ResMed

CE 0123

Declaration of Conformity

Manufacturer:	Authorised 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: Lumis HFT

Intended Use: The Lumis HFT is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. The flow may be from 15-40L/min. The Lumis HFT is for patients > 30kg in homes, hospitals and long-term care facilities.

Classification: IIa according to Rule 11

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, 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.

EC Certificate Number: G1 049861 0158

Signed at Sydney, Australia on: 22 May 2020

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

EC195

First issued: 22 May 2020