

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

**Registration No.:** HL 60023157 0001

**Report No.:** 10023496 001

**Manufacturer:** Eumed Biotechnology Co., Ltd.  
3F, No. 789, Boai St., Jubei City,  
Hsinchu Hsien, Taipei  
Taiwan

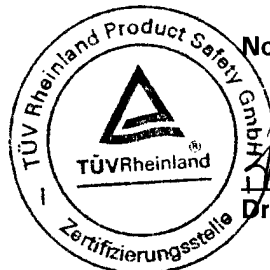
**Scope:** Design/Development and Manufacture of Blood Glucose  
Meters, Strips and Glucose Control Solutions  
for self-testing

Replaces Approval, Registration No.: HL 60018756 0001

**Date of Expiry:** 04.11.2013

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, 05.11.2008



Notified Body

  
Dr. H. 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 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**