



Declaration of Conformity

Manufacturer:

Authorized Representative:

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

Product: Astral External Battery

Intended Use:

The External Battery is an external lithium-ion battery intended for hospital and home use to provide increased battery capacity and autonomy to the Astral series of ventilators.

Classification: I according to Rule 13

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

Hardware Accessories

Conformity Assessment Route: Annex II and III, Regulation EU 2017/745

Basic UDI-DI: 619498EC1546L
Common Specification: N/A

We herewith declare that the above mentioned products are in conformity with the Council Regulation 2017/745 for medical devices, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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.

SRN: AU-MF-000011753

Signed at Sydney, Australia on: 29 June 2023

DocuSigned by:

Nicole Wilson

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Nicole Wilson

Person Responsible for Regulatory Compliance (PRRC)

ResMed Pty. Ltd.

EC154.1

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