



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 015581 0608 Rev. 00

Manufacturer:

Respironics, Inc.

1001 Murry Ridge Lane
Murrysville PA 15668
USA

Product Category(ies):

**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,
Nasal Cannulae, and Sleep Position Training Devices for the
Treatment of Positional Sleep Apnea**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

72152273

Valid from:

2020-01-28

Valid until:

2024-05-26

Date,

2020-01-28

Christoph Dicks
Head of Certification/Notified Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 015581 0608 Rev. 00

Facility(ies):

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

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

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

Philips GmbH Respironics
Gewerbestr, 17, 82211 Herrsching, GERMANY

./.