ResMed

Declaration of Conformity

CE 0123

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 4RW United Kingdom	*TÜV SÜD Product Service GmbH* Ridlerstraße 65 80339 München Germany

Product: AirSense 10 AutoSet

The AirSense 10 AutoSet self-adjusting device 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.

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

Standards Applied:	EN ISO 14971:2009 EN ISO 17510-1:2009 EN 60601-1:2006/AC:2010 EN 60601-1-2:2007/AC:2010 EN ISO 8185:2009 EN ISO 10993-1:2009 EN 60601-1-11:2010 EN 60601-1-6:2010 EN 62366:2008
Classification:	IIa (according to Rule 9)
GMDN:	37234 - Positive Airway Pressure Unit, Continuous Auto.
GMDN:	12050 - Humidifier, 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: .....***7 August 2014***.....

(GREG DOCKAR) FOR SIMON LEWI

Dr. Simon Lewi
Director – Regulatory Affairs
ResMed Ltd

EC149
First issued: 4th June 2014