

Declaration of Conformity

Manufacturer:

ResMed Pty. Ltd.
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Bella Vista
NSW 2153
Australia

Authorised Representative:

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292 Allée Jacques Monod
69791 Saint Priest Cedex
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Notified Body:

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

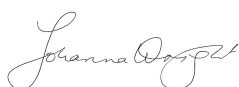
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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