

## Declaration of Conformity to Council Directive 93/42 EEC (Including Directive 2007/47/EEC) Concerning Medical Devices

**Manufacturer:** Shenzhen Hingmed Medical Instrument Co., Ltd.  
**Address:** 4<sup>th</sup> Floor, Zhonghangfeixiang Building, NO. 371,  
Guangshen Road, Baoan District, Shenzhen.  
Guangdong, People's Republic of China

**European Representative:** Well Kang Ltd  
Enterprise Hub, NW Business Complex,1  
Beraghmore Road,Derry, BT48 8SE, Northern Ireland,UK.

**Product:** Wearable Ambulatory Blood Pressure Monitor  
**Model:** WBP-02A  
**Classification:** Rule 10/II a (MDD, Annex IX)  
**Conformity assessment route:** MDD, Annex II (excluding section 4)

We, the manufacturer, herewith declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June, 1993, concerning medical devices; including, at 21 march, 2010, the amendments by Council Directive 2007/47/EEC. All supporting documentation is retained at the premises of the manufacturer. The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product and/or by the expiration date of the related Annex II certificate issued by the notified body.

**Standards applied:** list of (harmonized) standards for which documented evidence of compliance can be provided, see the links below:

See the appendix table A

**Notified Body:** SGS Belgium NV  
SGS House Noorderlaan 87 2030 Antwerp Belgium

**Identification Number:**  1639

**(EC) Certificate(s):** CN19/41011

**Start of CE-marking:** 07 August, 2015

**Place, Date of Issue:** 16 December, 2019

**Signature:** Name: Zhang Pizhi  
Position: General Manager



**Appendix A – List of Harmonized Standards**

EN ISO 13485: 2016	EN ISO 14971:2012	EN 60601-1: 2006 + A1:2013
EN 60601-1-2: 2015	EN 60601-1-6: 2006	ISO 10993-1: 2009
ISO 10993-5: 2009	ISO 10993-10: 2010	EN 1060-1: 1995+A2:2009
EN 1060-3: 1997 + A2:2009	EN 62304: 2006	EN 62366: 2008
EN 60601-1-6: 2010	EN 80601-2-30: 2010	EN ISO 15223-1:2012
EN 1041: 2008	ISO 81060-2:2009	EN ISO 14155:2011
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