ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 049861 0261 Rev. 00

Manufacturer:

ResMed Pty Ltd
1 Elizabeth Macarthur Drive
Bella Vista NSW 2153
AUSTRALIA

SRN Manufacturer - AU-MF-000011753

Authorized Representative:

ResMed SAS
Parc Technologique de Lyon, 292 Allée Jacques Monod, 69791
Saint-Priest Cedex, FRANCE

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G15 049861 0261 Rev. 00

Report No.: JA200350004666
Preceding Certificate No.: G10 049861 0162 Rev. 04

Valid from: 2025-06-29
Valid until: 2030-06-28

Issue date: 2025-05-28

Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class IIa
Device Group:	MDA 0307 - Active non-implantable respiratory devices
Classification:	Class IIa
Device Group:	MDA 0318 - Other active non-implantable devices
Classification:	Class IIa
Device Group:	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
Classification:	Class IIb
Device Group:	Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS
Intended Purpose:	To provide continuous or intermittent ventilatory support for patients requiring non-invasive or invasive ventilation

The validity of this certificate depends on conditions and/or is limited to the following: -/-

Rev.	Dated	Report	Description
00	2025-06-29	JA200350004666	Renewal of certificate

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