CE 0123

Declaration of Conformity

Manufacturer:	Authorized Representative:	Notified Body:
ResMed Pty. Ltd. 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia	ResMed SAS Parc Technologique de Lyon 292 Allée Jacques Monod 69791 Saint Priest Cedex France	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany

Product: HumidAir 11

Intended Use:
The HumidAir 11 enables the provision of humidification. It is intended for home and hospital use.

Classification: IIa according to Rule 9

EMDN: Z1203019080 Various Instruments for Anaesthesia and Pulmonary Ventilation Support - Hardware Accessories

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

Basic UDI-DI: 619498EC1856X

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.

EC185b.1
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