

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)

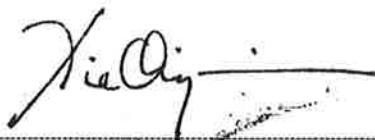
classified as Others in the directive 98/79/EC,

**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



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 TSH EIA Test Kit (I231-3011)

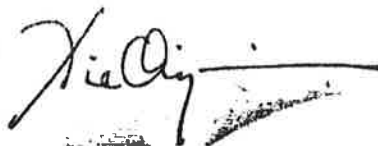
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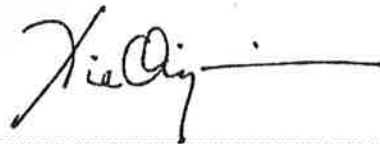
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**We, the manufacturer, declare under our sole responsibility that the
in vitro diagnostic device:**

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

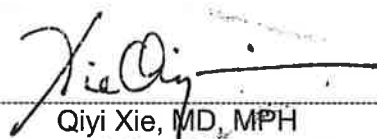
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**We, the manufacturer, declare under our sole responsibility that the
in vitro diagnostic device:**

Foresight Rubella IgM EIA Test Kit (I231-1121)

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

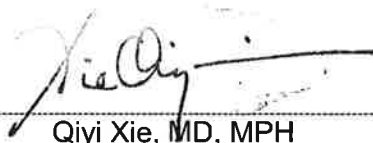
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**The declaration according to Annex IV of the Directive
is based on approval by the notified body
TÜV SÜD Product Service GmbH,
Ridlerstraße 65,
80339 MÜNCHEN, Germany,
notified under No. 0123 to the EC Commission.**

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

Authorized Representative:
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**We, the manufacturer, declare under our sole responsibility that the
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Foresight Rubella IgG EIA Test Kit (I231-1111)

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

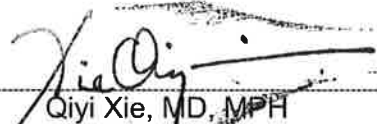
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**We, the manufacturer, declare under our sole responsibility that the
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Foresight LH EIA Test Kit (I231-4021)

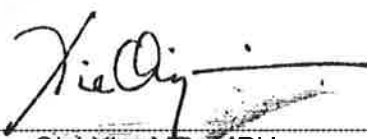
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**We, the manufacturer, declare under our sole responsibility that the
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Foresight HSV 2 IgM EIA Test Kit (1231-1181)

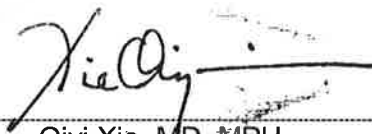
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**We, the manufacturer, declare under our sole responsibility that the
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Foresight HSV 2 IgG EIA Test Kit (1231-1171)

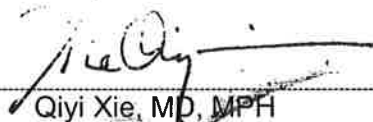
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**We, the manufacturer, declare under our sole responsibility that the
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Foresight HSV ½ IgM EIA Test Kit (1231-1201)

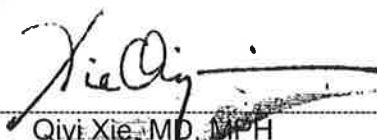
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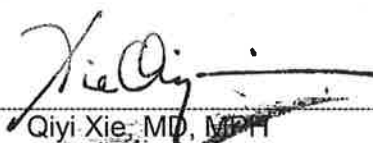
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Foresight HSV 1 IgM EIA Test Kit (1231-1161)

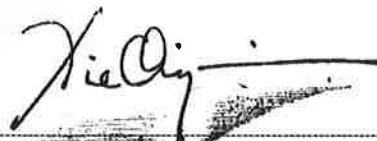
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Foresight HSV 1 IgG EIA Test Kit (1231-1151)

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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)

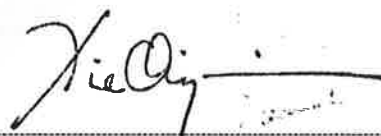
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**We, the manufacturer, declare under our sole responsibility that the
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Foresight hCG EIA Test Kit (I231-4051)

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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)

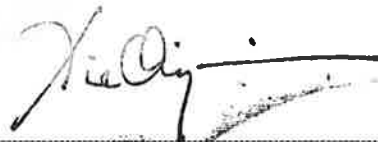
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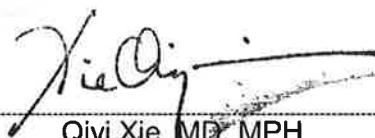
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Foresight FSH EIA Test Kit (I231-4031)

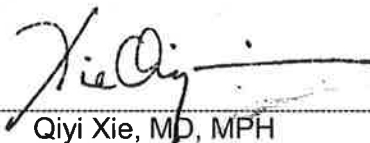
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Foresight Free T4 EIA Test Kit (1231-3031)

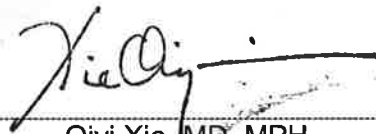
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Foresight Free T3 EIA Test Kit (1231-3051)

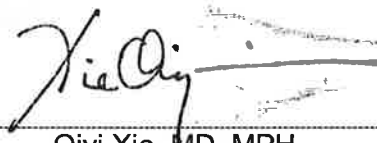
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Foresight CMV IgM EIA Test Kit (I231-1141)

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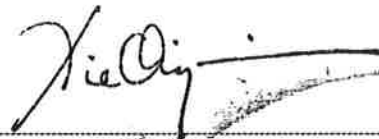
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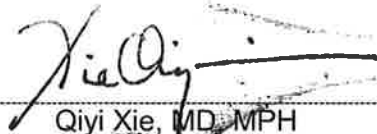
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Foresight CEA EIA Kit (I231-2021)

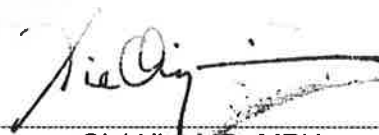
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**We, the manufacturer, declare under our sole responsibility that the
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Foresight Allergen Test Kit (I031-1011)

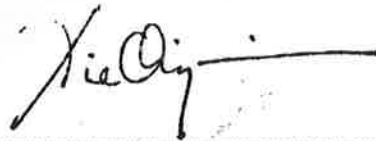
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**We, the manufacturer, declare under our sole responsibility that the
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Foresight AFP EIA Kit (I231-2011)

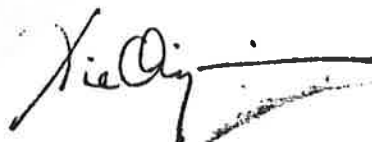
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