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: F20 AirMini Setup Pack+ HumidX

Intended Use: The F20 AirMini Setup pack + HumidX allows for connection of the AirFit F20 and AirTouch F20 full face mask to the AirMini device. It consists of the AirMini breathing tube, the full face mask connector and HumidX F20.

Classification: IIa according to Rule 2

GMDN: 37705 Breathing circuit, ventilator, reusable

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: 2 September 2020

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

EC189b

First issued: 2 September 2020