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

TÜV SÜD 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 062364 0042 Rev. 00

Manufacturer:

Respironics Respiratory Drug Delivery (UK) Ltd
Chichester Business Park
City Fields Way
Tangmere
Chichester, West Sussex PO20 2FT
UNITED KINGDOM

Facility(ies):

Respironics Respiratory Drug Delivery (UK) Ltd
Chichester Business Park, City Fields Way, Tangmere,
Chichester, West Sussex PO20 2FT, UNITED KINGDOM

Product Category(ies):

Non active medical devices for respiratory care (Respiratory muscle trainers, nebulizers, mouthpieces, facemasks, tubing, connectors and T pieces) and active medical devices for respiratory care (nebulizers and ventilators).

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.: 75946505

Valid from: 2020-02-18
Valid until: 2024-05-26

Date, 2020-02-18

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany