

Declaration of Conformity

Manufacturer:

ResMed Pty. Ltd.
1 Elizabeth Macarthur Drive
Bella Vista
NSW 2153
Australia

Authorised 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: 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

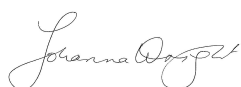
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous 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