



Declaration of Conformity

Manufacturer: <i>ResMed Ltd</i> 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia	European Representative: <i>ResMed (UK) Ltd</i> 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: **Tx Link**
The Tx Link is intended to provide connectivity between ResMed EasyCare Tx software and ResMed continuous positive airway pressure (CPAP) or Bi-level devices that incorporates ResMed's proprietary communication protocol. The Tx Link relays real-time signals measured by the CPAP or Bilevel device to a polysomnograph (PSG).

Standards Applied: EN ISO 14971:2009
EN 60601-1:1990/A2:1995
EN 60601-1-2:2007

Classification: IIb (according to Rule 9)

GMDN: 16305 - Patient data recorder.

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. Compliance to the MDD and the standards referenced above is applicable from the date listed below. All supporting documentation is retained at the premises of the manufacturer.

Signed at Sydney, Australia on:**1st August 2011**.....

Dr. Simon Lewi
Director – Regulatory Affairs
ResMed Ltd

EC102
First issued: 11 December 2009