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.

TERATECH Corporation

77-79 Terrace Hall Avenue Burlington, Massachusetts 01803, United States

Manufacturer SRN: US-MF-000033295

Authorised Representative:
Wellkang Ltd
Enterprise Hub, NW Business Complex,, BT48 8SE Derry, Northen Ireland

Scope:
Ultrasound imaging devices

Certificate Number:
28620253687

Revision:
00

Initial Certification Date:
13 August 2026

Certificate Decision Date:
13 August 2026

Certificate Issue Date:
13 August 2026

Certificate Expiry Date:
01 March 2031

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

Last Audit report reference	**ACTY-2023-622232**
	ACTY-2025-386671
Last Technical Assessment report reference	**TD00552-001**
	TD00552-002
	TD00552-003

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620253687	13 August 2026	Initial certificate

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PRODUCT LIST FOR CERTIFICATE

Issued to: TERATECH Corporation

Certificate number: 28620253687

Certificate valid from: 2026-08-13

Product list issue date:
13 August 2026

Product	Classification and EMDN	Intended use[1]	Date Added
Ultrasound imaging devices			
Basic UDI-DI: 852698007003HV			
UDI-DI: 00852698007003 - 15L4 Transducer	Class IIa Z11040299		2026-08-13
Basic UDI-DI: 852698007010HS			
UDI-DI: 00852698007010 - 5C2A Transducer	Class IIa Z11040299		2026-08-13
Basic UDI-DI: 852698007027JB			
UDI-DI: 00852698007027 - 4V2A transducer	Class IIa Z11040299		2026-08-13
Basic UDI-DI: 852698007058JN			
UDI-DI: 00852698007058 - 8V3A Transducer	Class IIa Z11040299		2026-08-13
Basic UDI-DI: 852698007065JK			
UDI-DI: 00852698007065 - 9MC3 Transducer	Class IIa Z11040299		2026-08-13
Basic UDI-DI: 852698007072JG			
UDI-DI: 00852698007072 - 16HL7 Transducer	Class IIa Z11040299		2026-08-13
Basic UDI-DI: 852698007096JW			
UDI-DI: 00852698007096 - 12L5A Transducer	Class IIa Z11040299		2026-08-13
Basic UDI-DI: 85269800714OJ8			

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

Product	Classification and EMDN	Intended use[1]	Date Added
UDI-DI: 00852698007140 - 15L4A Transducer	Class IIa Z11040299		2026-08-13
Basic UDI-DI: 852698007218JL			
UDI-DI: 00852698007218 - uSmart3200T	Class IIa Z11040103		2026-08-13
Basic UDI-DI: 852698007225JH			
UDI-DI: 00852698007225 - uSmart3300	Class IIa Z11040103		2026-08-13
Basic UDI-DI: 852698007409JV			
UDI-DI: 00852698007409 - 8BP4 Bi-Plane	Class IIa Z1104020201		2026-08-13
Basic UDI-DI: 852698007508JY			
UDI-DI: 00852698007508 - uSmart3200T Plus	Class IIa Z11040103		2026-08-13
Basic UDI-DI: 852698007522JS			
UDI-DI: 00852698007522 - 15WL4 (50mm) Linear Wide Transducer	Class IIa Z11040299		2026-08-13
Basic UDI-DI: 852698007539KB			
UDI-DI: 00852698007539 - XY Transducer	Class IIa Z11040299		2026-08-13

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