

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

VINNO Technology (Suzhou) Co., Ltd

5F Building A, 4F Building C, No.27 Xinfu Road,
Suzhou Industrial Park, Suzhou, 215123 Jiangsu,
China

WellKang Ltd (www.CE-marking.eu)
Enterprise Hub, NW Business Complex,
1 Beraghmore Road, Derry, BT48 8SE,
Northern Ireland, UK

We, the manufacturer, herewith declare that the products

Product Name:

Ultrasound Diagnostic System

Product Model Number or Designator:

VINNO G90, VINNO G90E, VINNO M90, VINNO M90E,
VINNO G86, VINNO G86E with probes as below:
G2-5C, F2-5C, X2-6C, B2-6C, S1-8C, S2-9C, D3-6C, D3-6CE, D3-6CX, D4-9E, F4-9E, G4-9E, X4-9E, G3-9M, G4-9M, I4-11T, I7-18L, U5-15L, U5-15LE, F4-12L, X4-12L, X3-10L, X6-16L, X9-22L, X10-23L, S1-6P, G1-4P, G3-10PX, G4-12P, BP4-9

VINNO M86, VINNO M86E, VINNO 75, VINNO 75E, VINNO 75P, VINNO 75D, VINNO X9, VINNO X9E, VINNO X9P, VINNO X9D, VINNO G65, VINNO G65E, VINNO G65P, VINNO G65D, VINNO 65, VINNO 65E, VINNO 65P, VINNO 65D, VINNO X8, VINNO X8E, VINNO X8P, VINNO X8D
probes as below:
G2-5C, F2-5C, X2-6C, B2-6C, S1-8C, S2-9C, D3-6C, D3-6CE, D3-6CX, D4-9E, F4-9E, G4-9E, X4-9E, G3-9M, G4-9M, I4-11T, I7-18L, U5-15L, U5-15LE, F4-12L, X4-12L, X3-10L, X6-16L, X9-22L, X10-23L, S1-6P, G1-4P, G3-10PX, G4-12P, BP4-9

VINNO G80, VINNO M80, VINNO G60, VINNO 60, VINNO 70, VINNO 80 with probes as below:
G2-5C, X2-6C, B2-6C, S1-8C, S2-9C, D3-6C, D3-6CX, D4-9E, G4-9E, X4-9E, G4-9M, I4-11T, U5-15L, X3-10L, X4-12L, X6-16L, X9-22L, S1-6P, G1-4P, G3-10PX

VINNO G55, VINNO G55E, VINNO G55P, VINNO M55, VINNO M55E, VINNO M55P, VINNO E35, VINNO E35E, VINNO E35P, VINNO G50, VINNO M50, VINNO E30, VINNO X5, VINNO X6, VINNO X7, VINNO X65, VINNO X55, VINNO X35 with probes as below:
G2-5C, F2-5C, X2-6C, B2-6C, S1-8C, S2-9C, D3-6C, D3-6CE, D3-6CX, D4-9E, F4-9E, G4-9E, X4-9E, G3-9M, G4-9M, I4-11T, U5-15LE, F4-12L, X4-12L, X3-10L, X6-16L, X9-22L, S1-6P, G1-4P, G3-10PX

VINNO 8, VINNO 6, VINNO 5, VINNO 6EXP, VINNO 6PRO, VINNO 5EXP, VINNO 5PRO, VINNO 3, VINNO 3EXP, VINNO 3PRO, eZono5000 with probes and carts as below:
Probes: D3-6C, D3-6CE, D4-9E, F2-5CE, F4-9E, F4-12L, G1-4P, G2-5C, G4-9E, G4-9M, I4-11T, I7-18L, S1-6P, U5-15LE, X4-12L, X6-16L, X10-23L, X9-22L, G3-8M, G3-10P, G3-10PX, X6-16LG.
Carts: CART-F, CART-S, CART-L

VINNO A6, VINNO A6e, VINNO A6p, VINNO A5, VINNO A5e, VINNO A5p, VINNO A3, VINNO A3p, VINNO A2, VINNO A2p, VINNO A1, VINNO A1p with probes and carts as below:
Probes: A2-5C, A3-6D, A4-9E, A4-9M, A4-12L, A1-4P

Carts: CART

VINNO E20, VINNO E10, VINNO E10E, VINNO E10P, VINNO X3, VINNO X2, VINNO X2E, VINNO X2P, VINNO X1, VINNO X1E, VINNO X1P with probes as below:
D3-6C, D3-6CE, F4-9E, F4-12L, G1-4P, F2-5C, G4-9E, G4-9M and X4-12L

VINNO Q3E-3C, VINNO Q3-3C, VINNO Q3S-3C, VINNO Q5E-3C, VINNO Q5-3C, VINNO Q5S-3C, VINNO Q3E-7L, VINNO Q3-7L, VINNO Q3S-7L, VINNO Q5E-7L, VINNO Q5-7L, VINNO Q5S-7L, VINNO Q3E-2P, VINNO Q3-2P, VINNO Q3S-2P, VINNO Q5E-2P, VINNO Q5-2P, VINNO Q5S-2P

meet the provisions of Directives below and their transpositions in national laws which apply to it.

- Council directive 93/42/EEC concerning medical devices
- Council directive 2014/53/EU on radio equipment directive
- Directive 2011/65/EU of European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC .

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: DD 60137559 0001

Issue date: 2019-05-22

Expiry date: 2024-05-27

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: VINNO Technology (Suzhou) Co., Ltd

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Suzhou, 2022-04-02

Name: Xishui

Title: GM, VINNO Technology (Suzhou) Co., Ltd.

