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## EC Declaration of Conformity to Council Directive 93/42/EEC

**MANUFACTURER:** Shenzhen Wisonic Medical Technology Co., Ltd.

**ADDRESS:** 1st, 2nd & 5th Floor, NO.6 Building, Pingshan Technology Park, Taoyuan Street, Nanshan District, 518055, Shenzhen, P. R. China

**PRODUCT:** Ultrasonic Diagnostic System and Patient Monitor

**MODEL:** Navi i, Navi s, Navi e, Navi u, Navi T, Navi X; Clover 50, Clover 60, Clover 70, Clover 50T, Clover 60T, Clover w, Clover i, Clover s; Piloter Exp, Piloter, Piloter T, Piloter PE, Piloter P, Piloter S, Piloter B, Piloter D, Piloter F, Piloter R, Piloter RE, Piloter V, Piloter U, Piloter SE, Piloter i, Piloter X;

**CLASSIFICATION - ANNEX IX:** CLASS IIA, RULE 10

**CONFORMITY ASSESSMENT ROUTE:** Annex II Excluding (4)

We, Shenzhen Wisonic Medical 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 OJ L 169 of 12 July 1993, the amendments by Council Directive 2007/47/Recall supporting documentation is retained at the premises of the manufacturer. We are exclusively responsible for the DoC.

**STANDARDS APPLIED:** (published in the Official Journal of the European Communities) applicable to this product are: EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016, EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010, EN 60601-2-37:2008, EN ISO10993-1:2009/AC:2010, EN 62304:2006/AC:2008, EN ISO 13485: 2016,

**NOTIFIED BODY:** TÜV SÜD Product service GmbH  
Ridlerstr 65, D-80339 München, Germany

**IDENTIFICATION NUMBER:** 0123

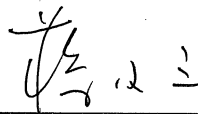
**(EC) CERTIFICATE(S):** G1 093557 0009, Rev.00

**EUROPEAN REPRESENTATIVE:** Wellkang Ltd  
The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

### START OF CE-MARKING:

**PLACE, DATE OF DECLARATION:** SHENZHEN, Feb 14, 2020

**SIGNATURE:**



NAME: JIANG XIAOSAN

POSITION: MANAGEMENT REPRESENTATIVE