RESMED

Declaration of Conformity

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

European Representative: *ResMed (UK) Ltd*
96 Milton Park
Abingdon
Oxfordshire OX14 4RY
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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Product: **Mirage SoftGel**

The Mirage SoftGel channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.
The Mirage SoftGel is:

- to be used by adult patients (>30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home and multipatient re-use in the hospital/institutional environment.

Standards Applied: ISO 14971:2007; ISO 17510-2:2007;
ISO 10993-1:2003(E); ISO 5356-1:2004 (sections 5.1 and 5.2);
ISO 594-1: 1986; ISO 17664:2004.

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 including the MDD amendment (2007/47/EC), for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Sydney, ... 10 SEPT, 09.

Steven Lukie for DIRECTOR- REGULATORY AFFAIRS

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Dr. Lionel King
Vice President Global Quality Assurance and Regulatory Affairs
ResMed Ltd

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