ResMed

CE 0123

Declaration of Conformity

Manufacturer:	Authorised Representative:	Notified Body:
ResMed Pty. Ltd. 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia	ResMed SAS Parc Technologique de Lyon 292 Allée Jacques Monod 69791 Saint Priest Cedex France	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany

Product: Stellar 100/130/150

Intended Use: The Stellar 100/130/150 is intended to provide ventilation for non-dependent, spontaneously breathing adult and pediatric patients (30 lb / 13 kg and above) with respiratory insufficiency or respiratory failure, with or without obstructive sleep apnea. The device is for non-invasive use, or invasive use (with the use of the ResMed leak valve). Operation of the device includes both stationary, such as in hospital or home, or mobile, such as wheelchair usage.

Classification: IIb according to Rule 9

GMDN: 47083 Portable ventilator, electric

Conformity Assessment Route: Annex II (excluding Section 4), 93/42/EEC

We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Compliance is applicable from the date listed below. All supporting documentation is retained at the premises of the manufacturer.
This declaration is issued under the sole responsibility of ResMed Pty. Ltd.

EC Certificate Number: G1 049861 0158

Signed at Sydney, Australia on: 23 April 2020

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

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First issued: 26 April 2017