

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ThermoGenesis Corp.
2711 Citrus Road
Rancho Cordova
California
95742
USA

Facility ID Number: F003279

Holds Certificate No:

MDSAP 704865

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development, manufacture, installation, and servicing of cell separation systems.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-03-12

Effective Date: 2023-01-13

Expiry Date: 2026-01-12



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 1

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