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## **Declaration of Conformity**

Manufacturer:

ResMed Corp. 9001 Spectrum Center Blvd. San Diego CA 92123 USA **Authorized Representative:** 

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

**Notified Body:** 

TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany

Product: EasyCare Tx 2

## **Intended Use:**

The EasyCare Tx 2 software is intended to be used with ResMed compatible therapy devices in a clinical environment. EasyCare Tx 2 provides therapy device setting changes and displays real-time data and treatment settings from compatible ResMed therapy devices when used together with the Tx Link 2 module.

Classification: Ila according to Rule 11

EMDN: Z1203019092 Various instruments for anesthesia and pulmonary ventilation support -

medical device software

Conformity Assessment Route: Annex IX (excluding Chapter II), Regulation EU 2017/745

Basic UDI-DI: 8401934EC205L7

## Common Specification: N/A

We herewith declare that the above mentioned products are in conformity with the Council Regulation 2017/745 for medical devices.

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 Corp.

EC Certificate Number: G10 083904 0009

**SRN:** US-MF-000011805

Signed at San Diego CA, USA on: 14 December 2022

Sheila Bruschi

Senior Director of Regulatory Affairs

ResMed Corp.

EC205.1

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