EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60137559 0001

Report No.: 15081806 011

Manufacturer:
VINNO Technology (Suzhou)
Co., Ltd.
5F Building A,4F Building C
No. 27 Xinfa Rd.
Suzhou Industrial Park
Suzhou
215123 Jiangsu
China

Products:
Ultrasound Diagnostic Systems

Replaces Approval, Registration No.: DD 60109994 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-07-20

Date: 2019-05-22

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Lungu Ion
Date: 2024.02.08 15:24:56 EET
Reason: MoldSign Signature
Location: Moldova

EC Declaration of Conformity

Manufacturer:

VINNO Technology (Suzhou) Co., Ltd

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

whose single Authorized Representative:

Wellkang Ltd

The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

We, the manufacturer, herewith declare that the products

Product Name: **Ultrasound Diagnostic System**

Product Model Number or Designator:

VINNO G86, VINNO G86E, VINNO G86P, VINNO M86, VINNO M86E, VINNO M86P with probes as below:
G2-5C, 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-IIT, I7-18L, U5-15L, F4-12L, X4-12L, X3-10L, X6-16L, X9-22L, X10-23L, S1-6P, G1-4P, G3-10PX, G4-12P

VINNO 75, VINNO 75E, VINNO 75P, VINNO G65, VINNO G65E, VINNO G65P, VINNO G80, VINNO M80, VINNO G60, VINNO X8, VINNO X9, 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 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

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

Suzhou, 2020-07-20

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

证书编号：04721Q10049R2M

质量管理体系认证证书

兹证明

飞依诺科技（苏州）有限公司

（统一社会信用代码：91320594553842486 8）

住　　所：苏州工业园区新发路 27 号 A 栋 5 楼、C 栋 4 楼

生产地址：苏州工业园区新发路 27 号 C 栋 4 楼、B 栋 2 楼

质量管理体系符合：

GB/T 19001-2016 idt ISO 9001:2015

体系覆盖：

便携式数字化彩色超声诊断仪、数字化彩色超声诊断仪、掌上彩色超声诊断仪、超声工作站系统软件的设计开发、生产和服务。

颁证日期：2021 年 03 月 02 日

有效期至：2024 年 03 月 01 日

总经理：

北京国医械华光认证有限公司

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

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证书编号：04721Q10000064

医疗器械

质量管理体系认证证书

兹证明

飞依诺科技（苏州）有限公司

（统一社会信用代码：91320594553842486 8）

住　　所：苏州工业园区新发路27号A栋5楼、C栋4楼

生产地址：苏州工业园区新发路27号C栋4楼、B栋2楼

质量管理体系符合：

YY/T 0287-2017 idt ISO 13485:2016

体系覆盖：

便携式数字化彩色超声诊断仪、数字化彩色超声诊断仪、掌上彩色超声诊断仪、超声工作站系统软件的设计开发、生产和服务。

颁证日期：2021 年 03 月 02 日

有效期至：2024 年 03 月 01 日

总经理：李朝晖

北京国医械华光认证有限公司

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REGISTRATION NO. 04721Q10049R2M

CERTIFICATE
OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

VINNO Technology (Suzhou) Co., Ltd.

Registered Address: 5F Building A, 4F Building C No. 27 XinFa Rd. Suzhou Industrial Park, SuZhou Jiangsu China

Manufacturing Address: 4F Building C, 2F Building B No. 27 XinFa Rd. Suzhou Industrial Park, SuZhou Jiangsu China

Has been assessed and conformed to the following standard(s)

GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

The design, development, production and service of Portable Ultrasound Diagnostic Systems, Ultrasound Diagnostic Systems , Hand-held Ultrasound Diagnostic Systems and Ultrasound workstation system.

Date of issue: March 02,2021

Date of expiry: March 01,2024

General Manager:

BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

CNAS

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

REGISTRATION NO. 04721Q10000064

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

VINNO Technology (Suzhou) Co., Ltd.

Registered Address: 5F Building A, 4F Building C No. 27 XinFa Rd. Suzhou Industrial Park, SuZhou Jiangsu China

Manufacturing Address: 4F Building C, 2F Building B No. 27 XinFa Rd. Suzhou Industrial Park, SuZhou Jiangsu China

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The design, development, production and service of Portable Ultrasound Diagnostic Systems, Ultrasound Diagnostic Systems , Hand-held Ultrasound Diagnostic Systems and Ultrasound workstation system.

Date of issue: March 02,2021

Date of expiry: March 01,2024

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993