



Declaration of Conformity

Manufacturer: Authorised Representative: Notified Body:

ResMed Pty. Ltd. ResMed SAS TÜV SÜD Product Service

1 Elizabeth Macarthur DriveParc Technologique de LyonGmbHBella Vista292 Allée Jacques MonodRidlerstraße 65NSW 215369791 Saint Priest Cedex80339 MünchenAustraliaFranceGermany

Product: N20 AirMini Setup Pack

Intended Use: The N20 AirMini Setup pack allows for connection of the AirFit N20 nasal mask to the

AirMini device. It consists of the AirMini breathing tube, nasal mask adaptor, HumidX

and HumidX Plus.

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.

First issued: 6 February 2019