

## 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)

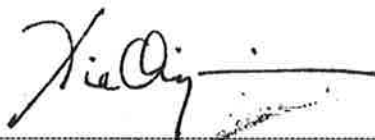
**classified as Others in the directive 98/79/EC,**

**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 11<sup>th</sup> day of December, 2019  
in San Diego, CA, USA



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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)

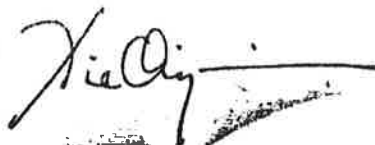
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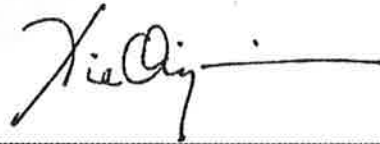
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Foresight Total Syphilis Antibody EIA Test Kit (1231-1041)

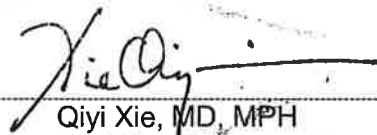
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**We, the manufacturer, declare under our sole responsibility that the  
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Foresight Rubella IgM EIA Test Kit (I231-1121)

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

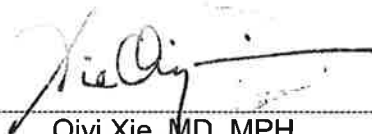
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**The declaration according to Annex IV of the Directive  
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TÜV SÜD Product Service GmbH,  
Ridlerstraße 65,  
80339 MÜNCHEN, Germany,  
notified under No. 0123 to the EC Commission.**

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

Authorized Representative:  
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Schiffgraben 41  
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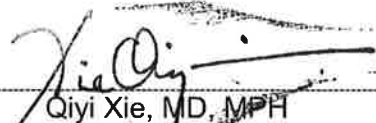
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**ACON**

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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**We, the manufacturer, declare under our sole responsibility that the  
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Foresight LH EIA Test Kit (I231-4021)

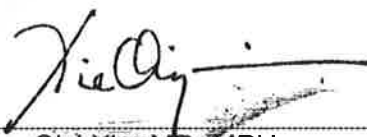
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**We, the manufacturer, declare under our sole responsibility that the  
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Foresight HSV 2 IgM EIA Test Kit (1231-1181)

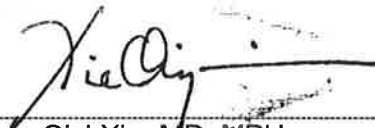
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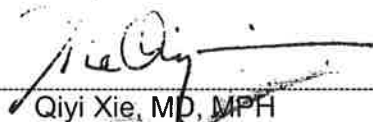
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Foresight HSV ½ IgM EIA Test Kit (1231-1201)

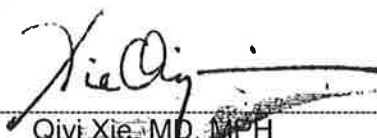
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Foresight HSV ½ IgG EIA Test Kit (1231-1191)

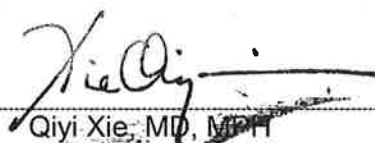
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Foresight HSV 1 IgM EIA Test Kit (1231-1161)

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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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Foresight HEV IgM EIA Kit (I231-1211)

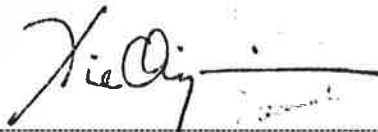
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Foresight hCG EIA Test Kit (I231-4051)

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

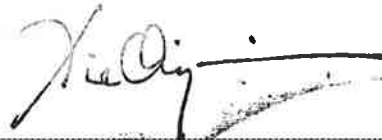
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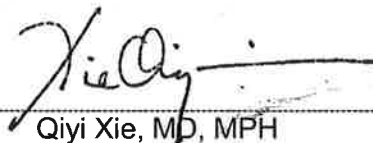
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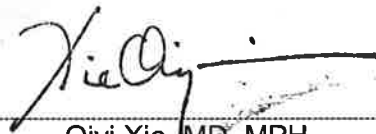
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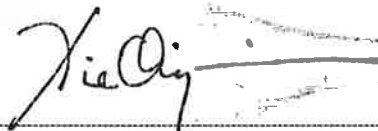
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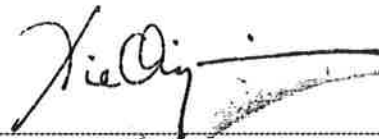
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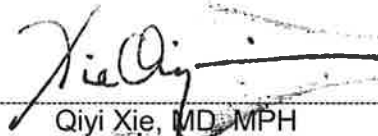
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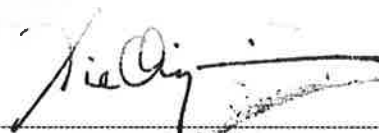
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Foresight Allergen Test Kit (I031-1011)

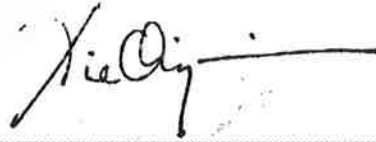
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medical devices which apply to it**

**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 11<sup>th</sup> day of December, 2019  
in San Diego, CA, USA



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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 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**

**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 11<sup>th</sup> day of December, 2019  
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Acon Laboratories, Inc.

