Declaration of Conformity

For the following products:

Blood Pressure Monitor

(Product Name)

RAK268

(Model Designation) *We manufacturer 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), is issued for Dr.Max Pharma.s.r.o*

Applicable harmonized standards are:

EN ISO 13485: 2016, EN ISO 14971: 2019, EN 60601-1: 2006+A1: 2013,

EN 60601-1-2: 2015, EN 60601-1-11: 2015, IEC 80601-2-30: 2018,

EN 60601-1-6: 2010+A1: 2015, EN 62366: 2008, EN 62304: 2006+A1: 2015,

EN ISO10993-1: 2009, EN ISO 10993-5: 2009, EN ISO 10993-10: 2010,

ENISO 15223-1:2016, EN 1041:2008

Product Classification: IIa

Conformity Assessment Route:

Annex II excluding section 4 of Medical Device Directive

Notified Body:

DNV Product Assurance AS (NB No. 2460)

Veritasveien 3, 1363 Hovik, Norway (NB No. 2460)

CE Mark: CE 2460

(EC) CERTIFICATE(S):

EC CERTIFICATE(S) NUMBER(S) 10000403189-PA-NA-CHN Rev. 00

SHOW ONLY THE EC CERTS WITH A SCOPE THAT COVERS THE PRODUCTS LISTED

The following European Authorized Representative is stated to the declaration:

EU REP:

Company Name: Wellkang Ltd

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

The following manufacturer is exclusively responsible for issue the EU Declaration of Conformity :

Company Name: Shenzhen Ruiankang Technology Co., Ltd.

Company Address: Floor 4, Building A, NO.10 Shibi Hongling Industrial Area, Liulian Community, Pingdi Street, Longgang District, Shenzhen, Guangdong, China

(Legal Signature)

Genera] Manager
(Position/title)

2022/03/29
(Date)