ACON

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,

ACON LABORATORIES, INC.

Jassy Alvarenga

Account Manager, International Sales

ACON Laboratories

Digitally signed by Rodnițchii Andrei
Date: 2019.11.01 10:59:06 EET
Reason: MoldSign Signature
Location: Moldova

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

TÜV SÜD
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:

TÜV SÜD
EN ISO 13485
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

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

A4 / 07.17

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

TÜV®

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

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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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

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,

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

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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

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

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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www.zlg.de
ZLG BS 244.10.08

TÜV SÜD 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 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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www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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

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

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TÜV®

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.

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 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.

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.

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 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.

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 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.

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

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 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 EIATest 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.

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 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:

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

Qiyi Xie, MD, MPH
Senior Staff, Regulatory 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 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.

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 21th day of March, 2016
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:

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.

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 *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.

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