Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

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 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
Head of Certification/Notified Body

Digitally signed by Monastîrschii Viorica
Date: 2022.09.14 11:01:44 EEST
Reason: MoldSign Signature
Location: Moldova

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

TÜV SÜD 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 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

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

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Product Service

EC Certificate

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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

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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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 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

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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:

On Call® Sure Blood Glucose Monitoring System (G115-10U)

On Call® Sure Blood Glucose Meter (G115-11U, G115-12U, G115-13U)

On Call® Sure Blood Glucose Test Strip (G135-10U, G135-11U)

On Call® Sure Glucose Control Solution (G125-12U)

classified as *Annex II List B* of 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 declaration according to Annex IV of the Directive is based on approval by the notified body TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 MÜNCHEN, Germany, notified under No. 0123 to the EC Commission.

This declaration is valid until expiration of EC Certificate
No. V1 104507 0003 Rev. 01
Expiration Date: 2022-09-12

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

Signed this 6 day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

5850 Oberlin Drive #340 · San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

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® Urinalysis Reagent Strips (U031-XX1)

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 day of February, 2020
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 medical device:

Mission® Lancets (C121-3041)
On Call® Lancets (G124-10A)
Insight® Lancets (C121-3045)
Swiss Point of Care Lancets (G124-90AA)

of class IIA according to Annex IX rule 6 of the directive 93/42/EEC,

meets all the provisions of the directive 93/42/EEC as amended by directive 2007/47/EC concerning medical devices which apply to it.

This declaration is according to Annex II of the Directive and thus is based on approval by the notified body
TÜV SÜD Product Service GmbH,
Ridlerstraße 65,
80339 MÜNCHEN, Germany,
notified under No. 0123 to the EC Commission.

This declaration is valid until expiration of EC Certificate
No. G1 104507 0002 Rev. 01
Expiration Date: 2023-09-06

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

Signed this 17 day of August, 2021
in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

5850 Oberlin Drive #340·San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

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:

Device Name	REF Number	Model Number
Mission® Liquid Urine Control	U021-011	n/a
SPINREACT Liquid Urine Control	U021-013A	n/a
Insight® Liquid Urine Control	U021-015	n/a
Mission® Liquid Diptube Urine Control	U021-071	n/a
Insight® Liquid Diptube Urine Control	U021-075	n/a

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 22 day of October, 2021
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

Declaration of Conformity

We, the manufacturer, under compliance to Article 17 of regulation (EU) 2017/746, declare under our sole responsibility that the medical device:

Device Name	REF Number
Mission® U500 Urine Analyzer	U211-101, U211-111
Mission® U500 Data Transfer Kit	U221-131
Mission® Urine Analyzer Barcode Reader	U221-111
Mission® Printer Paper Rolls	U121-101

of class A according to Rule 5(b) of Annex VIII of regulation (EU) 2017/746, is in conformity with

Regulation (EU) IVDR 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

and

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and further amendments to the directive issued and in force at the date of this declaration.*

It has been demonstrated that the requirements specified in Article 4 have been met.

The materials in ACON's products are assessed in accordance with ACON's procedure for approval which uses documents and contractual agreements to evaluate compliance and approve new materials and components.*

This declaration is based on:

Manufacturer's Name: ACON Laboratories, Inc.

Manufacturer's Address: 5850 Oberlin Drive, #340 San Diego, CA 92121

Manufacturer's SRN: US-MF-000023913

Authorized Representative Name: Medical Device Safety Service GmbH

Authorized Representative Address: Schiffgraben 41, 30175 Hannover, Germany

Basic UDI-DI: 68260799999900424B

Intended Purpose of device: The U500 Urine Analyzer is intended for use in conjunction with the Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in human urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Leukocytes, Ascorbic Acid, Albumin, Creatinine, and Calcium, as well as the qualitative detection of Nitrite. The instrument is intended for professional, in vitro diagnostic use only.

Signed this 20 day of May, 2022
in San Diego, CA USA

5850 Oberlin Drive #340·San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

* This statement is based on information and data provided by third parties and may not have been verified through destructive testing or other chemical analysis.

5850 Oberlin Drive #340･San Diego, CA 92121, USA ･ Tel: (858) 875-8000 ･ Fax: (858) 875-8099
E-mail: info@aconlabs.com

Declaration of Conformity

We, the manufacturer, under compliance to Article 19 of EU MDR 2017/745, declare under our sole responsibility that the medical device:

Mission® Lancing Device (C121-3051)
Insight® Lancing Device (C121-3055)
On Call® Lancing Device (G124-11A)
On Call® GenTouch Lancing Device (G124-17A)
Swiss Point of Care Lancing Device (G124-91AA)
GIMA Lancing Device (G124-91AC)
Go-Keto Lancing Device (G124-97AA)

of class I according to Rule 13 of Annex VIII of regulation (EU) 2017/745,

is in conformity with EU MDR 2017/745.

This declaration is based on:

Manufacturer's Name: ACON Laboratories, Inc.

Manufacturer's Address: 5850 Oberlin Drive, #340 San Diego, CA 92121

Manufacturer's SRN: US-MF-000023913

Authorized Representative Name: Medical Device Safety Service GmbH

Authorized Representative Address: Schiffgraben 41, 30175 Hannover, Germany

Basic UDI-DI: 8260799999900013V

Intended Purpose of device: The device is intended for injuring the fingertip in combination with a disposable lancet for obtaining a small amount of blood sample.

Signed this 18 day of May 2022
in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

5850 Oberlin Drive #340·San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

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® Hb Hemoglobin Testing System (C111-3021, C111-3031)

Mission® Hb Hemoglobin Test Strips (C131-3011, C131-3021)

Mission® Hb Hemoglobin Control Solution (C121-3091)

Mission® Hb Hemoglobin Control Strip (C121-3031)

Mission® Hb Data Transfer Kit (C121-3021)

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 30 day of September, 2020
in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

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

November 11th 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

ACON LABORATORIES, INC. S.A.

Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc.
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* authorize SRL Sanmedico having a registered office at *A. Corobceanu street 7A, apt. 9, Chisinău, MD-2012, Moldova* .

to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: June 2, 2022

Signature: 

Qiyi Xie, Md, MPH
Sr. Officer, Regulatory & Clinical Affairs
ACON Laboratories, Inc.
Ph: 858-875-8011
Email: qxie@aconlabs.com

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 104507 0001 Rev. 01

Holder of Certificate: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Certification Mark:

tuv-sud.com/ps-cert

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 104507 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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