

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:**

Foresight Total T3 EIA Test Kit (1231-3041)

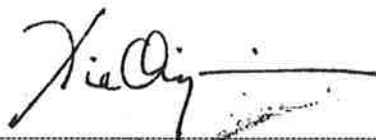
classified as Others in the directive 98/79/EC,

**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.



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:**

Foresight TSH EIA Test Kit (I231-3011)

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**

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5850 Oberlin Drive #340
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Foresight TSH EIA Test Kit (I231-3011)

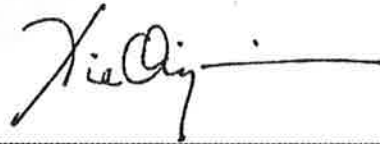
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Declaration of Conformity

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 ® U120 Smart Urine Analyzer (U117-101, U117-111)

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**

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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 ® U120 Ultra Urine Analyzer (U114-101, U114-111)

**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**

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5850 Oberlin Drive #340
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**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,
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medical devices which apply to it**

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

Foresight Total Syphilis Antibody EIA Test Kit (1231-1041)

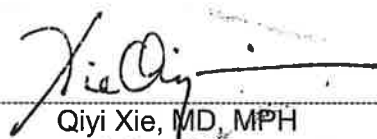
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5850 Oberlin Drive #340
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**We, the manufacturer, declare under our sole responsibility that the
in vitro diagnostic device:**

Foresight Rubella IgM EIA Test Kit (I231-1121)

classified as *Annex II List B* of the directive 98/79/EC,

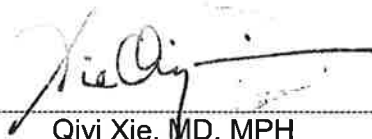
**meets all the provisions of the directive 98/79/EC on *in vitro*
diagnostic medical devices which apply to it**

**The declaration according to Annex IV of the Directive
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.**

This declaration is valid until expiration of EC Certificate
No. V1 104507 0003 Rev. 01
Expiration Date: 2022-09-12

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

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Qi Yi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.



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:**

Foresight Rubella IgG EIA Test Kit (I231-1111)

classified as *Annex II List B* of the directive 98/79/EC,

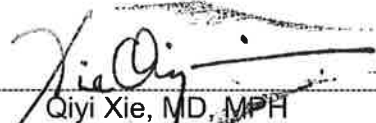
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San Diego, CA 92121, USA

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

Foresight Rapid hCG EIA Test Kit (I231-4011)

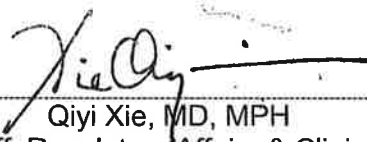
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San Diego, CA 92121 USA

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

Mission® PT/INR Monitoring System (C112-4021)

Mission® PT/INR Control Solution (C122-4011)

Mission® PT/INR Test Strips (C132-4011)

classified for *Self-testing* of the directive 98/79/EC,

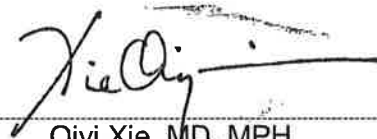
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**We, the manufacturer, declare under our sole responsibility that the
in vitro diagnostic device:**

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

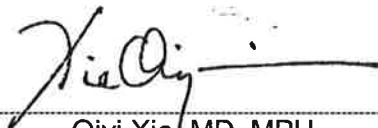
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**We, the manufacturer, declare under our sole responsibility that the
in vitro diagnostic device:**

Mission® Hb Hemoglobin Test Strips (C131-3011, C131-3021)

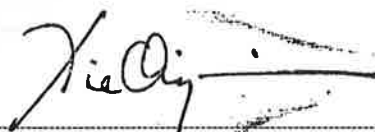
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San Diego, CA 92121, USA

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

Mission® Cholesterol Monitoring System (C111-2021)
Mission® Cholesterol 3-in-1 Lipid Panel Test Device (C131-2041, C131-2051)
Mission® Cholesterol TRIG Triglyceride Test Device (C131-2021, C131-2071)
Mission® Cholesterol HDL High Density Lipoprotein Test Device (C131-2031, C131-2081)
Mission® Cholesterol CHOL Total Cholesterol Test Device (C131-2011; C131-2061)
Mission® Cholesterol CTRL Control Device (C121-2021)

