

**EC Certificate**  
**Directive 98/79/EC Annex IV, excluding Sections 4 and 6**  
**Full Quality Assurance System**  
**In Vitro Diagnostic Medical Devices**

**Registration No.:** HL 60088877 0001

**Report No.:** 31291251 001

**Manufacturer:** ACON Laboratories, Inc.  
10125 Mesa Rim Road  
San Diego CA 92121  
USA

**Products:** Blood glucose measuring systems and chromatographic  
immunoassay in-vitro diagnostic medical devices

(see attachment for Products included)

Replaces Approval, Registration No.: HL 60029269 0001

**Expiry Date:** 2018-09-06

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

**Effective Date:** 2013-09-20

**Date:** 2013-09-20



Notified Body

  
Dr. H. Lüdemann

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

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10125 Mesa Rim Road  
San Diego CA 92121  
USA

**Professional Use Devices:**

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

**Self Testing Devices:**

- Pregnancy Test Devices
- Ovulation Test Devices
- Menopause Test Devices
- On call Blood Glucose Visual Strips
- Urine Single and Multi-Constituent Test Strips
- Urinary Tract Infection Test Strips

**Date:** 2013-09-20



**Notified Body**

  
**Dr. H. Lüdemann**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
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**Manufacturer:** ACON Laboratories, Inc.  
10125 Mesa Rim Road  
San Diego CA 92121  
USA

**Products:**

**Blood Glucose Monitoring Systems:**

- On Call Now Blood Glucose Monitoring Systems
- On Call Plus Blood Glucose Monitoring Systems
- On Call XP Blood Glucose Monitoring Systems
- On Call Resolve Blood Glucose Monitoring Systems
- TESTamed Diabetes Care GlucoCheck Plus Blood Glucose Monitoring Systems
- On Call EZ Blood Glucose Monitoring System
- On Call EZ II Blood Glucose Monitoring System
- On Call Redi Blood Glucose Monitoring System
- On Call Advanced Blood Glucose Monitoring System
- Ratisbonne BGM Blood Glucose Monitoring System
- GlucoSure Blood Glucosing Monitoring System
- On-Call Platinum Blood Glucose Monitoring System
- On-Call Platinum Pal Blood Glucose Monitoring System
- On-Call Chosen Blood Glucose Monitoring System

**Date:** 2013-09-20



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**Dr. H. Lüdemann**

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Blood Glucose Monitoring Systems (cont.)

- Brendan Monitor BGM Blood Glucose Monitoring System
- On Call Vivid Blood Glucose Monitoring System
- On Call Simple Blood Glucose Monitoring System
- D-ONE Blood Glucose Monitoring System
- On Call Vivid Pal Blood Glucose Monitoring System

Additional Facility:

AZURE Institute, Inc.  
10125 Mesa Rim Road  
San Diego, CA 92121 USA

Scope: Activities related to design and development of  
in-vitro diagnostic testing kits

**Date:** 2013-09-20



**Notified Body**

  
**Dr. H. Lüdemann**