RESMED

CE 0123

Declaration of Conformity

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

Product: **Astral 150**

The Astral device provides continuous or intermittent ventilatory support for patients weighing more than 5 kg who require mechanical ventilation. The Astral device is intended to be used in home, institution/hospital and portable applications for both invasive and non-invasive ventilation.

Standards Applied:
EN ISO 14971:2012
EN 60601-1-2:2007
EN 60601-1-6:2010
EN ISO 10651-2:2009
EN ISO 10993-1:2009
EN 60601-1:2006
EN 60601-1-11:2010
EN 60601-1-8:2007
EN ISO 10651-6:2009
EN 62304:2006

Classification: IIb (according to Rule 11)

GMDN: 47083 – Portable ventilator, electric

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 December 2013***.....

Dr. Lionel King
Snr VP Global QA & RA
ResMed Ltd