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 OX14 4RY United Kingdom	***TÜV SÜD Product Service GmbH*** Ridlerstraße 65 80339 München Germany

Product: **Astral 100**

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: .....***8 May 2014***.....

Dr. Simon Lewi
Director Regulatory Affairs
ResMed Ltd