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 1090225 M Amara Mask w/ RS Frame and Hgr 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 1090235 M Amara Mask SE w/RS Frame and Hgr Int 1090228 L Amara Mask w/RS Frame and Hgr Int 1090236 L Amara Mask SE w/RS Frame and Hg Int 1090420 P Amara Gel Mask w/RS Frame and Hgr Int 1090421 S Amara Gel Mask w/RS Frame and Hgr Int 1090425 M Amara Gel Mask w/ RS Frame and Hgr Int 1090426 L Amara Gel Mask w/ RS Frame and Hgr Int 1090430 P Amara Gel Mask SE w/ RS Frame and Hgr Int 1090431 S Amara Gel Mask SE w/ RS Frame and Hgr Int 1090435 M Amara Gel Mask SE w/ RS Frame and Hg Int 1090436 L Amara Gel Mask SE w/ RS Frame and Hg Int
Control Designator	Initial Issue Date — Part Numbers June 19, 2012 — 1090220, 1090221 August 3, 2012 — 1090230 1090231 March 14, 2013 — 1090225, 1090235 June 19, 2013 — 1090228, 1090236 July 1, 2013 — 1090420, 1090421, 1090425, 1090426, 1090430, 1090431, 1090435, 1090436
Device Classification and Rule	Class IIa, Rule 2
Global Medical Device Nomenclature Code (GMDN)	57814 CPAP/BiPAP Face Mask Reusable 57813 CPAP/BiPAP Face Mask Single Use
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. Copies of the Quality System certificates are available upon request.	
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, Sleep
Signature	Michelle Brinker
Date (MM/DD/YYYY)	4/8/2014
Place of Issue	Monroeville