



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

Registration No.: HD 60013655 0001

Report No.: 30491925 001

Manufacturer: Thermogenesis Corporation
2711 Citrus Road
Rancho Cordova, CA 95742
USA

Scope: Design, Development, Manufacturing and Servicing of
Medical Devices

Products: see attachment

Replaces Approval, Registration No.: HD 60009010 0001

Date of Expiry: 21.03.2011

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.

Cologne, 22.03.2006



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
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.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
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Scope: Products:

- Freezers for Biological Material
BioArchive
- Freezers for Blood Plasma
- Fibrin Sealant System
CryoSeal FS System
TPD

Cologne, 07.04.2006



Dr. G. Viola

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