



# Certificate

No. Q5 015581 0609 Rev. 02

**Holder of Certificate:** **Respironics, Inc.**  
1001 Murry Ridge Lane  
Murrysville PA 15668  
USA

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production, Distribution and Service of Continuous Ventilators, Non-Continuous Ventilators, Positive Airway Pressure Units (Bi-Level Continuous), Masks, Breathing Circuits, Humidifiers, Ventilatory Effort Recorders, Electroencephalograph, Sleep Therapy Diagnostic Devices, Controllers for Sleep Therapy and Ventilator Devices, Oxygen Therapy, Physiological Monitoring Equipment, Mechanical Positive Pressure Airway Secretion-Clearing Devices, Data Management Software, Respiratory Sensors, Nasal Cannulae, Oxygen Monitoring Devices. Design, Production, and Distribution of Sleep Position Training Devices for the Treatment of Positional Sleep Apnea and Active and Non-Active Drug Delivery and Respiratory Care Systems. Contract Manufacturer of Nebulizers.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 015581 0609 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 015581 0609 Rev. 02)

**Report No.:** 72171332

**Valid from:** 2022-02-11  
**Valid until:** 2024-05-21

**Date,** 2022-02-11

Christoph Dicks  
Head of Certification/Notified Body

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## Applied Standard(s):

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

## Facility(ies):

Respironics, Inc.  
1001 Murry Ridge Lane, Murrysville PA 15668, USA

Design and Development, Production, Distribution and Service of Continuous Ventilators, Non-Continuous Ventilators, Positive Airway Pressure Units (Bi-Level / Continuous), Masks, Breathing Circuits, Humidifiers, Ventilatory Effort Recorders, Electroencephalograph, Sleep Therapy Diagnostic Devices, Controllers for Sleep Therapy and Ventilator Devices, Oxygen Therapy, Physiological Monitoring Equipment, Mechanical Positive Pressure Airway Secretion-Clearing Devices, Data Management Software, Respiratory Sensors, Nasal Cannulae, Oxygen Monitoring Devices. Design, Production, Distribution of Sleep Position Training Devices for the Treatment of Positional Sleep Apnea; Contract Manufacturer of Nebulizers. Subcontractor of Distribution and Service for Current Product Category.

Respironics, Inc.  
174 Tech Center Drive, Mt. Pleasant PA 15666, USA

Production and Distribution, Repackaging and Relabeling, and Servicing of Continuous Ventilators, Non-Continuous Ventilators, Positive Airway Pressure Units (Bi-level/Continuous), Masks, Breathing Circuits, Humidifiers, Ventilatory Effort Recorders, Sleep Therapy Diagnostic Devices, Electroencephalograph, Controllers for Sleep Therapy and Ventilator Devices, Oxygen Therapy, Oxygen Monitoring Systems, Data Management Software, Physiological Monitoring Equipment, Mechanical Positive Pressure Airway Secretion-Clearing Devices, Respiratory Sensors and Nasal Cannulae and Nebulizers. Active and Non-Active Drug Delivery and Respiratory Care Systems Subcontractor of Distribution and Service for Current Product Category.

Respironics, Inc.  
1010 Murry Ridge Lane, Murrysville PA 15668, USA

Call Center of Continuous Ventilators, Non-Continuous Ventilators, Positive Airway Pressure Units (Bi-level/Continuous), Masks, Breathing Circuits, Humidifiers, Ventilatory Effort Recorders, Sleep Therapy Diagnostic Devices, Electroencephalograph, Controllers for Sleep Therapy and Ventilator Devices, Oxygen Therapy, Oxygen Monitoring Devices, Data Management Software, Physiological Monitoring Equipment, Mechanical Positive Pressure Airway Secretion-Clearing Devices, Respiratory Sensors, Nasal Cannulae, and Nebulizers. Active and Non-Active Drug Delivery and Respiratory Care Systems

Respironics, Inc.  
920 SW Emkay Drive, Suite 100, Bend OR 97702, USA

# Certificate

No. Q5 015581 0609 Rev. 02

Service and Distribution of Physiological Monitoring Equipment

Respironics, Inc.  
6501 Living Place, Pittsburgh PA 15206, USA

Management, Design and Development of Continuous Ventilators, Non-Continuous Ventilators, Positive Airway Pressure Units (Bi-level/Continuous), Masks, Breathing Circuits, Humidifiers, Ventilatory Effort Recorders, Sleep Therapy Diagnostic Devices, Electroencephalograph, Controllers for Sleep Therapy and Ventilator Devices, Oxygen Therapy, Oxygen Monitoring Devices, Data Management Software, Physiological Monitoring Equipment, Mechanical Positive Pressure Airway Secretion-Clearing Devices, Respiratory Sensors and Nasal Cannulae. Active and Non-Active Drug Delivery and Respiratory Care Systems

Respironics, Inc.  
Chichester Business Park, City Fields Way, Tangmere, West Sussex PO20 2FT, UNITED KINGDOM

Production and Distribution of Continuous Ventilators, Non-Continuous Ventilators, Positive Airway Pressure Units (Bi-level/Continuous), Masks, Breathing Circuits, Humidifiers, Ventilatory Effort Recorders, Sleep Therapy Diagnostic Devices, Electroencephalograph, Controllers for Sleep Therapy and Ventilator Devices, Oxygen Therapy, Oxygen Monitoring Systems, Data Management Software, Physiological Monitoring Equipment, Mechanical Positive Pressure Airway Secretion-Clearing Devices, Respiratory Sensors, Nasal Cannulae, and Nebulizers. Sleep Position Training Devices for the Treatment of Positional Sleep Apnea; Active and Non-Active Drug Delivery and Respiratory Care Systems

Respironics, Inc.  
312 Alvin Drive, New Kensington PA 15068, USA

Labs, Complaint Handling, Production and Distribution of Continuous Ventilators, Non-Continuous Ventilators, Oxygen Therapy, Positive Airway Pressure Units (Bi-level/Continuous), Humidifiers, and Controllers for Sleep Therapy and Ventilator Devices

Respironics Deutschland GmbH & Co. KG  
Gewerbestrasse 17, 82211 Herrsching, GERMANY

Production and Distribution of Continuous Ventilators, Non-Continuous Ventilators, Positive Airway Pressure Units (Bi-level/Continuous), Masks, Breathing Circuits, Humidifiers, Ventilatory Effort Recorders, Sleep Therapy Diagnostic Devices, Electroencephalograph, Controllers for Sleep Therapy and Ventilator Devices, Oxygen Therapy, Oxygen Monitoring Systems, Data Management Software, Physiological Monitoring Equipment, Mechanical Positive Pressure Airway Secretion-Clearing Devices,

# Certificate

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Respiratory Sensors, Nasal Cannulae, and Nebulizers.  
Sleep Position Training Devices for the Treatment of Positional  
Sleep Apnea; Active and Non-Active Drug Delivery and  
Respiratory Care Systems

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