



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 17 08 80997 017

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 diagnostics for the detection of human
infections and tumor markers, blood glucose
measuring self-testing systems, self-testing devices
for clinical chemistry, hematology and pregnancy

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.: SH17743EXT01

Valid from: 2017-09-13
Valid until: 2022-09-12

Date, 2017-08-30

Stefan Preiß



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

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(List A and B and devices for self-testing)

No. V1 17 08 80997 017

Model(s): For Detail Models see attachment

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 17 08 80997 017

Supplement 001 dated 2017-08-30



Product Service

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

On Call Plus Blood Glucose Monitoring System,
 On Call Plus Blood Glucose Test Strips,
 On Call EZ II Blood Glucose Monitoring System,
 On Call Redi Blood Glucose Monitoring System,
 On Call Redi II Blood Glucose Test Strips,
 On Call Advanced Blood Glucose Monitoring System,
 On Call Advanced Blood Glucose Test Strips,
 On Call Platinum Blood Glucose Monitoring System,
 On Call Platinum Blood Glucose Test Strips,
 On Call Chosen Blood Glucose Monitoring System,
 On Call Chosen Blood Glucose Test Strips,
 On Call Vivid Blood Glucose Monitoring System (OGM-101),
 On Call Vivid Blood Glucose Test Strips (OGS-101),
 On Call Vivid Pal Blood Glucose Monitoring System (OGM-102),
 On Call Sharp Blood Glucose Monitoring System (OGM-121),
 On Call Sharp Blood Glucose Test Strips (OGS-121),
 On Call Plus II Blood Glucose Monitoring System (OGM-171),
 On Call Plus II Blood Glucose Test Strips (OGS-171),
 On Call Extra Blood Glucose Monitoring System (OGM-191),
 On Call Extra Blood Glucose Test Strips (OGS-191),
 On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
 On Call Blood Ketone Test Strips (OGS-161),
 D-ONE Blood Glucose Monitoring System,
 D-ONE Blood Glucose Test Strips,
 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,

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Product Service

Total PSA EIA Test Kit,
 PT Coagulation Monitoring System (CCM-121),
 PT Coagulation Test Strips (CCS-121),
 Cholesterol Monitoring System (CCM-111),
 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,
 Cholesterol Monitoring System (CCM-101),
 CHOL Total Cholesterol Test Strips (CCS-101),
 PT/INR Monitoring System (CCM-151),
 PT/INR Test Strips (CCS-151),
 Hemoglobin Testing System (CCM-141),
 Hemoglobin Test Strips (CCS-141),
 hCG Pregnancy Rapid Test Cassette (Urine),
 Pregnancy Rapid Test Midstream

Munich, MHS-CRT, 2017-08-30

Stefan Preiß

Certification Medical Technology

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