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: Ultra Mirage NV

Intended Use: The Ultra Mirage NV is intended to be used with active-exhaust-valve ventilator systems, to provide ventilatory assistance to patients with respiratory insufficiency and respiratory failure.

The Ultra Mirage NV is:
• to be used by adult patients (> 66 lb/30 kg) requiring non-life-support ventilatory assistance.
• intended for single-patient re-use in the home or multipatient re-use in the hospital/institutional environment.

Classification: IIa according to Rule 2

GMDN: 57815 CPAP/BPAP nasal 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: 03 May 2021

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

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First issued: 15 August 2002