



YourTrustedPartner

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,

A handwritten signature in black ink, appearing to read "Jassy Alvarenga".

Jassy Alvarenga

Account Manager, International Sales



ACON Laboratories

TÜV SÜD
ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ СЕРТИФИКАТ ♦ CERTIFICADO ♦ CERTIFICAT

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:



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 TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ♦ CERTIFICATE ♦ 認證書 ♦ СЕРТИФИКАТ ♦ CERTIFICADO ♦ CERTIFICAT



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 104507 0002 Rev. 01

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

Product Category(ies): Lancets, Safety Lancets

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 categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1974310

Valid from: 2019-10-24
Valid until: 2023-09-06

Date, 2019-10-24

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ♦ CERTIFICATE ♦ 認 證 證 書 ♦ СЕРТИФИКАТ ♦ CERTIFICADO ♦ CERTIFICAT



Benannt durch/Designated by
Zentralstelle der Länder
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www.zglg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 104507 0002 Rev. 01

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

Declaration of Conformity

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
Hangzhou, P.R.China 310030

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

On Call Plus Blood Glucose Monitoring System
On Call Plus Blood Glucose Meter
On Call Plus Blood Glucose Test Strip
On Call Plus Glucose Control Solution


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

This declaration is according to Annex IV 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.**

Authorized Representative:
Wellkang Ltd t/a Wellkang Tech Consulting
Suite B, 29 Harley Street,
LONDON W1G 9QR, England, UK

Detailed brand information and first place date, please refer to CE Product List.

Signed this 15 day of 9, 2015
in Hangzhou, China



.....
Junny You
International Regulatory Affairs Manager
ACON Biotech (Hangzhou) Co., Ltd.



ACON BIOTECH (HANGZHOU) CO., LTD.
No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R.China, 310030
Tel: +86-571-87963569 Fax: +86-571-87963570 E-mail: css@aconlab.com.cn

Declaration of Conformity

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
Hangzhou, P.R.China 310030

We declare under our sole responsibility that the medical device:

On Call Lancing device

of Class I according to Annex IX of the directive 93/42/EEC,

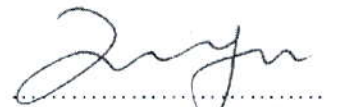
meets all the provisions of the directive 93/42/EEC as amended by directive 2007/47/EC concerning medical devices which apply to it.

This self-declaration is according to Annex VII of the Directive.

Authorized Representative:
Wellkang Ltd t/a Wellkang Tech Consulting
Suite B, 29 Harley Street,
LONDON W1G 9QR, England, UK

Detailed brand information and first place date, please refer to CE Product List.

Signed this 9 day of 5, 2016
in Hangzhou, China



.....
Junny You

International Regulatory Affairs Manager
ACON Biotech (Hangzhou) Co., Ltd.



ACON BIOTECH (HANGZHOU) CO., LTD.

No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R.China, 310030
Tel: +86-571-87963569 Fax: +86-571-87963570 E-mail: css@aconlab.com.cn

Declaration of Conformity

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
Hangzhou, P.R.China 310030

We declare under our sole responsibility that the medical device:

On Call Lancets

of Class IIA according to Annex IX of the directive 93/42/EEC,

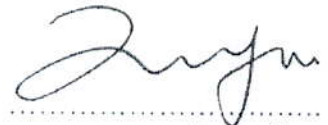
meets all the provisions of the directive 93/42/EEC as amended by directive 2007/47/EC concerning medical devices which apply to it.

This declaration is according to Annex V 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.**

Authorized Representative:
Wellkang Ltd t/a Wellkang Tech Consulting
Suite B, 29 Harley Street,
LONDON W1G 9QR, England, UK

Detailed brand information and first place date, please refer to CE Product List.

Signed this 15 day of 9, 2015
in Hangzhou, China



Junny You
International Regulatory Affairs Manager
ACON Biotech (Hangzhou) Co., Ltd.



ACON BIOTECH (HANGZHOU) CO., LTD.
No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R.China, 310030
Tel: +86-571-87963569 Fax: +86-571-87963570 E-mail: css@aconlab.com.cn

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:

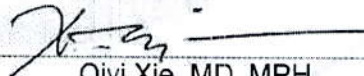
Mission[®] Hb Hemoglobin Meter

classified as Self Test 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

This declaration is according to Annex IV 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.

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

Signed this 24th day of Jan, 2017
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:


Mission® Hb Hemoglobin Testing System

classified as Self Test 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

This declaration is according to Annex IV 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.

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

Signed this 24th day of Jan, 2017
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:**

Mission[®] Hb Hemoglobin Test Strips

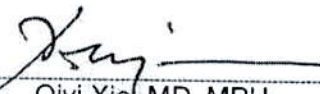
classified as Self Test in the directive 98/79/EC

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

**This declaration is according to Annex IV 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.**

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

Signed this 17th day of April, 2017
in San Diego, CA, USA



Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical 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, the manufacturer, declare under our sole responsibility that
the *in vitro* diagnostic device:

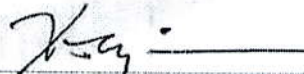
Mission® Hb Hemoglobin Control Strip

classified as Self Test 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

This declaration is according to Annex IV 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.

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

Signed this 24th day of Jan, 2017
in San Diego, CA, USA



Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
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

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:**

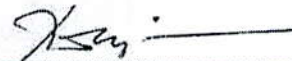
Mission[®] Hb Hemoglobin Control Solution

**classified as Self Test 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**

**This declaration is according to Annex IV 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.**

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

Signed this 24th day of Jan, 2017
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 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


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:

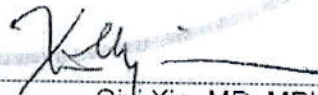
Foresight Rubella IgG EIA Test Kit
Foresight Rubella IgM EIA Test Kit

classified as List B in Annex II 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 declaration is according to Annex IV 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.

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 14 day of March, 2014
in San Diego, CA USA



Qiyl 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 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

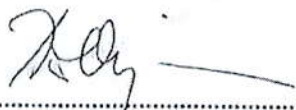
classified as others of the directive 98/79/EC,

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


.....
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 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.



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:

Forsight Total T3 EIA Test Kit

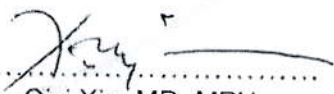
classified as others of the directive 98/79/EC,

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


.....
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:

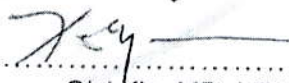
Foresight Total T4 EIA Test Kit

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


.....
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, 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:

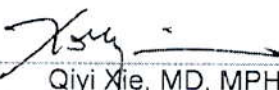
Foresight *H. pylori* IgG EIA Test Kit

**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



Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
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