



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

Registration No.: ED 2111254 01

Report No.: C 2171236 E 01

Manufacturer: Exergen Corporation
51 Water Street
Watertown, MA 02172
USA

Scope: Final Inspection and Test of Infrared Thermometers
Products: see attachment

Date of Expiry: 02.09.2006

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex VI, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex VI, Article 4 of the aforementioned EC-Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 03.09.2001



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 Medizinprodukten (ZLG).

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

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



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

**Attachment to
Registration No.:** ED 2111254 01
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51 Water Street
Watertown, MA 02172
USA

Scope: Infrared Thermometers

LTX-1, LTXP-1, LTN-1, LTN-2, LTP-1, LT-2, LXTA,
DT-1001, DT-1001-RS,
Accutemp IR Adult,
Accutemp IR Pediatric,
Accutemp IR Neonate,
Sensortouch,
TAT2000, TAT2000 HP, TAT2100, TAT4000, TAT5000

Cologne, 03.09.2001

Munkler
Dipl.-Ing. Munkler