Declaration for the Compliance with the REGULATION(EU)2023/607 For the Extension of the Validity of CE Certificate

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and/or
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service.

Name and address of the manufacturer:	Shenzhen Hingmed Medical Instrument Co., Ltd. 4th Floor, Zhonghangfeixiang Building, NO. 371, Guangshen Road, Baoan District, Shenzhen. Guangdong, People's Republic of China
SRN (Manufucturer) :	CN-MF-000004838
Name and address of Authorized Representative:	Wellkang Ltd Enterprise Hub, NW Business Complex,1 Beraghmore Road,Derry, BT48 8SE, Northern Ireland,UK.
SRN (EU Authorised) :	XI-AR-000001836
(EC)CERTIFICATE(S)	CN 19/41011
Confirmation Letter	CLNB1639 - CN/SZX50055
Medical Device:	Clinical Automatic Blood Pressure Monitor **Model:** DBP-01P

We declare that the following criteria set out in REGULATION (EU) 2023/607 are met to make them eligible for the extension of the validity of the CE Certificate;

- QMS is in place in accordance with Article 10(9) MDR
- There are no significant changes in the design .
- There is no change in the intended use of the devices.
- The devices do not present an unacceptable risk.
- The devices continue to comply with Directive 93/42/EEC MDD, as applicable.

• The MDR requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are met.
• Notified Body responsible for the surveillance of the devices.We confirm that, our existing MDD Certificate which expires on 2023-08-6, will benefit from the MDR transition period until 31st December 2028, taking into consideration the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

The required contract for MDR conformity assessment has already been signed by our Notified Body,SGS Belgium NV(NB#1639).

We confirm that all the products that are listed in the above mentioned certificate will benefit from this transition.

Shenzhen, 2024/05/31 — **Zhangpizhi General manager**

Place, date — **Name and function**