

**Către Agenția Medicamentului  
și Dispozitivelor Medicale**

**NOTIFICARE**

pentru înregistrarea dispozitivelor medicale în Registrul de stat  
al dispozitivelor medicale nr. **234** din **06.11.2023**

“**Health Medical Solutions**” SRL, cu sediul Republica Moldova, MD-2019, mun. Chișinău, str. Grenoble 128, of. 011, E-mail: [info@hms.md](mailto:info@hms.md), [srl.hms.moldova@gmail.com](mailto:srl.hms.moldova@gmail.com), solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a dispozitivelor **clasa de risc IIa**:

**1. SISTEM ULTRASONOGRAFIC PENTRU DIAGNOSTIC**, denumire comercială – **Ultrasound Diagnostic System**, model – **ULTIMUS 9E**, producător - **VINNO TECHNOLOGY (SUZHOU) CO., LTD.**, țara de origine - **China**;

**Se anexează următoarele acte:**

1. Certificat CE no. 6104728CE01 din 20.04.2023, valabil – 01.04.2028;
2. Certificat ISO 13485:2016 No. 6104727, valabil 01.07.2021 – 01.07.2024;
3. Declarație de conformitate VINNO TECHNOLOGY
4. Declarație pe proprie răspundere.

Data: **06.11.2023**

Semnătura

**Tabelul de recepționare a notificării**

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

**DECLARAȚIE PE PROPRIE RĂSPUNDERE**

“**Health Medical Solutions**” SRL, cu sediul Republica Moldova, MD-2019, mun. Chișinău, str. Grenoble 128, of. 011 E-mail: [info@hms.md](mailto:info@hms.md), [srl.hms.moldova@gmail.com](mailto:srl.hms.moldova@gmail.com), declar pe proprie răspundere, cunoscând prevederile art. 352<sup>1</sup>, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

**1. SISTEM ULTRASONOGRAFIC PENTRU DIAGNOSTIC**, denumire comercială – **Ultrasound Diagnostic System**, model – **ULTIMUS 9E**, producător - VINNO TECHNOLOGY (SUZHOU) CO., LTD., țara de origine - **China**;

**Sunt autentice și corespund realității.**

*Numele, prenumele și funcția*

*Lungu Ion, Administrator*

+37379627404, +37369423432

*Semnătura*

Data 06.11.2023

Number: 6104728CE01

# EU Quality Assurance Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex XI Part A

Manufacturer:

**VINNO Technology (Suzhou) Co., Ltd.**

5F, Building A, 4F Building C, No. 27, Xinfu Road

Suzhou Industrial Park

215123 Suzhou, Jiangsu

China

SRN ID.: CN-MF-000003949

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

## 0344

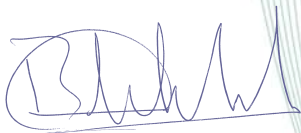
Supplement to certificate: 6104727CN

**Authorized Representative: Umedwings Netherlands B.V.**

**Treubstraat 1, 2288EG, Rijswijk, the Netherlands**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.M.A. McKenzie  
Principal Certification Manager

First Issued: **20 April 2023**

Date: **20 April 2023**

Expiry date: **1 April 2028**

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands  
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 6104728CE01

# EU Quality Assurance Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex XI Part A

This certificate covers the following device(s) / groups of device(s):

**Active non-implantable imaging devices utilizing non-ionizing radiation (MDA0202, IIa)**

**Device Name:** Ultrasound Diagnostic Systems

Conditions for or limitations to the validity of this certificate:

- N/A

## Certificate History

*Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.*

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	20 April 2023	6104727CN02	first issue

First Issued: **20 April 2023**

Date: **20 April 2023**

Expiry date: **1 April 2028**

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DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands  
T +31 88 96 83000 www.dekra.nl Company registration 09085396

## EU Declaration of Conformity

<p>MANUFACTURER (name and address):</p>	<p>VINNO Technology (Suzhou) Co., Ltd 5F Building A, 4F Building C, No.27 Xinfra Road, Suzhou Industrial Park, Suzhou, 215123 Jiangsu, China</p>
<p>SRN:</p>	<p>CN-MF-000003949</p>
<p>AUTHORIZED REPRESENTATIVE (name and address):</p>	<p>Umedwings Netherlands B.V. Treubstraat 1, 2288EG, Rijswijk, the Netherlands</p>

