ResMed

CE 0123

Declaration of Conformity

Manufacturer:

ResMed Corp.
9001 Spectrum Center Blvd.
San Diego CA 92123
USA

Authorised 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: myAir

Intended Use: myAir is a patient engagement software platform for use by patients who are prescribed a compatible ResMed device for the purpose of self-tracking therapy usage data and receiving coaching (educational videos, tips) in a personal home setting. The Personal Therapy Assistant (PTA) feature of myAir is intended for patients who are prescribed a compatible ResMed Air11 platform device to remotely simulate therapy prior to using their device with their prescribed settings. myAir is an optional software accessory to allow patients to acclimate to their therapy device.

Classification: IIa according to Rule 9

GMDN: 40582 Ventilator, Software

Conformity Assessment Route: Annex II (excluding Section 4), 93/42/EEC

We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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: G1 083904 0007

Signed at San Diego, USA on: 13 April 2022

Sheila Bruschi
Director of Regulatory Affairs
ResMed Corp.

EC188
First issued: 24 May 2021