



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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 0029 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

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

Product Category(ies): Patient Monitors, Pulse Oximeters,
Infusion Pumps, Syringe Pumps ,
Diagnostic Ultrasound System, Electrocardiographs,
Fetal Dopplers, Dynamic ECG Systems,
AI-ECG Platform

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.:

SH19265EXT01

Valid from:

2019-08-01

Valid until:

2024-05-26

Date,

2019-08-01

Stefan Preiß

Head of Certification/Notified Body



Shenzhen Carewell Electronics Co., Ltd.

深圳市凯沃尔电子有限公司

Add.: Floor 4, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street,

Nanshan District 518108, Shenzhen, P.R. China

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<http://www.carewell.com.cn>

Declaration of Identical Construction

October 8th 2019

We Shenzhen Carewell Electronic Co.,Ltd,

Located in Floor 3, BLD9, Baiwangxin High- Tech Industrial Paark, Songbai Road , Xili Street, Nanshan District, Shenzhen, China.

Hereby declare the following Kalamed Products

Model : KES-301; KES-301T; KES-601T & KES-121T

Are identical with Certified Shenzhen Carewell Electronic Co.,Ltd's devices

Model: 1103G; 1103L; 1106L & 1112M.


2019.10.8
Shenzhen Carewell Electronic Co.,Ltd.
