



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 16 01 15581 049

Manufacturer: **Respironics, Inc.**
1001 Murry Ridge Lane
Murrysville PA 15668-8550
USA

EC-Representative: **Respironics Deutschland GmbH**
Gewerbestrasse 17
82211 Herrsching
GERMANY

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
and Physiological Monitoring
Equipment**

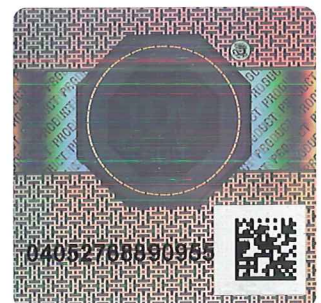


The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms 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.: 72107915
Valid from: 2016-03-02
Valid until: 2021-03-01

Date, 2016-02-26


Stefan Preiß



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

Page 1 of 2



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(Devices in Class IIa, IIb or III)****No. G1 16 01 15581 049****Facility(ies):**Respironics, Inc.
1001 Murry Ridge Lane, Murrysville PA 15668-8550, USARespironics, Inc.
312 Alvin Drive, New Kensington PA 15068, USARespironics, Inc.
175 Chastain Meadows Court, Kennesaw GA 30144-3724, USARespironics, Inc.
Chichester Business Park, City Fields Way, Tangmere, West
Sussex PO20 2FT, UNITED KINGDOM