

# 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 |
|------|

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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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PRODUCT LIST FOR CERTIFICATE

Issued to:

Guangzhou Sonostar Technologies Co., Ltd.

Certificate number:

28620203593

Certificate valid from:

2025-01-22

Product List Issue Date:

17 March 2025

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



**Brian Mather**  
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<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

