

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

**Registration No.:** HD 60022696 0001

**Report No.:** 30793605 001

**Manufacturer:** ACON Laboratories, Inc.  
4108 Sorrento Valley Blvd.  
San Diego, CA 92121  
USA

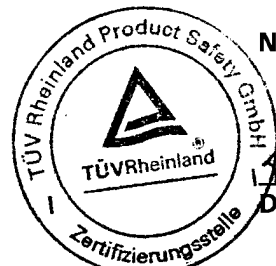
**Scope:** Design/Development and Manufacture of  
Diagnostic Medical Devices and Pricking Devices

Products: see attachment  
Replaces Approval, Registration No.: HD 60014380 0001

**Date of Expiry:** 21.09.2013

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, 22.09.2008



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**

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

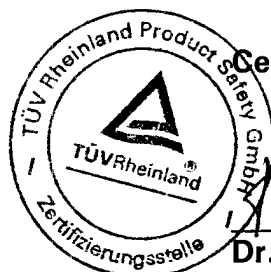
Doc. 1/1, Rev. 0

**Attachment to**  
**Registration No.:** HD 60022696 0001  
**Report No.:** 30793605 001

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4108 Sorrento Valley Blvd.  
San Diego, CA 92121  
USA

**Scope:** Products:  
- Thermometers  
- Sphygmomanometers  
- Lancets

Cologne, 22.09.2008



**Certification Body**

  
**Dr. H. Lüdemann**