



San Diego July 11th, 2018

We, ACON Laboratories Inc. having a registered office at 10125 Mesa Rim Road. San Diego, CA 92121, USA assign SRL Sanmedico having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

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.

ACON reserves the right to cancel this authorization at any time with a one month notice. If this is the case, ACON will honor any obligation to supply to our representative SanMedico SRL all the products distribution acquired or in the process of being acquired in Public Price bids and Public Tenders process.

Sincerely,


Jassy Alvarenga
Account Manager, International Sales



ACON Laboratories



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

S. Preiß

Stefan Preiß

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

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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 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

ZERTIFIKAT ♦ CERTIFICATE ♦ 認証証書 ♦ CERTIFICADO ♦ CERTIFIKAT ♦ СЕРТИФИКАТ



Product Service

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

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

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

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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Product Service

CERTIFICATE

No. Q1N 16 05 42074 027

Holder of Certificate: **Acon Biotech (Hangzhou) Co., Ltd.**

No.210 Zhenzhong Road
West Lake District
310030 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Acon Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
310030 Hangzhou, PEOPLE'S REPUBLIC OF
CHINA



Certification Mark:



Scope of Certificate: **Design and Development,
Production and Distribution of
In Vitro Diagnostic Test Kits
and Related Instruments,
Lancet and Lancing Device**

**Applied
Standard(s):**

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TUV 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.: SH1610619

Valid from: 2016-07-15

Valid until: 2019-07-14

Date, 2016-07-08

S. Preis
Stefan Preis



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Declaration of Conformity

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

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

Foresight Free T4 EIA Test Kit


classified as others 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

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

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 26 day of Aug, 2014
in San Diego, CA USA


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

ACON

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

Declaration of Conformity

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

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

Foresight HSV 1 IgG EIA Test Kit
Foresight HSV 2 IgG EIA Test Kit
Foresight HSV 1/2 IgG EIA Test Kit
Foresight HSV 1 IgM EIA Test Kit
Foresight HSV 2 IgM EIA Test Kit
Foresight HSV 1/2 IgM EIA Test Kit

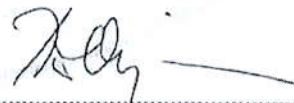
classified as others of the directive 98/79/EC,

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

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

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 8th day of Oct, 2013
in San Diego, CA USA



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



Declaration of Conformity

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

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

Foresight Free T3 EIA Test Kit

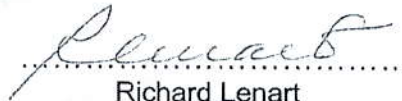
classified as others of the directive 98/79/EC,

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

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

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 14th day of March, 2011
in San Diego, CA USA


Richard Lenart
Regulatory Affairs Manager
ACON Laboratories, Inc.



Declaration of Conformity

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

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

Foresight Total T3 EIA Test Kit


classified as others of the directive 98/79/EC,

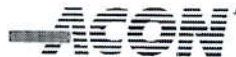
meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

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

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 26 day of Aug, 2014
in San Diego, CA USA


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



Declaration of Conformity

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

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

Foresight Total T4 EIA Test Kit

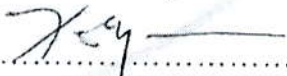
classified as others of the directive 98/79/EC,

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

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

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 26 day of Aug, 2014
in San Diego, CA USA


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

ACON

Declaration of Conformity

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

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

Mission U500 Urine Analyzer
Mission U500 Urine Analyzer with Barcode Reader
Mission Urine Analyzer Barcode Reader
Mission Printer Paper Rolls (Sticker/Thermal)
Mission U500 Data Transfer Kit

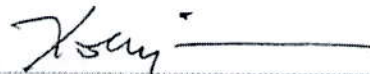
classified as others of the directive 98/79/EC,

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

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

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 21st day of March, 2016
in San Diego, CA USA



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



Declaration of Conformity

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

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

Foresight[®] TSH EIA Test Kit

classified as others 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**

**This 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 02 day of November, 2017
in San Diego, CA USA



Jinn-nan Lin
President
Acon Laboratories, Inc.



Declaration of Conformity

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

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

Foresight *H. pylori* IgG EIA Test Kit

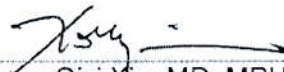
classified as others of the directive 98/79/EC,

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

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

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 22 day of Sep, 2014
in San Diego, CA USA



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

