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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 0605 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.: 72147304

Valid from: 2019-10-21
Valid until: 2024-05-26

Date, 2019-10-21

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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312 Alvin Drive, New Kensington PA 15068, USA

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

Respironics, Inc.
175 Chastain Meadows Court, Kennesaw GA 30144, USA

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

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