ResMed

CE 0123

Declaration of Conformity

Manufacturer:	Authorised Representative:	Notified Body:
ResMed Pty. 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: Air10 Serial Adapter

Intended Use: The Air 10 Serial Adapter is intended to be used with ResMed devices during sleep studies, the serial adapter transmits patient therapy data between the Air10 device and compatible Portable Diagnostic Systems (PDS).

It is intended for use in the home and hospital/institutional environment.

Classification: IIa according to Rule 9

GMDN: 60711 Home CPAP unit

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 Pty. Ltd.

EC Certificate Number: G1 049861 0158

Signed at Sydney, Australia on: 20 August 2020

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

EC132a

First issued: 31 August 2017