

# 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

