

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:**

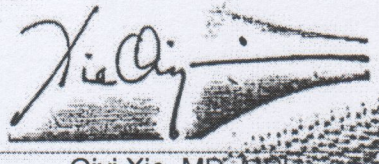
Mission ® U500 Urine Analyzer (U211-101, U211-111)

**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 11th 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

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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)

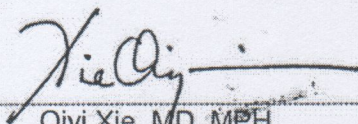
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Product Service

Certificate

No. Q5 104507 0001 Rev. 01

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

Certification Mark:



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

S. Preiß

Stefan Preiß
 Head of Certification/Notified Body



