

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.

TOMCO2 Systems Company Corp DBA phasetwo

1110 Ridgeland Parkway, Suites 110 and 104, Alpharetta, Georgia, 30004,
United States

Manufacturer SRN: US-MF-000035246

Authorised Representative:

MedEnvoy Global BV [EN]

33, Prinses Margrietplantsoen, 2595 AM, The Hague

Scope:

Cryogenic storage devices

Certificate Number:
28620236311

Revision:
00

Initial Certification Date:
19 January 2026

Certificate Decision Date:
19 January 2026

Certificate Issue Date:
19 January 2026

Certificate Expiry Date:
15 February 2030



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	Stage 1 - ACTY-2024-179291
	Stage 2 - ACTY-2024-179293
Technical Assessment Report Reference	TD00414-001 - Cryogenic Rack Freezer

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620236311	19 January 2026	Initial certificate



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PRODUCT LIST FOR CERTIFICATE

Issued to: TOMCO2 Systems Company Corp DBA
Phasetwo

Certificate number: 28620236311

Certificate valid from: 2026-01-19

Product list issue date:
19 January 2026

Product	Classification and EMDN	Intended use ¹	Date Added
Cryogenic storage devices			
Basic UDI-DI: 081012237ALUMINUM00HZ			
LN2 DEWAR	Class IIa U08020401		2026-01-19
LN2 DEWAR	Class IIa U08020401		2026-01-19
LN2 DEWAR	Class IIa U08020401		2026-01-19
LN2 DEWAR	Class IIa U08020401		2026-01-19
LN2 DEWAR	Class IIa U08020401		2026-01-19
LN2 DEWAR	Class IIa U08020401		2026-01-19
LN2 DEWAR	Class IIa U08020401		2026-01-19
LN2 DEWAR	Class IIa U08020401		2026-01-19
LN2 DEWAR	Class IIa U08020401		2026-01-19
Basic UDI-DI: 081012237STAINLESS00M5			
LN2 DEWAR, W/O CONTROL	Class IIa U08020401		2026-01-19
LN2 DEWAR, W/O CONTROL	Class IIa U08020401		2026-01-19
LN2 DEWAR, W/O CONTROL	Class IIa U08020401		2026-01-19

¹The 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
LN2 DEWAR, W/O CONTROL	Class IIa U08020401		2026-01-19



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