

DECLARATION OF CONFORMITY

Respironics, Inc

1001 Murry Ridge Lane
 Murrysville, PA 15668-8550, USA

Tel: 800-345-6443

Declares under our sole responsibility that the product:

Product Name	Amara View	
Product Part Number	1090602 S Amara View Mask w/Hgr 1090603 M Amara View Mask w/Hgr 1090604 L Amara View Mask w/Hgr 1090612 S Amara View Mask w/o Hgr 1090613 M Amara View Mask w/o Hgr 1090614 L Amara View Mask w/o Hgr 1090662 S Amara View Mask w/HGR, INTL 1090663 M Amara View Mask w/HGR, INTL 1090664 L Amara View Mask w/HGR, INTL	
Control Designator	Initial Issue Date February 13, 2015 May 4, 2015	Part Numbers 1090602- 1090604, 1090612-1090614 1090662-1090664
Device Classification and Rule	Class IIa, Rule 2	
Global Medical Device Nomenclature Code (GMDN)	57814 CPAP/BIPAP Face 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 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
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Authorized EU Representative	Respironics Deutschland Gewerbestrasse 17 82211 Herrsching, Germany Tel: +49 8152 93060
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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 and Patient Interface
Signature	
Date (MM/DD/YYYY)	5/4/2015
Place of Issue	Monroeville