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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

Product Service

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 0031 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**

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. See also notes overleaf.

Report No.: SH1926517

Valid from: 2019-11-14
Valid until: 2024-05-26

Date, 2019-11-14

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Belan Irina
Date: 2021.06.30 17:38:48 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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

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