



Declaration of Conformity

Manufacturer:

ResMed Ltd
1 Elizabeth Macarthur Drive
Bella Vista
NSW 2153
Australia

European Representative:

ResMed (UK) Ltd
96 Milton Park
Abingdon
Oxfordshire OX14 4RY
United Kingdom

Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany

Product: ResMed CPAP Wipes & Spray

The ResMed CPAP Wipes & Spray are intended to be used in the home environment as part of cleaning of CPAP masks.

Standards Applied: EN ISO 10993-1:2009

Classification: I (according to Rule I - Non Invasive Devices)

GMDN: 58077 - Medical device cleaning/disinfecting wipe

Conformity

Assessment Route: Annex II (excluding Section 4), 93/42/EEC.

We herewith declare that the above mentioned products meet the transposition into national law of the provisions of Council Directive 93/42/EEC including the MDD amendment (2007/47/EC), for medical devices. Compliance to the MDD and the standards referenced above is applicable from the date listed below. All supporting documentation is retained at the premises of the manufacturer.

Signed at Sydney, Australia on:**20 March 2013**.....

GABO DECKARD FOR S.L.

Dr. Simon Lewi
Director – Regulatory Affairs
ResMed Ltd

EC128

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