CE 0123

Declaration of Conformity

Manufacturer:	EU Representative:	Notified Body:
ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia	ResMed SAS Parc Technologique de Lyon 292 Allée Jacques Monod 69791 Saint Priest Cedex France	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany

Product: Tx Link

Intended Use: The Tx Link is intended to provide connectivity between ResMed EasyCare Tx software and ResMed compatible therapy devices. The Tx Link relays real-time signals measured by the ResMed compatible therapy device to a polysomnograph (PSG).
The Tx Link is intended to be used in a clinical environment.

Classification: IIb according to Rule 9

GMDN: 36862 Patient monitoring system module, interfacing

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 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 Ltd.

EC Certificate Number: G1 17 08 49861 149

Signed at Sydney, Australia on: 26-Jun-18

Johanna Wright
Director of Regulatory Affairs
ResMed Ltd

EC102

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