

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) Coöperatief U.A.

Address: Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, 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
OmniECG C120 AI, NeoECG S120, NeoECG T180, LeECG OS12, LeECG OT12

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

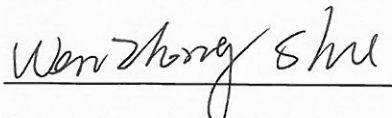
Address: Ridlerstrasse 65, 80339 Munich, Germany

Certificate No.: G1 050440 0033 Rev.00

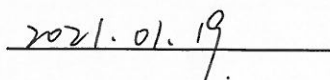
The Certificate is valid until: 2024-05-26

Place, Date of issue: Shenzhen, 2021-01-19

Signature:



Date:



Name: Wenzhong Shu

Position: General Manager