**PRODUCTS:**

Product Name	Product code	Basic UDI-DI	Description	Classification
Ultrasound Diagnostic System	GMDN: 40761; NBOG code MDA0202	697047288V01010 19Y	Cart type (Traditional size)	Class IIa
Ultrasound Diagnostic System	GMDN: 40761; NBOG code MDA0202	697047288V01010 2A2	Portable machine (Laptop size)	
Ultrasound Diagnostic System	GMDN: 40761; NBOG code MDA0202	697047288V01010 3A4	Handheld (Compact size)	

CONFORMITY ASSESSMENT ROUTE	MDR 2017/745 Annex XI (Part A, Sec.10)
Classification	Class IIa

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED:	Applied standards are listed in the General Safety and Performance Requirements Checklist
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NOTIFIED BODY:	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands Notified body number: <b>0344</b>
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EU CERTIFICATE:	6104728CE01
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EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE:	N/A
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Place, Date of issue: Suzhou 2023-05-22

SIGNATURE:



Shui Xi  
General Manager  
For and on behalf of  
VINNO Technology (Suzhou) Co., Ltd.

Product Models	UDI-DI	Description	probes
VINNO R300	06970472882241	Cart type (Traditional size)	G1-4P、G2-5C、S2-9C、 X4-12L、X3-10L、X6- 16L、X9-22L、D3-6C、G3- 9M、G4-9M、B2-6C、U5- 15LE、D4-9E、S1-6P、F2- 5C、F4-12L、F4-9E、X4- 9E、G3-10PX、X2-6C、 G4-9E、X10-23L、G3- 10P、G4-12P、G1-3R、 BP4-9、I7-18L、D2-6C、 D2-7C、S1-8CM、S1-6PS
VINNO R310	06970472882258		
VINNO R320	06970472882265		
VINNO R330	06970472882272		
VINNO R350	06970472882289		
VINNO R360	06970472882296		
VINNO R370	06970472882302		
VINNO R380	06970472882319		
VINNO R500	06970472882326		
VINNO R510	06970472882333		
VINNO R520	06970472882340		
VINNO R530	06970472882357		
VINNO R550	06970472882364		
VINNO R560	06970472882371		
VINNO R570	06970472882388		
VINNO R580	06970472882395		
VINNO R600	06970472882401		
VINNO R610	06970472882418		
VINNO R620	06970472882425		
VINNO R630	06970472882432		
VINNO R650	06970472882449		
VINNO R660	06970472882456		
VINNO R680	06970472882463		
VINNO R700	06970472882470		
VINNO R710	06970472882487		
VINNO R720	06970472882494		
VINNO R730	06970472882500		
VINNO R750	06970472882517		
VINNO R760	06970472882524		
VINNO R780	06970472882531		
VINNO 9	06970472882876	Portable machine (Laptop size)	S2-9C、X2-6C、G2-5C、 F2-5C、B2-6C、D3-6C、 D2-6C、D2-7C、D4-9E、 G4-9E、X4-9E、F4-9E、 BP4-9、G4-9M、G3-9M、 X4-12L、X3-10L、X6-16L、 X6-16LG、U5-15LE、F4- 12L、I7-18L、X9-22L、 X10-23L、G1-4P、G4- 12P、S1-6P、G3-10PX、 G1-3R、S1-8CM Carts: CART-F, CART-S, CART-L
VINNO 9E	06970472882883		
VINNO 9P	06970472882890		
VINNO 10	06970472882906		
VINNO 10E	06970472882913		
VINNO 10P	06970472882920		
ULTIMUS 9E	06970472883071	Cart type (Traditional size)	S1-8CM、S1-9C、S2-9C、 F2-5C、G2-5C、X2-6C、
ULTIMUS 9P	06970472883088		

