



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: Amara Full Face Mask
Amara SE Full Face Mask

Product Part Number: 1090220 P Amara Mask w/ RS Frame and RS Hgr Int
1090221 S Amara Mask w/ RS Frame and RS Hgr Int
1090222 S Amara Mask w/ Hrg Int
1090223 M Amara Mask w/ Hrg Int
1090224 L Amara Mask w/ Hrg Int
1090230 P Amara Mask SE W/RS Frame and RS Hg Int
1090231 S Amara Mask SE W/RS Frame and RS Hg Int
1090232 S Amara Mask SE W/Hgr Int
1090233 M Amara Mask SE W/Hgr Int
1090234 L Amara Mask SE W/Hgr Int

Control Designator: Initial Issue Date Part Numbers
June 19, 2012 1090220 – 1090224
See date below 1090230 – 1090234

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



Signature:

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

Date: 8/3/2012

Printed Name: David A. Scala

Place of Issue: Monroeville

Title: Senior Manager, Quality Systems
Sleep and Home Respiratory Group