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: Quattro Air NV

Intended Use: The Quattro Air NV is a non-invasive accessory used for channelling air-flow (with or without supplemental oxygen), intended to be used with active-exhaust-valve ventilators, to provide ventilatory assistance to patients with respiratory insufficiency and respiratory failure.

The Quattro Air NV is:
• to be used by patients weighing (>66 lb/30 kg) requiring non-life support ventilatory assistance
• intended for single patient re-use in the home environment and/or multi-patient re-use in the hospital/institutional environment

Classification: IIa according to Rule 2

GMDN: 57814 CPAP/BPAP face mask, reusable

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.

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: 11 December 2019

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

EC147

First issued: 13 June 2014