RESMED

Declaration of Conformity

Manufacturer: *ResMed Ltd*
1 Elizabeth Macarthur Drive
Bella Vista
NSW 2153
Australia

European Representative: *ResMed (UK) Ltd*
65 Milton Park
Abingdon
Oxfordshire OX14 4RX
United Kingdom

Notified Body: *SGS United Kingdom Ltd*
Weston-Super-Mare
Unit 202b, Worle Parkway
Weston-Super-Mare, BS22 0WA
United Kingdom

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0120

Product: **Ultra Mirage Non-Vented Full Face Mask**

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.

Standards Applied: ISO 14971:2000
ISO 10993-1:2003(E)
ISO 5356-1:2004 (Sections 5.1 and 5.2)
ISO 594-1:1986 (Sections 3 and 4.1)

Classification: IIa

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

We herewith declare that the above mentioned products meet the transposition into national law of the provisions of Council Directive 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Sydney, ...

1st December, 2006

Dr. Lionel King (acting delegate)
Vice President Global Quality Assurance and Regulatory Affairs
ResMed Ltd

RESMED ISO 9001 & ISO 13485:2003 CERTIFIED

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