EC CERTIFICATION

EU Quality Management System Certificate

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Guangzhou Sonostar Technologies Co., Ltd.

504#, C Building, #27 Yayingshi Road, Science Town, Guangzhou, China 510665

Manufacturer SRN: CN-MF-000030303

Authorised Representative Name

SUNGO Europe B.V.

Fascinatio Boulevard 522, Unit 1.7,, 2909 VA Capelle aan den Ijssel, Netherlands

Scope:

- Ultrasound scanners

Certificate Number:
28620203593

Revision:
00

Initial Certification Date:
22 January 2025

Certificate Decision Date:
22 January 2025

Certificate Issue Date:
22 January 2025

Certificate Expiry Date:
18 November 2029

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00229-02 Ultrasound scanner**
Audit Report Reference	**Stage 1 audit ACTY-2022-590752**
	Stage 2 audit ACTY-2022-590758
	Repeat Stage 2 audit ACTY-2024-226023

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620203593	22 January 2025	Initial Certificate

Certificate Number:
28620203593

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PRODUCT LIST FOR CERTIFICATE

Issued to: Guangzhou Sonostar Technologies Co., Ltd.

Certificate number: 28620203593

Certificate valid from: 2025-01-22

Product List Issue Date:
22 January 2025

Product	Classification and EMDN	Intended use[1]	Date Added
Ultrasound scanners			
Basic UDI-DI: 697067275CProbe9A			
BProbe - Wireless Probe Type Ultrasound Scanner	Class IIa Z110401		2025-01-22
CProbe - Wireless Probe Type Ultrasound Scanner	Class IIa Z110401		2025-01-22
UProbe-C - Wireless Probe Type Ultrasound Scanner	Class IIa Z110401		2025-01-22
Basic UDI-DI: 697067275WirelessProbeR7			
UProbe-L - Wireless Probe Type Ultrasound Scanner	Class IIa Z110401		2025-01-22

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.