  
80339 München, Germany

Notified Body Identification Number: 0123

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. Additionally the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying documentation.

Signature: *Colleen Witt*

Date: 08 Nov 2013

Printed Name: Colleen Witt

Place of Issue: Monroeville

Title: Manager, Regulatory Affairs  
Patient Interface