



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