

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			
I			

Certificate Number:

28620203593

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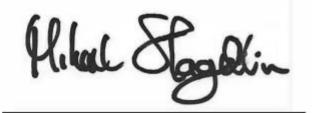
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CERTIFICATE HISTORY

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





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Issued to: Guangzhou Sonostar Technologies Co., Ltd.

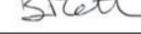
17 March 2025

Product List Issue Date:

Certificate number: 28620203593

Certificate valid from: 2025-01-22

Product	Classification and EMDN	Intended use ¹	Date Added			
Ultrasound scanners						
Basic UDI-DI: 697067275WirelessProbeR7						
BProbe - Wireless Probe Type	Class Ila		2025-01-22			
Ultrasound Scanner	Z110401					
CProbe-CL - Wireless Probe Type	Class Ila		2025-03-17			
Ultrasound Scanner	Z110401					
CProbe-CT - Wireless Probe Type	Class Ila		2025-03-17			
Ultrasound Scanner	Z110401					
CProbe-C - Wireless Probe Type	Class Ila		2025-03-17			
Ultrasound Scanner	Z110401					
CProbe-L - Wireless Probe Type	Class Ila		2025-03-17			
Ultrasound Scanner	Z110401					
UProbe-C - Wireless Probe Type	Class Ila		2025-01-22			
Ultrasound Scanner	Z110401					
UProbe-L - Wireless Probe Type	Class Ila		2025-01-22			
Ultrasound Scanner	Z110401					



Brian Mather

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