DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 2014/53/EU 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 / NeoECG S120, NeoECG T180, NeoECG T120, LeECG OS12, LeECG OT12
We, Shenzhen Carewell Electronics Co., Ltd., Ltd. here with declare that the above mentioned products meet the provisions of the Directive 2014/53/EU and following Standards. The product described to be in conformity with the essential requirements Article 3.1(a), 3.1(b), and 3.2 of RED 2014/53/EU. 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	ETSI EN 300 328 V2.2.2 (2019-07) ETSI EN 301 893 V2.1.1 (2017-05) ETSI EN 300 440 V2.1.1 (2017-03) ETSI EN 301 908-1 V13.1.1 (2019-11) ETSI EN 301 908-13 V13.1.1 (2019-11) ETSI EN 301 489-1 V2.2.3 (2019-11) Draft ETSI EN 301 489-3 V2.1.2 (2021-03) ETSI EN 301 489-17 V3.2.4 (2020-09) Draft ETSI EN 301 489-52 V1.1.2(2020-12) EN 50566: 2017 EN 62209-2: 2010 EN 50663: 2017 IEC 60601-1:2005, AMD1:2012
Certificate issued by	Notified Body 1177, TIMCO Engineering, Inc.
Certificate number	E1177-211144/ E1177-211148
Place, Date of issue	Shenzhen, October 25, 2021
Signature	
Name and Position	Wenzhong Shu, management representative