ResMed

Declaration of Conformity

CE 0123

Manufacturer:	European Representative:	Notified Body:
ResMed Ltd	***ResMed (UK) Ltd***	***TÜV SÜD Product Service GmbH***
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Bella Vista	Abingdon	80339 München
NSW 2153	Oxfordshire OX14 4RW	Germany
Australia	United Kingdom	

Product: AirMini

The AirMini self-adjusting system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66 lb (30 kg).

It is intended for home and hospital use.

Standards Applied: EN ISO 14971:2012
ISO 80601-2-70:2015
EN ISO 17510-1:2009
EN 60601-1:2006/AC:2010
EN 60601-1-2:2007/AC:2010
EN ISO 10993-1:2009
EN 60601-1-11:2010
EN 60601-1-6:2010
EN 62366:2008
EN 62304:2006/AC:2008

Classification: IIa (according to Rule 9)

GMDN: 60711 - Home CPAP unit

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.

This declaration is issued under the sole responsibility of ResMed Ltd.

EC Certificate number G1 16 06 49861 115

Signed at Sydney, Australia on: .....***1 February 2017***.....

Johanna Wright
Director, Regulatory Affairs
ResMed Ltd

EC174d
First issued: 17th Jan 2017