DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 073649 0012 Rev. 01

Holder of Certificate: **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

Facility(ies): 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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Multi-channel ECG, Holter, ECG Workstation, PC-ECG, Bluetooth ECG**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ1915901

Valid from: 2020-01-17
Valid until: 2022-12-14

Date, 2020-01-17

Christoph Dicks
Head of Certification/Notified Body

TÜV®

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

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