



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 050440 0032 Rev. 02

Holder of Certificate: **Shenzhen Carewell Electronics Co., Ltd.**

Floor 4, BLD 9
Baiwangxin High-Tech Industrial Park
Songbai Road, Xili Street
Nanshan District
518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development,
Production and Distribution of
Electrocardiographs, AI-ECG Platform,
AI-ECG Tracker, Holter Recorder**

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). 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:Q5 050440 0032 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_050440_0032_Rev._02)

Report No.: SH25026501

Valid from: 2025-10-31

Valid until: 2028-10-30

Date, 2025-08-14

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Shenzhen Carewell Electronics Co., Ltd.**
Floor 4, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai
Road, Xili Street, Nanshan District, 518108 Shenzhen, PEOPLE'S
REPUBLIC OF CHINA

See Scope of Certificate