

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:

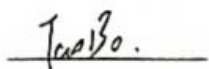
CE Mark End time:


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


(Legal Signature)

General Manager

(Position/title)

2021. 4. 27
(Date)