ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 17 08 49861 149

Manufacturer:
ResMed Limited
1 Elizabeth Macarthur Drive
Bella Vista NSW 2153
AUSTRALIA

EC-Representative:
ResMed SAS
Parc Technologique de Lyon
292 Allée Jacques Monod
69791 Saint Priest Cedex
FRANCE

Product Category(ies):
Positive Airway Pressure Devices, Ventilators, Humidifiers, Masks, Tubes and associated Accessories, Patient Data Recorders (Respiratory).

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.: **JAQ235030142**

Valid from: **2017-09-01**
Valid until: **2021-10-03**

Date, 2017-08-10

Stefan Preiß

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

TÜV®

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Facility(ies):

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AUSTRALIA