



## 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	AF531 Oro-Nasal Single-Use EE Leak 1 AF531 Oro-Nasal Single-Use EE Leak 2 AF531 Oro-Nasal Single-Use SE AF531 Oro-Nasal, Single-Use, Circuit with Filter, EE Leak 1 Nebulizing Elbow Bronchoscopy Elbow AF531 Oro-Nasal Single-Use EE Leak 1 with Nebulizing Elbow AF531 Oro-Nasal Single-Use SE with Nebulizing Elbow
Product Type	Oro-Nasal Mask Circuit with Filter Nebulizing Elbow Bronchoscopy Elbow
Product Part Number	<u>Single Packs</u> 1061718 AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 1, Small 1061719 AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 1, Medium 1061720 AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 1, Large 1061721 AF531 Oro-Nasal, Single-Use, Four Point Headgear, SE, Small 1061722 AF531 Oro-Nasal, Single-Use, Four Point Headgear, SE, Medium 1061723 AF531 Oro-Nasal, Single-Use, Four Point Headgear, SE, Large 1061724 AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 2, Small 1061725 AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 2, Medium 1061726 AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 2, Large 1061727 AF531 Oro-Nasal, Single-Use, CapStrap Headgear, EE, Leak 1, Small 1061728 AF531 Oro-Nasal, Single-Use, CapStrap Headgear, EE, Leak 1, Medium 1061729 AF531 Oro-Nasal, Single-Use, CapStrap Headgear, EE, Leak 1, Large 1061730 AF531 Oro-Nasal, Single-Use, CapStrap Headgear, SE, Small 1061731 AF531 Oro-Nasal, Single-Use, CapStrap Headgear, SE, Medium 1061732 AF531 Oro-Nasal, Single-Use, CapStrap Headgear, SE, Large 1134804 M, AF531, SE, RS 4PT HDG, SU

10 Packs

- 1072621 AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 1, Small
- 1072622 AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 1, Medium
- 1072623 AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 1, Large
- 1072624 AF531 Oro-Nasal, Single-Use, Four Point Headgear, SE, Small
- 1072625 AF531 Oro-Nasal, Single-Use, Four Point Headgear, SE, Medium
- 1072626 AF531 Oro-Nasal, Single-Use, Four Point Headgear, SE, Large
- 1072627 AF531 Oro-Nasal, Single-Use, CapStrap Headgear, EE, Leak 1, Small
- 1072628 AF531 Oro-Nasal, Single-Use, CapStrap Headgear, EE, Leak 1, Medium
- 1072629 AF531 Oro-Nasal, Single-Use, CapStrap Headgear, EE, Leak 1, Large
- 1072630 AF531 Oro-Nasal, Single-Use, CapStrap Headgear, SE, Small
- 1072631 AF531 Oro-Nasal, Single-Use, CapStrap Headgear, SE, Medium
- 1072632 AF531 Oro-Nasal, Single-Use, CapStrap Headgear, SE, Large
- 1100390 S AF531 Leak 2 W/ Cap Strap, 10PK
- 1100391 M AF531 Leak 2 W/ Cap Strap, 10PK
- 1100392 L AF531 Leak 2 W/ Cap Strap, 10PK
- 1100393 S AF531 LEAK 2 4PT HDG, 10 PACK
- 1100394 M AF531 LEAK 2 4PT HDG, 10 PACK
- 1100395 L AF531 LEAK 2 4PT HDG, 10 PACK
- 1134715 M, AF531, SE, RS 4PT HDG, SU, 10 PACK

Circuit 5 Packs

- 1072639 AF531 Oro-Nasal, Single-Use, Circuit w/Filter (Main), 4 Point Headgear, EE, Leak 1, Small
- 1072640 AF531 Oro-Nasal, Single-Use, Circuit w/Filter (Main), 4 Point Headgear, EE, Leak 1, Medium
- 1072641 AF531 Oro-Nasal, Single-Use, Circuit w/Filter (Main), 4 Point Headgear, EE, Leak 1, Large

Nebulizing Elbows

- 1072649 EE Nebulizing Elbow Kit, Single
- 1072650 EE Nebulizing Elbow Kit, 5 Pack
- 1076755 SE Nebulizing Elbow Kit, Single
- 1076754 SE Nebulizing Elbow Kit, 5 Pack

Bronchoscopy Elbows

- 1072651 Bronchoscopy Elbow (BE) Kit, Single
- 1072652 Bronchoscopy Elbow (BE) Kit, 5 Pack

AF531 Oro-Nasal Mask with Nebulizing Elbow

- 1072633 S AF531 EE LEAK1 NE 4PT HDG, SU,10 PACK
- 1072634 M AF531 EE LEAK1 NE 4PT HDG, SU,10 PACK
- 1072635 L AF531 EE LEAK1 NE 4PT HDG, SU,10 PACK
- 1072636 S AF531 EE LEAK1 NE CAP STRAP,SU,10 PACK
- 1072637 M AF531 EE LEAK1 NE CAP STRAP,SU,10 PACK
- 1072638 L AF531 EE LEAK1 NE CAP STRAP,SU,10 PACK

	1072642 S AF531 EE LEAK1,CKT,NE CAP STP,SU,5 PCK 1072643 M AF531 EE LEAK1,CKT,NE CAP STP,SU,5 PCK 1072644 L AF531 EE LEAK1,CKT,NE CAP STP,SU,5 PCK 1100396 S AF531 SE NE W/ CAPSTRAP, SU, 10PK 1100397 M AF531 SE NE W/ CAPSTRAP, SU, 10PK 1100438 L AF531 SE NE W/ CAPSTRAP, SU, 10PK																						
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Device Classification, Annex and Rule	Class IIa, Annex IX, Rule 2																						
Global Medical Device Nomenclature Code (GMDN)	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, as indicated in the Product Part Number section above:**

- 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 GmbH & Co. KG 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.

**Standards:**

The products listed above are fully compliant with the harmonized standards listed below.

<b>Quality System</b>	
EN ISO 13485:2012	Medical devices – Quality management systems – Requirements for regulatory purposes
<b>Particular Standards</b>	
<b>Patient Interface</b>	
EN ISO 17510-2:2009	Sleep apnoea breathing therapy – Part 2: Masks and application accessories
<b>Biocompatibility</b>	
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10: 2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
<b>Accompany Documents and Labeling</b>	
EN 980:2008	Symbols for use in the labeling of medical devices
ISO 15223-1: 2012	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN 1041: 2008	Information supplied by the manufacturer of medical devices
<b>Risk Management</b>	
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
<b>Usability</b>	
EN 62366:2008	Medical devices – Application of usability engineering to medical devices

Name	Frank Kadi
Title	Manager, Regulatory Affairs
Signature	
Date (MM/DD/YYYY)	05/25/2017
Place of Issue	Monroeville