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 FX**

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

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

Standards Applied: ISO 17510-2:2007;
ISO 10993-1:2009; ISO 5356-1:2004 (sections 5.1 and 5.2);
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,..... 16 SEPTEMBER 2010

Simon Lewi - Director – Regulatory Affairs
As Delegate For

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

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ISO 9001 &
ISO 13485:2003
CERTIFIED

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