ResMed

CE 0123

Declaration of Conformity

Manufacturer:

ResMed Corp.
9001 Spectrum Center Blvd.
San Diego CA 92123
USA

Authorised Representative:

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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: ResScan

Intended Use: ResScan is intended to augment the standard follow-up care of patients by providing transfer of machine and therapeutic information. This includes the ability to remotely change settings in non-life support devices only.

It is intended to be used by clinicians in conjunction with ResMed compatible therapy devices, using ResMed's proprietary communication protocol.

Classification: IIb according to Rule 9

GMDN: 40582 Ventilator, software

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 Corp.

EC Certificate Number G1 083904 0007

Signed at San Diego, California, USA on: 13 October 2021

Sheila Bruschi
Director of Regulatory Affairs
ResMed Corp.

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