ResMed

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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: H4i

Intended Use:
The H4i is indicated for humidification of the air delivered from a ResMed compatible CPAP, bilevel and non-invasive ventilation device. The H4i is for use only as recommended by a physician.

Classification: IIa according to Rule 9

GMDN: 12050 Humidifier, heated

Conformity Assessment Route: Annex II (excluding Section 4), 93/42/EEC

We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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: G1 049861 0158

Signed at Sydney, Australia on: 28 July 2021

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

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First issued: 17 June 2008