

## 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:** AcuCare High Flow Nasal Cannula

**Intended Use:** The AcuCare HFNC (high flow nasal cannula) system is intended to provide high flow oxygen therapy for adult patients with acute respiratory failure. The AcuCare HFNC is designed to deliver air, with or without blended oxygen, up to a maximum flow of 60 l/min. The AcuCare HFNC is for single-patient use (maximum 7 days) in the hospital/clinical environment.

**Classification:** IIa according to Rule 5

**GMDN:** 35201 Cannula, nasal, oxygen

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

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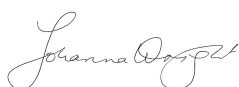
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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.

**EC158**

First issued: 5 May 2017