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

Product Service

# Certificate

## No. Q5 050440 0032 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

See Scope of Certificate

**Certification Mark:**

tuv-sud.com/ps-cert

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

**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). All applicable requirements of the testing and certification regulation of 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. 00

**Report No.:** SH2026501
**Valid from:** 2021-01-15
**Valid until:** 2022-10-30

**Date,** 2021-01-15

Christoph Dicks
Head of Certification/Notified Body


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

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

# 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 050440 0033 Rev. 00**

**Manufacturer:**

**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

**Product Category(ies):** **Infusion Pumps, Syringe Pumps, Electrocardiographs, AI-ECG Platform, AI-ECG Tracker, Holter Recorder**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 050440 0033 Rev. 00

**Report No.:** SH2026501

**Valid from:** 2021-01-19
**Valid until:** 2024-05-26

**Date,** 2021-01-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD ◆ CERTIFICAT ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 证书 ◆ CERTIFICATE ◆