



Certificate

No. Q5 050440 0030 Rev. 00

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

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

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Infusion Pumps, Syringe Pumps, Electrocardiographs, AI-ECG Platform, AI-ECG Tracker**

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.: SH1926517

Valid from: 2019-11-11
Valid until: 2022-10-30

Date, 2019-11-11

Christoph Dicks
Head of Certification/Notified Body