



## 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: REMstar CPAP System, REMstar Plus C-Flex CPAP System, REMstar Pro C-Flex CPAP System, REMstar Pro C-Flex+ CPAP System, REMstar Auto A-Flex CPAP System, BiPAP Pro Bi-Flex BiPAP System, BiPAP Auto Bi-Flex BiPAP System

Product Part Number:	151P	REMstar, INT
	AU151HS	REMstar w/ HUMID, SD Card AUS
	AU151S	REMstar w/ SD Card AUS
	CA151HS	REMstar w/ HUMID, CD Card CA
	CA151S	REMstar w/ SD Card CA
	IN151HS	REMstar w/ HUMID, SD Card INT
	IN151S	REMstar w/ SD Card, INT
	LA151HS	REMstar w/ HUMID, SD Card LA
	LA151S	REMstar w/ SD Card LA
	251P	REMstar Plus, INTL
	AU251HS	REMstar Plus C-Flex w/ HUMID, SD Card AUS
	AU251S	REMstar Plus C-Flex w/ SD Card AUS
	CA251HS	REMstar Plus C-Flex w/ HUMID, SD Card CAN
	CA251S	REMstar Plus C-Flex w/ SD Card CAN
	IN251HS	REMstar Plus C-Flex w/ HUMID, SD Card INT
	IN251S	REMstar Plus C-Flex w/ SD Card INT
	LA251HS	REMstar Plus C-Flex w/ HUMID, SD Card LA
	LA251S	REMstar Plus C-Flex w/ SD Card LA
	255P	REMstar Plus, FR
	FR255HS	REMstar Plus C-Flex w/ HUMID, SD Card FR
	FR255S	REMstar Plus C-Flex w/SD Card FR
	355P	REMstar Pro, FR
	FR355HS	REMstar Pro C-Flex w/ HUMID, SD Card FR
	FR355S	REMstar Pro C-Flex w/SD Card, FR
	451P	REMstar Pro, INTL
	AU451HS	REMstar Pro C-Flex+ w/ HUMID, SD Card AUS
	AU451S	REMstar Pro C-Flex+ w/ SD Card AUS
	CA451HS	REMstar Pro C-Flex+ w/ HUMID, SD Card CAN
	CA451S	REMstar Pro C-Flex+ w/ SD Card CAN
	IN451HS	REMstar Pro C-Flex+ w/ HUMID, SD Card INT
	IN451S	REMstar Pro C-Flex+ w/ SD Card INT
	LA451HS	REMstar Pro C-Flex+ w/ HUMID, SD Card LA
	LA451S	REMstar Pro C-Flex+ w/ SD Card LA
	456P	REMstar Pro, JP
	JP456HS	REMstar Pro C-Flex+ w/ HUMID, SD Card JP
	JP456S	REMstar Pro C-Flex+ w/ SD Card JP
	551P	REMstar Auto, INTL
	AU551HS	REMstar Auto A-Flex w/ HUMID, SD Card AUS
	AU551S	REMstar Auto A-Flex w/ SD Card AUS
	CA551HS	REMstar Auto A-Flex w/ HUMID, SD Card CAN
	CA551S	REMstar Auto A-Flex w/ SD Card CAN
	IN551HS	REMstar Auto A-Flex w/ HUMID, SD Card INT
	IN551S	REMstar Auto A-Flex w/ SD Card INT
	LA551HS	REMstar Auto A-Flex w/ HUMID, SD Card LA
	LA551S	REMstar Auto A-Flex w/ SD Card LA

555P	REMstar Auto, FR
FR555HS	REMstar Auto A-Flex w/ HUMID, SD Card FR
FR555S	REMstar Auto A-Flex w/ SD Card FR

556P	REMstar Auto, JP
JP556HS	REMstar Auto A-Flex w/ HUMID, SD Card JP
JP556S	REMstar Auto A-Flex w/ SD Card JP

651P	BiPAP Pro, INT
AU651HS	BiPAP Pro BiFlex w/ HUMID, SD Card AUS
AU651S	BiPAP Pro BiFlex w/ SD Card AUS
CA651HS	BiPAP Pro BiFlex w/ HUMID, SD Card CA
CA651S	BiPAP Pro BiFlex w/ SD Card CA
IN651HS	BiPAP Pro BiFlex w/ HUMID, SD Card INT
IN651S	BiPAP Pro BiFlex w/ SD Card, INT
LA651HS	BiPAP Pro BiFlex w/ HUMID, SD Card LA
LA651S	BiPAP Pro BiFlex w/ SD Card LA

751P	BiPAP Auto, INT
AU751HS	BiPAP Auto BiFlex w/ HUMID, SD Card AUS
AU751S	BiPAP Auto BiFlex w/ SD Card AUS
CA751HS	BiPAP Auto BiFlex w/ HUMID, SD Card CA
CA751S	BiPAP Auto BiFlex w/ SD Card CA
IN751HS	BiPAP Auto BiFlex w/ HUMID, SD Card INT
IN751S	BiPAP Auto BiFlex w/ SD Card INT
LA751HS	BiPAP Auto BiFlex w/ HUMID, SD Card LA
LA751S	BiPAP Auto BiFlex w/ SD Card LA

Control Designator:	Initial Issue Date:	Part Number:
	August 25, 2009	251P, 451P, 551P, AU251HS, AU251S, AU451HS, AU451S, AU551HS, AU551S, CA251HS, CA251S, CA451HS, CA451S, CA551HS, CA551S
	October 22, 2009	355P, FR355HS, FR355S, IN251HS, IN251S, IN451HS, IN451S, IN551HS, IN551S, LA251HS, LA251S, LA451HS, LA451S, LA551HS, LA551S
	December 22, 2009	151P, 651P, 751P, CA151HS, CA151S, CA651HS, CA651S, CA751HS, CA751S
	January 21, 2010	255P, 555P, FR255HS, FR255S, FR555HS, FR555S, AU651HS, AU651S, AU751HS, AU751S, IN651HS, IN651S, IN751HS, IN751S, LA651HS, LA651S, LA751HS, LA751S
	March 26, 2010	AU151HS, AU151S, IN151HS, IN151S, LA151HS, LA151S
	December 17, 2010	456P, JP456HS, JP456S, 556P, JP556HS, JP556S

Device Classification and Rule: Class IIa, Rule 9

Global Medical Device  
 Nomenclature Code (GMDN): 36700 Positive Airway Pressure Unit, Continuous  
 37234 Positive Airway Pressure Unit, Continuous Auto  
 36990 Positive Airway Pressure Unit, Bi-Level

Product Accessories: Nasal and Full Face Masks, Humidifiers, Breathing Circuits, Data Management and Lab Titration PC Software

**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 62304	Medical Device Software - Software Life-Cycle Processes
EN 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety
EN 60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-4	Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems
EN 60601-1-6	Medical Electrical Equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability
EN ISO 17510-1	Sleep Apnoea Breathing Therapy - Part 1: Sleep Apnoea Breathing Therapy Equipment
EN ISO 8185	Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems

Note: EN ISO 8185 only applies to those devices that include a humidifier.

Signature:



Date:

12/17/2020

Printed Name: David A. Scala

Place of Issue: Monroeville

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