ResMed

CE 0123

Declaration of Conformity

Manufacturer:	European Representative:	Notified Body:
ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia	**ResMed (UK) Ltd** 96 Jubilee Ave Milton Park Abingdon Oxfordshire OX14 4 RW United Kingdom	**TÜV SÜD Product Service GmbH** Ridlerstraße 65 80339 Müchen Germany

Product ***AirCurve 10 VAuto***

The AirCurve 10 S device is indicated for the treatment of Obstructive leep Apnea in patients weighing (more than 66lb/30kg) and (more that 30lb/13kg in CPAP and S modes). It is intended for home and hospital use.

The humidifier is intended for single patient use in the home environment and re-sue in a hospital/institutional environment.

Standards Applied:
EN ISO 14971:2009
EN ISO 17510-1:2009
EN ISO 10651-6:2009
EN 60601-1:2006/AC:2010
EN 606011-1-2:2007/AC:2010
EN ISO 8185:2009
EN ISO 10993-1:2009
EN 606011-1-11:2010
EN 60601-1-6:2010
EN 62366:2008
EN1041:2008
EN 980:2008
EN 62304:2006/AC:2008

Classification: IIa (according to Rule 9)

GMDN:
47083 - Portable ventilator, electric
12050 - Humidifer, heated

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.

EC Certificate number: G1 12 05 49861 017

Signed at Sydney, Australia on: .....5 May 2015 .....

Dr. Simon Lewi
Vice President – Global Regulatory Affairs
ResMed Ltd

EC150c
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