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
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 096632 0011 Rev. 01

Manufacturer:

Resvent Medical Technology Co., Ltd.
Room-602, Building B&C
Gaoxinqi Industrial Park
Liuxian NO.1 Road
XingDong community
Bao`an
518100 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Infant incubator, Infant radiant warmer, Infant phototherapy unit, Positive Airway Pressure System, Ventilator, Pulse Oximeters, NCPAP System(Nasal Continuous Positive Airway Pressure System), Emergency and Transport ventilator, Masks for Sleep Apnoea Breathing Therapy**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: GZ19263EXT01

Valid from: 2020-04-21
Valid until: 2024-05-26

Date, 2020-04-21

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Dobrea Alexandru
Date: 2021.03.19 12:35:42 EET
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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