



## **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: HumidX and HumidX Plus

Intended Use: The HumidX and HumidX Plus are waterless humidifiers intended to provide

increased moisture levels when using the AirMini CPAP device.

Classification: IIa according to Rule 3

**GMDN:** 37597 Filter, humidifier, heat/moisture exchanger

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: 20 August 2020

Johanna Wright

**Director of Regulatory Affairs** 

ResMed Pty. Ltd.

First issued: 17 January 2017