



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

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



REGISTRATION NO. 04723Q10024R1S

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

Shenzhen Carewell Electronics Co.,Ltd.

Registered Address: Floor 4, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District 518108, Shenzhen, P.R. China

Manufacturing Address: Floor 4, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District 518108, Shenzhen, P.R. China

Has been assessed and conformed to the following standard(s)

GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

Design, Development, Production and Service of Electrocardiograph, ECG Workstation, Dynamic ECG Systems, AI-ECG Platform, OmniECG, Multichannel ECG Electrocardiograph, Tablet portable Electrocardiograph (Mobile communication and wireless data terminal type), AI-ECG Tracker;

Design and Development of eCardIoT.

Date of issue: February 24,2023

Date of expiry: February 23,2026

General Manager:

**BEIJING HUA-GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M