

0123

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: G15 049861 0261 Rev. 00

SRN: AU-MF-000011753

Signed at Sydney, Australia on: 30 June 2025

DocuSigned by:

Nicole Wilson

F9F55744DEA64A0

Nicole Wilson Person Responsible for Regulatory Compliance (PRRC)

ResMed Pty. Ltd.

EC182b.1

First issued: 28 June 2022