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: HumidAir

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

It is intended for use with the AirSense/AirCurve Series 10 CPAP or Bilevel devices.

Standards Applied: EN ISO 14971:2009
EN 60601-1:2006/AC:2010
EN 60601-1-2:2007/AC:2010
EN ISO 8185:2009

Classification: IIa (according to Rule 9)

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: .....***6 August 2014***.....

Dr. Simon Lewi
Director – Regulatory Affairs
ResMed Ltd

EC149d
First issued: 28th July 2014