

Declaration of Conformity

Manufacturer:

ResMed Pty. Ltd.
1 Elizabeth Macarthur Drive
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

Product: Ultra Mirage NV Full Face Mask

Intended Use: The Ultra Mirage Non-Vented (NV) Full Face Mask is intended to be used with active-exhaust valve ventilator systems, to provide ventilatory assistance to patients with respiratory insufficiency and respiratory failure. It is to be used on adult patients (>30kg), requiring non-life-support ventilatory assistance. The Ultra Mirage NV Full Face Mask is intended for single-patient re-use in the home 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

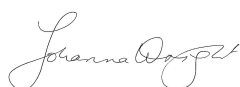
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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.

EC076

First issued: 1 December 2006