DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES

Name and Address of 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
Name and Address of European Representative	Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard, 36, Heerenveen, Netherlands
Product Name/Model	Electrocardiograph / 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-1112, ECG-1112L, ECG-1112M, ECG-1112D,T12,OmniECG C120AI,NeoECG S120,NeoECG T180,LeECG OS12,LeECG OT12
GMDN code	16231
Classification	Class IIa，Rule 10 according to Annex IX of the MDD
Conformity Assessment Route	Annex II excluding Chapter 4
We, Shenzhen Carewell Electronics Co., Ltd., Ltd. here with declare that the above mentioned products meet the provisions of the Directive 93/42/EEC and following Standards. All supporting documents is remained at the premises of the manufacturer. EU Declaration of Conformity is issued under sole responsibility of the manufacturer.	
Standards Applied	EN 60601-1:2006+A1:2013+A2:2020, EN 60601-1-2: 2015+A1:2020, EN 60601-1-6:2010+A1:2015+A2:2020, EN 60601-2-25:2015, EN ISO 10993-1:2020, EN ISO 10993-5:2018, EN ISO 10993-10:2013, EN ISO 14971:2019, EN 62304:2006+A1:2015, EN 62366-1:2015+A1:2020, EN ISO 15223-1:2021, EN 1041:2008+A1:2013, EN ISO 780: 2015
Name and Address of Notified Body	TUV SUD Product Service GMBH Ridlerstr 65, D-80339 Munchien.
Identification Number	0123
EC Certificate	G1 050440 0033 Rev.00
Place, Date of issue	Shenzhen, 2023.04.24
Signature	
Name and Position	Pan Zhou, management representative