Declaration of Conformity

For the following products:

Vital Signs Monitor

PC100S、PC100PRO、PC100SE、PC100

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 (MDD, 93/42/EEC as amended by 2007/47/EC)

Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive 2011/65/EU)

Risk class of the device in accordance with the rule 10 set out in Annex IX of MDD: Class IIb

Conformity Assessment Route:

Annex II excluding section 4 of Medical Device Directive

GMDN Code: 57960

Harmonised standards:

EN 1041:2008; EN ISO 15223-1:2016;ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2013;EN ISO 13485:2016; EN ISO 14971:2019; EN 60601-1-6:2010 + A1:2015; IEC 62366-1:2015; EN 62304:2006 + A1:2015; EN 60601-1:2006 + A1:2013; EN 60601-1-2:2015; EN 80601-2-30:2010+A1:2015; IEC 60601-2-49:2018; ISO 80601-2-56:2017; ISO 80601-2-61:2017;2011/65/EU RoHS

Notified Body:

NOTICE Belgelendirme Muayene ve Denetim Hizmetleri A.S.

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

Company Name: Wellkang Ltd

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

CE Mark Start time： *CE Mark End time:* *Add：*

The following manufacturer is responsible for making this declaration:

Company Name: WUHAN UNION BIO-MEDICAL TECHNOLOGY CO.,LTD.

Company Address: BLD23 NO.5(1) DONGXIHU ROAD NO.5647 DONGXIHU DISTRICT WUHAN CITY, HUBEI, CHINA

	General Manager	2021.4.27
(Legal Signature)	(Position/title)	(Date)