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: 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

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

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

EC158

First issued: 5 May 2017