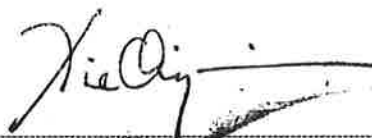
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**We, the manufacturer, declare under our sole responsibility that the
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Mission® Cholesterol Monitoring System (C111-2021)
Mission® Cholesterol 3-in-1 Lipid Panel Test Device (C131-2041, C131-2051)
Mission® Cholesterol TRIG Triglyceride Test Device (C131-2021, C131-2071)
Mission® Cholesterol HDL High Density Lipoprotein Test Device (C131-2031, C131-2081)
Mission® Cholesterol CHOL Total Cholesterol Test Device (C131-2011; C131-2061)
Mission® Cholesterol CTRL Control Device (C121-2021)

classified as Self Test and Others in the directive 98/79/EC,

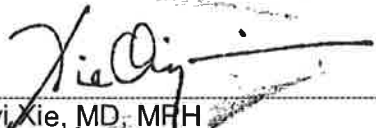
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Schiffgraben 41
30175 Hannover, Germany

Signed this ____ day of _____
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Qiyi Xie, MD - MFH

Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

ACON

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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)

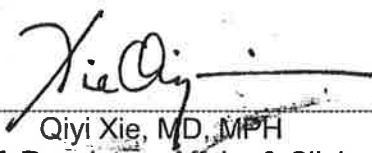
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**We, the manufacturer, declare under our sole responsibility that the
in vitro diagnostic device:**

Foresight LH EIA Test Kit (I231-4021)

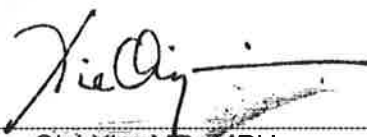
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**We, the manufacturer, declare under our sole responsibility that the
in vitro diagnostic device:**

Foresight HSV 2 IgM EIA Test Kit (1231-1181)

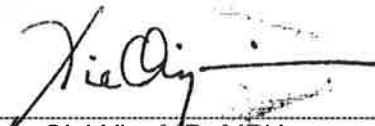
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**We, the manufacturer, declare under our sole responsibility that the
in vitro diagnostic device:**

Foresight HSV 2 IgG EIA Test Kit (1231-1171)

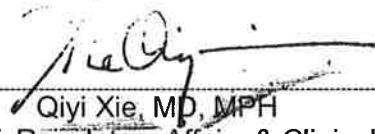
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**We, the manufacturer, declare under our sole responsibility that the
in vitro diagnostic device:**

Foresight HSV ½ IgM EIA Test Kit (1231-1201)

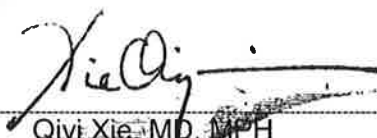
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Foresight HSV ½ IgG EIA Test Kit (1231-1191)

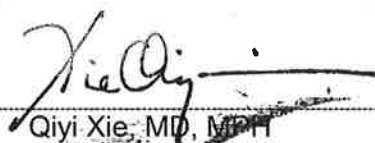
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**We, the manufacturer, declare under our sole responsibility that the
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Foresight HSV 1 IgM EIA Test Kit (1231-1161)

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**We, the manufacturer, declare under our sole responsibility that the
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Foresight HSV 1 IgG EIA Test Kit (1231-1151)

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**We, the manufacturer, declare under our sole responsibility that the
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Foresight HEV IgM EIA Kit (I231-1211)

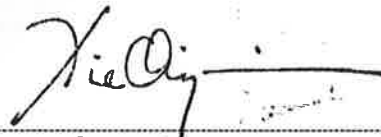
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**We, the manufacturer, declare under our sole responsibility that the
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Foresight hCG EIA Test Kit (I231-4051)

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**We, the manufacturer, declare under our sole responsibility that the
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Foresight H. pylori Antigen EIA Test Kit (I231-1231)

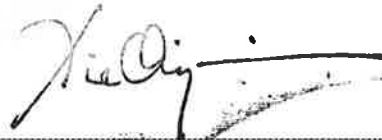
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**meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic
medical devices which apply to it**

**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.



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:**

Foresight H. pylori Antigen EIA Test Kit (I231-1231)

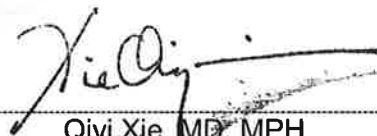
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Acon Laboratories, Inc.



