1. Declaration of Conformity

Declaration of Conformity

For the following products:

Digital Multi-channel Electrocardiograph

(Product Name)

iMAC 12, iMAC 12pro

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)

EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, EN 1041:2008, EN 60601-1:2006/A1:2013, IEC 60601-2-25:2011, EN 60601-1-2:2015, EN 62304:2006/A1:2015, EN 62366-1:2015,EN 60601-1-6:2010/A1:2015, ETSI EN 300328 V2.2.2(2019-07), ETSI EN301489-1 V2.2.3(2019-11), Draft ETSI EN301489-17 V3.2.2(2019-12), EN 62479:2010.

Product Code

GMDN Code: 16231

GMDN Term: Electrocardiograph, interpretive

Classification and Conformity Assessment Route:

Classification: IIa

Conformity Assessment Route: Annex II excluding section 4 of Medical Device Directive

Notified Body:

DNV Product Assurance AS (NB No. 2460)

Veritasveien 1, 1363 Høvik, Norway

The following representative in Europe is responsible for making this declaration:

Company Name: Well kang Limited

Company Address: Enterprise Hub, NW Business Complex, 1 Beraghmore Road, Derry, BT48 8SE, Northern Ireland

Single Registration Number (SRN): XI-AR-000001836

The following manufacturer is responsible for making this declaration:

Company Name: Wuhan Zoncare Bio-medical Electronics Co., Ltd.

Company Address: #380, High-tech 2nd road, Eastlake high-tech district, Wuhan, Hubei, P. R. China

Single Registration Number (SRN): CN-MF-000010439

Qi Wang	General Manager	2023-3-20
(Legal Signature)	(Position/title)	(Date)