By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 614420**

Issued To: **ThermoGenesis Corp.**
2711 Citrus Road
Ranch Cordova
California
95742
USA

In respect of:

Design, development and manufacture of cord blood processing systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-01-13** Date: **2021-01-11** Expiry Date: **2024-05-26**

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Supplementary Information to CE 614420

Issued To:

ThermoGenesis Corp.
2711 Citrus Road
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NBOG code(s)	Device description	Intended Purpose
Class IIa		
MD 1101 MD 0102	Cord blood processing system and accessories	N/A for class IIa

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	**Service(s) supplied**
MDSS GmbH Schiffgraben 41 Hannover 30175 Germany	**EU Representative**
Synergy Health AST, SRL B16, Street 4, Avenue O El Coyol Free Zone El Coyol Alajuela 20102 Costa Rica	**Radiation (E Beam Sterilization)**
Viant Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal de Heredia 40101 Costa Rica	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 614420**

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Issue Date	Reference Number	Description
13 January 2015	8153014	First issue. Transfer from another Notified Body.
26 October 2015	8351134	Change of Legal manufacturer name as 'ThermoGenesis Corp. (Cesca Therapeutics Inc.)'.
11 January 2016	8405704	Renewal. Reduction of scope to 'Design, Development and Manufacture of Freezers for Biological Materials, Stem Cell and Bone Marrow Processing Systems and Fibrin processing systems.' Inclusion of reference to sterile accessories associated with the Bone marrow processing system in the scope. Addition of 'Control of Sterilization' activity to significant subcontractors, Vention Medical. Addition of 'Synergy' and 'Steris' as significant subcontractors for sterilization activities.
30 August 2016	8573919	Change of Legal manufacturer name to 'Cesca Therapeutics Inc. Dba ThermoGenesis Corp'.
06 September 2017	8676453	Removal of subcontractors: - Vention Medical Inc - Steris Isomedix Services Reduction in scope to remove 'Those Aspects of.....' and 'Freezers for Biological Materials' Rewording of scope to replace stem cells with blood. Company name change to ThermoGenesis Corp.

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Issue Date	Reference Number	Description
27 February 2019	8868089	Traceable to NB 0086.
Current	9775360	Certificate renewal Reduction of scope from Design, development and manufacture of blood and bone marrow processing systems and fibrin processing systems. To Design, development and manufacture of cord blood processing systems. Removal of subcontractor Biotest Laboratories Inc.; 9303 West Broadway Ave, Brooklyn Park, Minnesota 55445 USA Change of name of subcontractor from Vention Medical Costa Rica to Viant Costa Rica, S.A Addition of product table