ResMed

CE 0123

Declaration of Conformity

Manufacturer:

ResMed Pty. Ltd.
1 Elizabeth Macarthur Drive
Bella Vista
NSW 2153
Australia

Authorised Representative:

ResMed SAS
Pac 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: NV Elbow F20

Intended Use: The NV Elbow F20 converts the AirFit F20 and AirTouch F20 Vented Masks into Non-Vented masks for the purpose of delivering non-invasive positive pressure ventilation. The converted Non-Vented mask systems are to be used with ventilators that have adequate alarms and safety systems for ventilator failure, to administer continuous or intermittent ventilatory support.

The NV Elbow F20 (when used with the converted Non-Vented AirFit F20 and Non-Vented AirTouch F20 masks) is:
• to be used by patients weighing more than 30 kg
• intended for single-patient re-use in the home environment and/or multi-patient re-use in the hospital/institutional environment

Classification: IIa according to Rule 2

GMDN: 42601 Connector, breathing circuit, reuseable

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: 21 May 2021

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

EC196

First issued: 21 May 2021