



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 104507 0003 Rev. 01

Manufacturer: ACON Laboratories, Inc.

5850 Oberlin Drive, #340 San Diego CA 92121

USA

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 and ovulation

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.: SH1974310

 Valid from:
 2019-10-24

 Valid until:
 2022-09-12

Date, 2019-10-24

Stefan Preiß

1. Pumil

Head of Certification/Notified Body

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



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 104507 0003 Rev. 01

Model(s): For Detail Models see attachment

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

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

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







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#### No. V1 104507 0003 Rev. 01

### 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,

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#### No. V1 104507 0003 Rev. 01

CMV IgM EIA Test Kit,

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,

On Call Extra Mobile Blood Glucose Monitoring System (OGM-281)

On Call Sure Blood Glucose Monitoring System (OGM-211)

On Call Sure Sync Blood Glucose Monitoring System (OGM-212)

On Call Sure Blood Glucose Test Strips (OGS-211)

On Call GU Dual Blood Glucose & Uric Acid Monitoring System (OGM-201)

On Call Blood Uric Acid Test Strips (OGS-201)

LH Ovulation Rapid Test Cassette (Urine)

Ovulation Rapid Test Midstream

Ovulation & Pregnancy Test Combo Pack

On Call Extra Voice Blood Glucose Monitoring System (OGM-291)

Early Detection Pregnancy Test

**Digital Pregnancy Test** 





# **Declaration of Conformity**

# ACON Laboratories, Incorporated 5850 Oberlin Drive #340 San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Mission ® U120 Smart Urine Analyzer (U117-101, U117-111)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11<sup>th</sup> day of December, 2019 in San Diego, CA, USA

Qiyi Xie, MD, MPH

Senior Staff, Regulatory Affairs & Clinical Affairs Acon Laboratories, Inc.

## **Declaration of Conformity**

# ACON Laboratories, Incorporated 5850 Oberlin Drive #340 San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the in vitro diagnostic device:

Mission ® Liquid Urine Control (U021-011, U021-021, U021-031)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative: Medical Device Safety Service GmbH Schiffgraben 41 30175 Hannover, Germany

Signed this 11<sup>th</sup> day of December, 2019 in San Diego, CA, USA

Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.







### Certificate

Certification Mark:

No. Q5 104507 0001 Rev. 01

Holder of Certificate: ACON Laboratories, Inc.

5850 Oberlin Drive, #340 San Diego CA 92121 USA

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Scope of Certificate: Design and Development,

Manufacture and distribution of

In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse,

Tumor/Cardiac Marker,

Fertility/Pregnancy and Blood Glucose

Monitoring System,

**Lancing Devices and Lancets** 

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1974310

 Valid from:
 2019-10-24

 Valid until:
 2022-09-06

Date, 2019-10-24

Stefan Preiß

Head of Certification/Notified Body





## Certificate

No. Q5 104507 0001 Rev. 01

EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

ACON Laboratories, Inc. Facility(ies):

5850 Oberlin Drive, #340, San Diego CA 92121, USA

ACON Laboratories, Inc.

10125 Mesa Rim Road, San Diego CA 92121, USA

ACON Laboratories, Inc.

6865 Flanders Dr., Suite B, San Diego CA 92121, USA

AZURE Institute, Inc.

10125 Mesa Rim Road, San Diego CA 92121, USA



10125 Mesa Rim Road. · San Diego, CA 92121 · USA Tel: (858) 875-8000 · Fax: (858) 875-8099 · E-mail: info@aconlabs.com

November 11<sup>th</sup> 2016

### **CERTIFICATION LETTER**

This letter is to certify that, Vitalie Goreacii, employed by Sanmedico SRL located at: Republic of Moldova, city Chisinau, str. Petricani 88/1 of. 10, MD-2059, have received all required training and is enabled and authorized to provide services with installation, commissioning, and maintenance to the products listed below:

Mission® U120 Urine Analyzer

Mission® U120 Ultra Urine Analyzer

Mission® U500 Urine Analyzer

Mission® PT/INR Coagulation Monitoring System

Mission® Cholesterol Monitoring System

Mission® Ultra Cholesterol Monitoring System

Mission® HB Hemoglobin Testing System

Mission® Plus HB Hemoglobin Testing System

OnCall® Glucose Meter

For further questions or inquiries regarding this matter, please refer to the contact information below.

Sincerely

Jassy Alvarenga

International Account Manager

ACON Laboratories, Incs.A.

jalvarenga@aconlabs.com

+1 858 875 8085



### **STATEMENT**

We, ACON Laboratories, Inc. having a registered office at 5850 Oberlin Drive #340, San Diego, CA 92121 assign SRL Sanmedico having a registered office at A. Corobceanu street 7A, apt. 9, Chisinău, MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This authorization will be valid for one year after the date of this statement.

Date: June 1, 2021

Signature:

Qiyi Xie, Md, MPH

Sr. Officer, Regulatory & Clinical Affairs

ACON Laboratories, Inc.

Ph: 858-875-8011

Email: gxie@aconlabs.com