



## **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:** Air11 Hypoallergenic Filter

**Intended Use:** 

The hypoallergenic filter provides air filtration during PAP therapy.

Classification: Ila according to Rule 3

EMDN: R040199 Ventilation Filters - Others

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

Basic UDI-DI: 619498EC13168
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.

EC131c.1

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