ULTIMUS 9	06970472883095		B2-6C, D3-6C, D2-6C, D2-7C, D4-9E, G4-9E, X4-9E, F4-9E, X4-12L, X6-16L, F4-12L, U5-15L, U5-15LE, X9-22L, X10-23L, X3-10L, G1-4P, S1-6P, G4-12P, G3-10PX, I7-18L, G3-9M, G4-9M, BP4-9, G1-3R
ULTIMUS 8E	06970472883101		
ULTIMUS 8P	06970472883118		
ULTIMUS 8	06970472883125		
ULTIMUS 7E	06970472883132		
ULTIMUS 7P	06970472883149		
ULTIMUS 7	06970472883156		
ULTIMUS 6E	06970472883163		
ULTIMUS 6P	06970472883170		
ULTIMUS 6	06970472883187		
ULTIMUS 5E	06970472883194		
ULTIMUS 5P	06970472883200		
ULTIMUS 5	06970472883217		
VINNO P3E-2P	06970472882722		
VINNO P5E-2P	06970472882746		
VINNO P7E-2P	06970472882760		
VINNO P3E-3C	06970472882609		
VINNO P5E-3C	06970472882623		
VINNO P7E-3C	06970472882647		
VINNO P3E-7L	06970472882661		
VINNO P5E-7L	06970472882685		
VINNO P7E-7L	06970472882708		
VINNO P3-2P	06970472882739		
VINNO P5-2P	06970472882753		
VINNO P7-2P	06970472882777		
VINNO P3-3C	06970472882616		
VINNO P5-3C	06970472882630		
VINNO P7-3C	06970472882654		
VINNO P3-7L	06970472882678		
VINNO P5-7L	06970472882692		
VINNO P7-7L	06970472882715		

# CERTIFICATE

Number: 6104727

The management system of:

## VINNO Technology (Suzhou) Co., Ltd.

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

including the implementation meets the requirements of the standard:

## EN ISO 13485:2016

Scope:

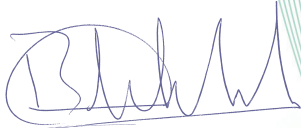
Manufacture and Distribution of Ultrasound Diagnostic Systems

Certificate expiry date: 1 July 2024

Certificate effective date: 1 July 2021

Certified since: 1 July 2021

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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Date: 6 November 2023

## LETTER OF AUTHORIZATION

To Whom it May Concern,

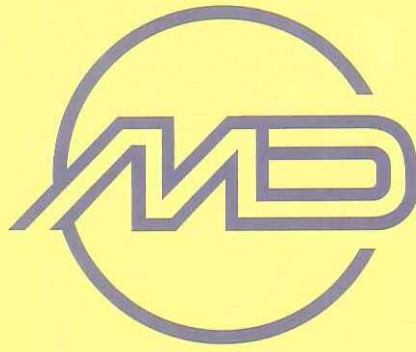
We, **VINNO Technology (Suzhou) Co., Ltd.**, who are official manufacturer of color Doppler ultrasound system, having headquarters at 5F Building A, No.27 Xinfu Road, Suzhou Industrial Park, 215123, P.R.China, assign - company **HEALTH MEDICAL SOLUTIONS S.R.L.**, based at Moldova Republic of, Chisinau, MD-2019, 128, Grenoble str., OF.011

- as authorized representative in the Republic of Moldova in correspondence with the conditions of *Directive Regulation (EU) n. 2017/745*.
- We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the in territory of Republic of Moldova, and to perform Essential Duties required by Law No. 102 on 09.06.2017 regarding Medical Devices.

This Authorization letter is valid until 31.12.2024.

*Signature and stamp*





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：913205945538424868）

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

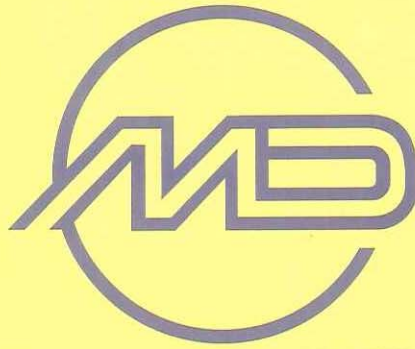
有效期至：2024 年 03 月 01 日

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



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:

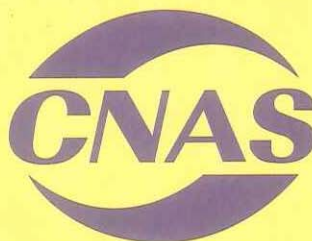
The design, development, production and service of Portable Ultrasound Diagnostic Systems, Ultrasound Diagnostic Systems, Hand-held Ultrasound Diagnostic Systems and Ultrasound workstation system.

Date of issue: March 02, 2021

Date of expiry: March 01, 2024

General Manager:

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



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