DECLARATION OF CONFORMITY

Respironics, Inc.

1001 Murry Ridge Lane
Murrysville, PA 15668-8550
800-345-6443

Declares under our sole responsibility that the product:

Product Name	Pico Traditional Nasal Mask
Product Part Number	1104940 S/M, L, XL Pico Nasal Mask Fitpack with Headgear, Global 1104915 S/M Pico Nasal Mask with Headgear, Global 1104916 L Pico Nasal Mask with Headgear, Global 1104917 XL Pico Nasal Mask with Headgear, Global 1104918 S/M Pico Nasal Mask without Headgear, Global 1104919 L Pico Nasal Mask without Headgear, Global 1104920 XL Pico Nasal Mask without Headgear, Global 1104921 S/M PICO NASAL MASK W/HGR INT 1104922 L PICO NASAL MASK W/HGR INT 1104923 XL PICO NASAL MASK W/HGR INT
Control Designator	Initial Issue Date: Part Number: 06/17/2014 1104940, 1104915, 1104916, 1104917, 1104918, 1104919, 1104920 9/26/2014 1104921, 1104922, 1104923
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:
1. 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC

The Manufacturer is certified by TÜV SÜD Product Service GmbH to EN ISO 13485 and is also certified by Annex II-Section 3.2 of the Medical Device Directive 93/42/EEC.	
Notified Body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany 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.

Name	Michelle Brinker
Title	Sr Manager, Regulatory Affairs
Signature	Michelle Brinker
Date (MM/DD/YYYY)	9/26/2014
Place of Issue	Monroeville