



Product Service

# EC Certificate

## Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

No. V1 14 06 80997 008

**Manufacturer:** **ACON Laboratories, Inc.**

10125 Mesa Rim Road  
San Diego CA 92121  
USA

**EC-Representative:** **Medical Device Safety Service GmbH**

Schiffgraben 41  
30175 Hannover  
GERMANY

**Product Category(ies):** **In Vitro diagnostic for self testing  
and List B products as specified in the  
attachment**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

**Report No.:** SH1474304

**Valid from:** 2014-08-26

**Valid until:** 2017-09-12



**Date,** 2014-08-27

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 3



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**EC Certificate****Full Quality Assurance System**

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

**No. V1 14 06 80997 008**

**Model(s):**

On Call Plus Blood Glucose Monitoring System,  
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,  
On Call XP Blood Glucose Monitoring System,  
On Call Platinum Blood Glucose Monitoring System,  
On Call Resolve Blood Glucose Monitoring System,  
On Call Chosen Blood Glucose Monitoring System,  
On Call Simple Blood Glucose Monitoring System (OGM-111),  
On Call Vivid Blood Glucose Monitoring System (OGM-101),  
On Call Vivid Pal Blood Glucose  
Monitoring System (OGM-102),  
On Call Sharp Blood Glucose Monitoring System (OGM-121),  
On Call Plus II Blood Glucose Monitoring System (OGM-171),  
On Call Extra Blood Glucose Monitoring System (OGM-191),  
On Call GK Dual Blood Glucose &  
Ketone Monitoring System (OGM-161),  
TESTAmed GlucoCheckPlus  
Blood Glucose Monitoring System,  
D-ONE Blood Glucose Monitoring System  
Urinalysis Reagent Strips (Urine),  
UTI Urinary Tract Infection Test Strips,  
Toxoplasma IgG EIA Test Kit, Toxoplasma IgM EIA Test Kit,  
Rubella IgG EIA Test Kit, Rubella IgM EIA Test Kit,  
CMV IgG EIA Test Kit, CMV IgM EIA Test Kit,  
Total PSA EIA Test Kit,  
PT Coagulation Monitoring System (CCM-121),  
Cholesterol Monitoring System (CCM-111),  
Cholesterol Monitoring System (CCM-101),  
CHOL Total Cholesterol Test Devices (CCS-111),  
TRIG Triglycerides Test Devices (CCS-112),  
HDL High Density Lipoprotein Test Devices (CCS-113),  
3-1 Lipid Panel Test Devices (CCS-114),  
Cholesterol CTRL Control Devices

**Facility(ies):**

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

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

Attachment for Certificate No V1 14 06 80997 008

Supplement 001 dated 2014-08-26



Product Service

For the product(s)/product category (ies):

**List B Product:**

**Human infections: cytomegalovirus, Rubella, Toxoplasma**

**Tumoral marker: PSA**

**Blood glucose measuring system for self testing**

**Device for self testing - Clinical chemistry**

**Device for self testing - Haematology**

Munich, CRT2, 2014-08-27

Hans-Heiner Junker  
Certification Medical Technology

Page 3 of 3