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

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Manufacturer SRN: US-MF-000035246

Authorised Representative:

MedEnvoy Global BV [EN]

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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
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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.