



Declaration of Conformity

Manufacturer:

ResMed Pty. Ltd. 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia **Authorized 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: ClimateLineAir 11

Intended Use:

The ClimateLineAir 11 is a heated breathing tube that delivers air to a compatible mask. It is intended for home and hospital use.

Classification: Ila according to Rule 2 and 9

EMDN: R020107 Thermoregulated Breathing Circuits

Conformity Assessment Route: Annex IX (excluding Chapter II), Regulation EU 2017/745

Basic UDI-DI: 619498EC1826R **Common Specification:** N/A

We herewith declare that the above mentioned products are in conformity with the Council Regulation 2017/745 for medical devices.

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: G10 049861 0162 Rev. 04

SRN: AU-MF-000011753

Signed at Sydney, Australia on: 17 December 2024

—DocuSigned by: *Nicole Wilson*

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Nicole Wilson

Person Responsible for Regulatory Compliance (PRRC)

ResMed Pty. Ltd.

EC182b.1

First issued: 28 June 2022