


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

|  |   |                    |            |
|--|---|--------------------|------------|
| <b>Name and Address of Manufacturer</b>  | Shenzhen Carewell Electronics Co., Ltd.<br>Floor 4, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518108 Shenzhen, PEOPLE'S REPUBLIC OF CHINA   |                    |            |
| <b>Name and Address of European Representative</b>   | Lepu Medical (Europe) Cooperatief U.A.<br>Abe Lenstra Boulevard, 36, Heerenveen, Netherlands  |                    |            |
| <b>Product Name/Model</b>  | 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 workstation), ECG-1112, ECG-1112L, ECG-1112M, ECG-1112D, T12, OmniECG C120AI, NeoECG S120, NeoECG T180, LeECG OS12, LeECG OT12 |                    |            |
| <b>GMDN code</b>   | 16231   |                    |            |
| <b>Classification</b>  | Class IIa , Rule 10 according to Annex IX of the MDD  |                    |            |
| <b>Conformity Assessment Route</b>   | Annex II excluding Chapter 4  |                    |            |
| <p>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.<br/>All supporting documents is remained at the premises of the manufacturer.<br/>EU Declaration of Conformity is issued under sole responsibility of the manufacturer.</p> |   |                    |            |
| <b>Standards Applied</b>   | 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  |                    |            |
| <b>Name and Address of Notified Body</b>   | TUV SUD Product Service GMBH<br>Ridlerstr 65, D-80339 Munchien.   |                    |            |
| <b>Identification Number</b>   | 0123  |                    |            |
| <b>EC Certificate</b>  | G1 050440 0033 Rev.00   | <b>Valid Until</b> | 2024-05-26 |
| <b>Place, Date of issue</b>  | Shenzhen,   |                    |            |
| <b>Signature</b>   |    |                    |            |
| <b>Name and Position</b>   | Wenzhong Shu,<br>management representative  |                    |            |