



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

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

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

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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:

Mission ® U500 Urine Analyzer (U211-101, U211-111)

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.



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 ® 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

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

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

# ACON BIOTECH (HANGZHOU) CO.,LTD CERTIFICATE OF ANALYSIS

PRODUCT NAME:

Urinalysis Reagent Strips'

**PURCHASE NO.:** 

37740068B

BATCH NO .:

URS0080059

**EXPIRATION DATE:** 

2022-09-19

**QUANTITY:** 

180,000pcs

ANALYSIS		SPECIFICATIONS (Color card)	TEST RESULT
Ascorbic acid	Neg. urine	Negative	Complies
	20mg/dl	>10mg/dl <40mg/dl	Complies
Glucose	Neg. urine	Negative	Complies
	250mg/dL	>100mg/dL <500mg/dL	Complies
Bilirubin	Neg. urine	Negative	Complies
	Yihua Urine controls	>++	Complies
Ketone	Neg. urine	Negative	Complies
	Yihua Urine controls	>40mg/dL <160mg/dL	Complies
S.G	1.000	≥1.000 <1.005	Complies
	1.025	>1.020 <1.030	Complies
Blood	Neg. urine	Negative	Complies
	Yihua Urine controls	>++ ≤ +++	Complies
рН	5.0	≥5.0 <6.0	Complies
	9.0	>8.0 ≤9.0	Complies
Protein	Neg, urine	Negative	Complies
	Yihua Urine controls	>+, ≤+++	Complies
Urobilinogen	Neg. urine	Negative	Complies
	4~12mg/dL	>4mg/dl ≤12mg/dl	Complies
Nitrite	Neg. urine	Negative	Complies
	Yihua Urine controls	+	Complies
Leukocyte	Neg. urine	Negative	Complies
	Yihua Urine controls	>+ <+++	Complies

Quality Department: Hedy 2horg

Date: 500, 23, 2020







### Certificate

No. Q5 104507 0001 Rev. 01

**Holder of Certificate:** 

ACON Laboratories, Inc.

5850 Oberlin Drive, #340 San Diego CA 92121 USA

**Certification Mark:** 



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

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### Certificate

No. Q5 104507 0001 Rev. 01

EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes (ISO 18485:2016)

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

