

# DECLARATION of CONFORMITY to Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices



**Manufacturer:** *BMV Technology Co., Ltd.,*  
*located: 4/F, BMV of Yinjin Building, Block 71, Baoan Centre District, Shenzhen 518010, People's Republic of China*

**Medical Device:** Diagnostic Ultrasound System

**Model(s):** PT50C

**Conformity assessment Route:** Annex 2 excluding (4)

We, BMV Technology Co., Ltd., herewith declare 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 Manufacturer is full charge of the current Declaration of Conformity.

*Standards applied: ISO 13485 2016, IEC 60601-1 2012, IEC 60601-1-2 2014, IEC 60601-1-8 2012, IEC 62304 2015, IEC 62366-1 2015, IEC 60601-1-6 2013, ISO/IEC 80601-2-12 2011, ISO 11195:2018, ISO 5367:2014, ISO 15223-1 2016, EN ISO 14971 2012, EN 1041 2008+A:2013, ISO 80601-2-55 2018, ISO 15001 2010, EN ISO 14155 2011, BS, EN ISO 780:2015, IEC/TR 60878 2015, IEC 60529 2013, ISO 5356-1 2015, MDD93/42/EEC, MEDDEV 2.7/1 rev. 4:2016.*

**Notified Body:** TÜV SÜD Product Service GmbH  
Ridlerstr 65, D-80339 München, Germany

**Identification number:** 0123

**(EC) Certificate(s):** G1 11 03 72132 002



**European Representative:** Shanghai Internation Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, Germany

**Start of CE-Marking:**

**Place, Date of Declaration:** Shenzhen, 2020.3.8

**Signature:**



*NAME: Mr. David Luo*

*POSITION: General Manager*