

## Declaration of Conformity

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**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

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**Product:** AirSense 10 Elite

**Intended Use:** The AirSense 10 Elite device is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (30 kg). It is intended for home and hospital use.

The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

**Classification:** IIa according to Rule 9

**GMDN:** 60711 Home CPAP unit 12050 Humidifier, heated

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

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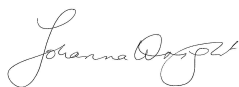
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Directive 2014/53/EU.

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: 11 December 2019



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Johanna Wright  
Director of Regulatory Affairs  
ResMed Pty. Ltd.

**EC149d**

First issued: 28 July 2014