



Declaration of Conformity

Manufacturer:

ResMed Pty. Ltd.
1 Elizabeth Macarthur Drive
Bella Vista
NSW 2153
Australia

Authorized Representative:

ResMed SAS
Parc Technologique de Lyon
292 Allée Jacques Monod
69791 Saint Priest Cedex
France

Product: TxLink 2

Intended Use:

The TxLink 2 is intended to provide connectivity between the ResMed EasyCare Tx 2 software and ResMed continuous positive airway pressure (CPAP), Bilevel or Non-invasive ventilator devices that incorporate ResMed's proprietary communication protocol. The TxLink 2 relays real time signals between a CPAP, Bilevel or Non-invasive ventilator devices and a polysomnography (PSG). The TxLink 2 is intended to be used in a clinical environment.

Classification: I according to Rule 13

EMDN: Z1203020280 Multi-Parameter Monitors - Hardware Accessories

Conformity Assessment Route: Annex II and III, Regulation EU 2017/745

Basic UDI-DI: 619498EC2066E

Common Specification: N/A

We herewith declare that the above mentioned products are in conformity with the Council Regulation 2017/745 for medical devices, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Compliance 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 Pty. Ltd.

SRN: AU-MF-000011753

Signed at Sydney, Australia on: 29 June 2023

DocuSigned by:

Nicole Wilson

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Nicole Wilson
Person Responsible for Regulatory Compliance (PRRC)
ResMed Pty. Ltd.

EC206.1

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