

Declaration of Conformity

Manufacturer: Shenzhen Carewell Electronics Co., Ltd.

Manufacturer Address:

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

Facility Address:

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

European Representative: Lepu Medical (Europe) Cooperatief U.A.

Address: De Marne 118, 8701 MC Bolsward, The Netherlands

Product: Electrocardiograph

Model: ECG-1101B, ECG-1101C, ECG-1101G,
ECG-1101B(I), ECG-1101C(I), ECG-1101G(I),
ECG-1103B, ECG-1103G, ECG-1103L, ECG-1103LW, ECG-1103GW,
ECG-1103B(I), ECG-1103G(I), ECG-1103L(I), ECG-1103LW(I), ECG-1103GW(I).
ECG-1106L, ECG-1106G, PCECG-500(ECG workstation)
ECG-1112, ECG-1112L, ECG-1112M, ECG-1112D, T12.

Main Accessory: ECG Cable, ECG Electrode

Classification (MDD, Annex IX): IIa (According to MDD, Rule 10)

Conformity Assessment Route: Annex V.3

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General Applicable Directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC) and its amended Directive 2007/47/EC.

Notified Body: TUV SUD Product Service GmbH

Address: Ridlerstrasse 65, 80339 Munich, Germany

Certificate No.: G1 050440 0031 Rev.00

The Certificate is valid until: 2024-05-26

Place, Date of issue: Shenzhen, 2019-11-14



Signature: Wenzhong Shu
Name: Wenzhong Shu
Date : 2019.11.14
Position: Management Representative





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

地址：深圳市南山区西丽街道松白公路百旺信工业区 9 栋 4 层北侧

Tel: +86-755-8617 0389, Fax: +86-755-8617 0478

<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.

Handwritten signature and date: 2019.10.8

Shenzhen Carewell Electronic Co.,Ltd.

