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: HumidX F20

Intended Use: The HMX F20 is a waterless humidification exchanger (HMX) designed to provide more comfort to users by capturing the heat and moisture present in the patient"s expired air and returning to the patient"s airway during inspiration. The HMX F20 is a non-invasive accessory to be used with compatible full face masks and Positive Airway Pressure (PAP) devices. It is intended for single-patient reuse in the home and hospital / institutional environment.

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: 2 September 2020

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

EC190b

First issued: 2 September 2020