

## APPROVAL

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

**Registration No.: HL 60027035 0001**

**Report No.: 30793605 001**

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

**Scope:** Design/Development and Manufacture of chromatographic immunoassay in-vitro diagnostic medical devices

Products: see attachment  
Replaces Approval, Registration No.: HL 60022694 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 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, 29.09.2009



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.:** HL 60027035 0001  
**Report No.:** 30793605 008

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

**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 XP Blood Glucose Monitoring System
- TESTamed Diabetes Care GlucoCheck Plus Blood Glucose Monitoring System
- On-Call EZ Blood Glucose Monitoring System
- On-Call Advanced Blood 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, 29.09.2009**



**Certification Body**



**Dr. H. Lüdemann**