



APPROVAL

EC Directive 98/79/EC Annex IV, Article 3
Full Quality Assurance System
In vitro diagnostic medical devices

Registration No.: HL 2111411 01

Report No.: C 2192134 E 01

Manufacturer: **77ELEKTRONIKA** Műszeripari Kft.
Fehérvári út 98
1116 Budapest
HUNGARIA

Scope: Design, manufacturing and sales of self-diagnosis systems for the measurement of blood sugar

Products: see attachment

Date of Expiry: 20.11.2006

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

Cologne, 21.11.2001



Notified Body

H. Lüdemann
Dr. Lüdemann

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.

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