



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 073649 0010 Rev. 01

Manufacturer:

**Shenzhen ECGMAC Medical
Electronics Co., Ltd.**

2nd Floor of Block 2
Haoye Industrial Park, Tiegang Road
Xixiang Street
Baoan District
518102 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies): Multi-Channel ECG, PC-ECG,
Bluetooth ECG and Holter**

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.:

GZ1915902

Valid from:

2019-12-03

Valid until:

2024-05-26

Date, 2019-12-03

Christoph Dicks
Head of Certification/Notified Body



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