

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

ThermoGenesis Corporation
2711 Citrus Road
Rancho Cordova CA 95742
USA

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture, Installation and
Servicing of Medical Devices Producing Components of Fibrin
Sealant (Cryoprecipitate and Thrombin), Cell Separation
Systems and Freezers for Biological Materials**

Proof has been furnished that the requirements specified in

EN ISO 13485:2003

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60037354 0001

An audit was performed. Report No.: 30491925 009

This Certificate is valid until: 13.01.2016



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Date 05.06.2011



Certification Body


Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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APPROVAL
EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60037355 0001

Report No.: 30491925 009

Manufacturer: ThermoGenesis Corporation
2711 Citrus Road
Rancho Cordova CA 95742
USA

Scope: Design/Development and Manufacture of Freezers for
Biological Materials, Stem Cell and Bone Marrow Processing
Systems and Fibrin and human Thrombin Processing Systems
(see attachment for products included)

Replaces Approval, Registration No.: HD 60013655 0001

Date of Expiry: 13.01.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Date 05.06.2011




Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HD 60037355 0001
Report No.: 30491925 009

Manufacturer: ThermoGenesis Corporation
2711 Citrus Road
Rancho Cordova CA 95742
USA

Scope:

Products:

Freezers for Biological Material

- BioArchive System
- Freezers for Blood Plasma

Cord Blood and Bone Marrow Processing

- AXP
- AXP Processing Bagset
- MarrowXpress
- MarrowXpress Processing Bagset
- Res-Q 60 BMC Processing Kit
- Art 21 BMC Processing Kit


Fibrin and Human Thrombin Processing

- CS-1 CryoSeal FS System
- TPD Reagent
- Clotalyst Reagent
- TPD Thrombin Processing Device
- CP3 Plasma Processing Disposable
- Spray Tip
- Line/Drop Tip

Certification Body

Date 05.06.2011




Dr. H. Lüdemann