

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 17 03 62364 028

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).

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.:

75938391

Valid from:

2017-04-06

Valid until:

2022-04-05

Date. 2017-04-03

Stefan Preiß



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

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