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:**

Foresight FSH EIA Test Kit (I231-4031)

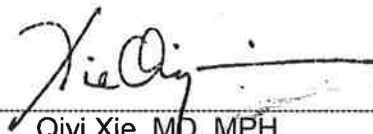
classified as Others in the directive 98/79/EC,

**meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic
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Authorized Representative:
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Schiffgraben 41
30175 Hannover, Germany

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Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.



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:**

Foresight Free T4 EIA Test Kit (1231-3031)

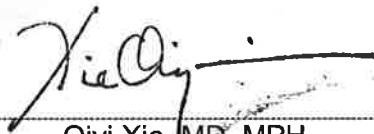
classified as Others in the directive 98/79/EC,

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

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Authorized Representative:
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30175 Hannover, Germany

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Acon Laboratories, Inc.



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:**

Foresight Free T3 EIA Test Kit (1231-3051)

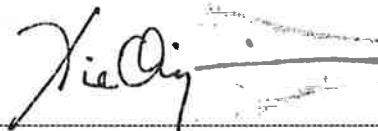
classified as Others in the directive 98/79/EC,

**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
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Authorized Representative:
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Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
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Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.



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 ® Expert Barcode Reader (U223-111)

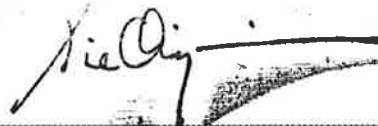
classified as Others in the directive 98/79/EC,

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

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Authorized Representative:
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30175 Hannover, Germany

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Acon Laboratories, Inc.



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:**

Foresight CMV IgM EIA Test Kit (I231-1141)

classified as *Annex II List B* of the directive 98/79/EC,

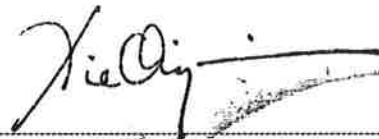
**meets all the provisions of the directive 98/79/EC on *in vitro*
diagnostic medical devices which apply to it**

**The declaration according to Annex IV of the Directive
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.**

This declaration is valid until expiration of EC Certificate
No. V1 104507 0003 Rev. 01
Expiration Date: 2022-09-12

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.



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:**

Foresight CMV IgG EIA Test Kit (I231-1131)

classified as *Annex II List B* of the directive 98/79/EC,

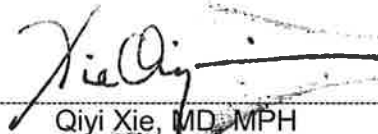
**meets all the provisions of the directive 98/79/EC on *in vitro*
diagnostic medical devices which apply to it**

**The declaration according to Annex IV of the Directive
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TÜV SÜD Product Service GmbH,
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notified under No. 0123 to the EC Commission.**

This declaration is valid until expiration of EC Certificate
No. V1 104507 0003 Rev. 01
Expiration Date: 2022-09-12

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.



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:**

Foresight CEA EIA Kit (I231-2021)

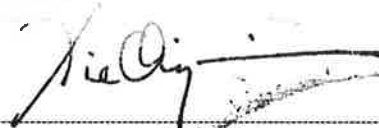
classified as Others in the directive 98/79/EC,

**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.



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 medical device:

Mission® Capillary Transfer Tubes (C121-3081)

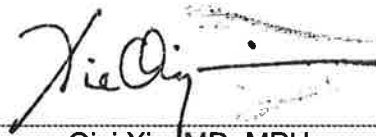
**of class I according to Annex IX of the directive 93/42/EEC,
meets all the provisions of the directive 93/42/EEC as amended by
directive 2007/47/EC concerning medical devices which apply to it.**

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

This declaration is valid until expiration of EC Certificate
No. G1 104507 0002 Rev. 01
Expiration Date: 2023-09-06

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.



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 ® Urine Analyzer Barcode Reader (U221-111)

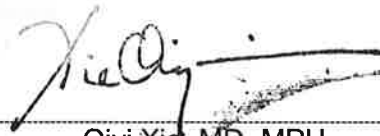
classified as Others in the directive 98/79/EC,

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

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Declaration of Conformity

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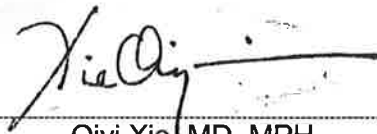
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Declaration of Conformity

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:**

Foresight Allergen Test Kit (I031-1011)

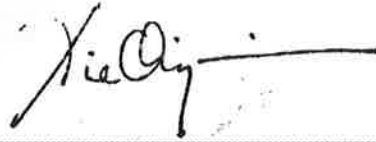
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Declaration of Conformity

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:**

Foresight AFP EIA Kit (I231-2011)

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**

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