

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

**Registration No.:** HL 60022694 0001

**Report No.:** 30793605 001

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

**Scope:** Design and Development, Manufacturing of chromatographic immunoassay in-vitro diagnostic medical devices

Products: see attachment  
Production facilities: see attachment  
Replaces Approval, Registration No.: HL 60007395 0001

**Date of Expiry:** 16.10.2013

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, 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

**Attachment to**  
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**Scope:**

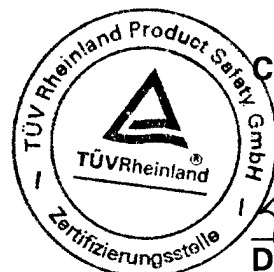
Self testing devices:

- Pregnancy test devices
- Ovulation test devices
- Menopause test devices
- On-Call Now Blood Glucose Monitoring System
- On-Call Plus Blood Glucose Monitoring System
- On-Call Now EZ Glucose Monitoring System
- On-Call Blood Glucose Visual Strips
- Urine Single and Multi-Constituent Test Strips
- Urinary Tract Infection Test Strips

Professional use devices:

- Prostate Specific Antigen Test Devices
- Devices for the detection of Chlamydia trachomatis

Cologne, 22.09.2008



**Certification Body**

  
**Dr. H. Lüdemann**