



DECLARATION OF CONFORMITY

Respironics, Inc
1001 Murry Ridge Lane
Murrysville, PA 15668-8559
Tel: 800-345-6443

Declares under our sole responsibility that the product:

Product Name: ComfortGel Full Face Mask, ComfortGel Full SE Face Mask, ComfortGel Blue Full Face Mask, ComfortGel Blue Full SE Face Mask

Product Part Number:	1040140	ComfortGel Full Face Mask, Small, International
	1040141	ComfortGel Full Face Mask, Medium, International
	1040142	ComfortGel Full Face Mask, Large, International
	1043550	ComfortGel Full SE Face Mask, Small, International
	1043551	ComfortGel Full SE Face Mask, Medium, International
	1043552	ComfortGel Full SE Face Mask, Large, International
	1054295	ComfortGel Full Face Mask, Launch Intro Kit, Small, International
	1054367	ComfortGel Full Face Mask, Launch Intro Kit, Medium, International
	1054368	ComfortGel Full Face Mask, Launch Intro Kit, Large, International
	1054369	ComfortGel Full Face Mask, DuoPack with Headgear, Small, International
	1054370	ComfortGel Full Face Mask, DuoPack with Headgear, Medium, International
	1054371	ComfortGel Full Face Mask, DuoPack with Headgear, Large, International
	1062014	ComfortGel Full Face Mask with Headgear, XL, International
	1062015	ComfortGel Full Face Mask, DuoPack with Headgear, XL, International
	1062016	ComfortGel Full Face Mask SE with Headgear, XL, International
	1081820	Small ComfortGel Blue Full, International
	1081821	Medium ComfortGel Blue Full, International
	1081822	Large ComfortGel Blue Full, International
	1081823	XL ComfortGel Blue Full, International
	1081825	Small ComfortGel Blue Full DuoPack, International
	1081826	Medium ComfortGel Blue Full DuoPack, International
	1081827	Large ComfortGel Blue Full DuoPack, International
	1081828	XL ComfortGel Blue Full DuoPack, International
	1081830	Small ComfortGel Blue Full SE, International
	1081831	Medium ComfortGel Blue Full SE, International
	1081832	Large ComfortGel Blue Full SE, International
	1081833	XL ComfortGel Blue Full SE, International

Control Designator:	Initial Issue Date:	Part Number:
	June 13, 2008	1040140, 1040141, 1040142, 1043550, 1043551, 1043552, 1054295, 1054367, 1054368, 1054369, 1054370, 1054371
	May 24, 2010	1062014, 1062015, 1062016
	See date below	1081820, 1081821, 1081822, 1081823, 1081825, 1081826, 1081827, 1081828, 1081830, 1081831, 1081832, 1081833

Device Classification and Rule: Class IIa, Rule 2

Global Medical Device
Nomenclature Code (GMDN): 12447 Masks

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
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, 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
EN ISO 17510-2	Sleep apnoea breathing therapy - Part 2: Masks and application accessories*

*ComfortGel Blue Full and ComfortGel Blue Full SE only

Signature:



Date:

3/23/2012

Printed Name: David A. Scala

Title: Sr.Manager, Quality Systems and Compliance

Place of Issue: Monroeville