

## Declaration of Conformity

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**Manufacturer:**

ResMed Pty. Ltd.  
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Bella Vista  
NSW 2153  
Australia

**Authorised Representative:**

ResMed SAS  
Parc Technologique de Lyon  
292 Allée Jacques Monod  
69791 Saint Priest Cedex  
France

**Notified Body:**

TÜV SÜD Product Service  
GmbH  
Ridlerstraße 65  
80339 München  
Germany

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**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

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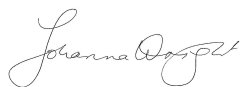
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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



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Johanna Wright  
Director of Regulatory Affairs  
ResMed Pty. Ltd.

**EC043**

First issued: 15 August 2002