

## 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)

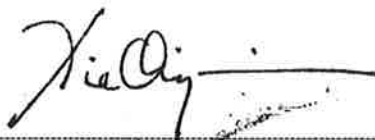
**classified as Others in the directive 98/79/EC,**

**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



---

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)


**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



---

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)

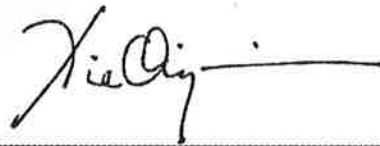
**classified as Others in the directive 98/79/EC,**

**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



---

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 Total Syphilis Antibody EIA Test Kit (1231-1041)

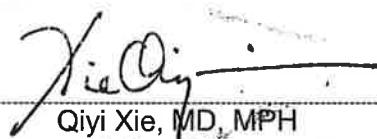
**classified as Others in the directive 98/79/EC,**

**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



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 Rubella IgM EIA Test Kit (I231-1121)

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

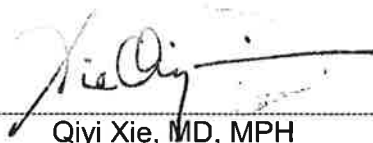
**meets all the provisions of the directive 98/79/EC on *in vitro*  
diagnostic medical devices which apply to it**

**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

Signed this 11<sup>th</sup> 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 Rubella IgG EIA Test Kit (I231-1111)

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

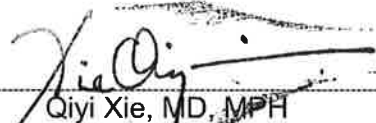
**meets all the provisions of the directive 98/79/EC on *in vitro*  
diagnostic medical devices which apply to it**

**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 11<sup>th</sup> 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 LH EIA Test Kit (I231-4021)

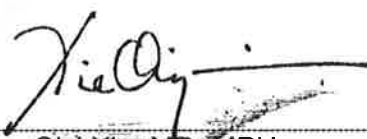
**classified as Others in the directive 98/79/EC,**

**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



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 HSV 2 IgM EIA Test Kit (1231-1181)

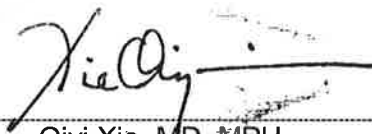
**classified as Others in the directive 98/79/EC,**

**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



---

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 HSV 2 IgG EIA Test Kit (1231-1171)

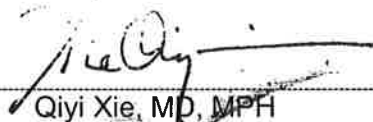
**classified as Others in the directive 98/79/EC,**

**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



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 HSV ½ IgM EIA Test Kit (1231-1201)

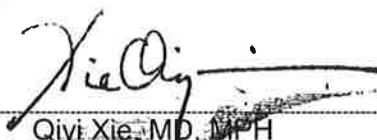
**classified as Others in the directive 98/79/EC,**

**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



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 HSV ½ IgG EIA Test Kit (1231-1191)

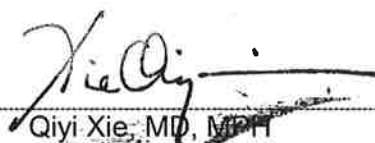
**classified as Others in the directive 98/79/EC,**

**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



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 HSV 1 IgM EIA Test Kit (1231-1161)

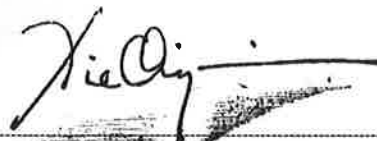
**classified as Others in the directive 98/79/EC,**

**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



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

**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



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 HEV IgM EIA Kit (I231-1211)

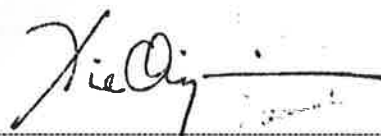
**classified as Others in the directive 98/79/EC,**

**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



---

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 hCG EIA Test Kit (I231-4051)

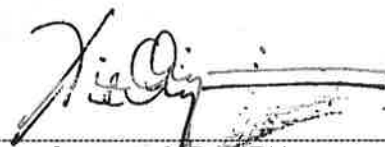
**classified as Others in the directive 98/79/EC,**

**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



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)

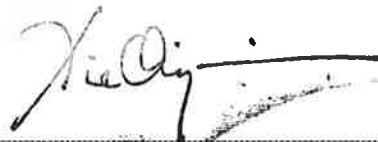
**classified as Others in the directive 98/79/EC,**

**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



---

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)

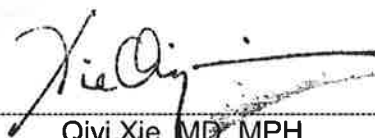
**classified as Others in the directive 98/79/EC,**

**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



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 FSH EIA Test Kit (I231-4031)

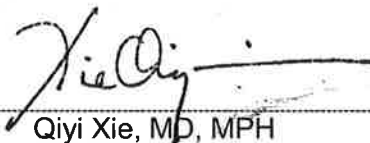
**classified as Others in the directive 98/79/EC,**

**meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic  
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



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 Free T4 EIA Test Kit (1231-3031)

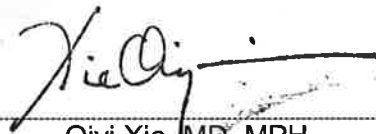
**classified as Others in the directive 98/79/EC,**

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

**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



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 Free T3 EIA Test Kit (1231-3051)

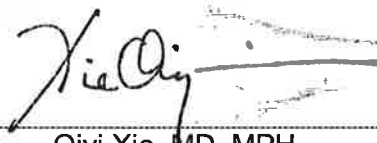
**classified as Others in the directive 98/79/EC,**

**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  
(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



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 IgM EIA Test Kit (I231-1141)

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

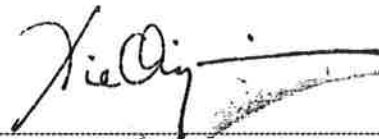
**meets all the provisions of the directive 98/79/EC on *in vitro*  
diagnostic medical devices which apply to it**

**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 11<sup>th</sup> 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,**

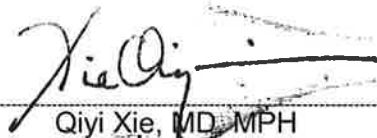
**meets all the provisions of the directive 98/79/EC on *in vitro*  
diagnostic medical devices which apply to it**

**The declaration according to Annex IV of the Directive  
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 11<sup>th</sup> 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 CEA EIA Kit (I231-2021)

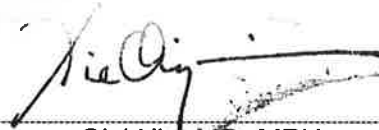
**classified as Others in the directive 98/79/EC,**

**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 11<sup>th</sup> 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 Allergen Test Kit (I031-1011)

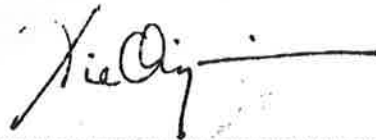
**classified as Others in the directive 98/79/EC,**

**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



---

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)

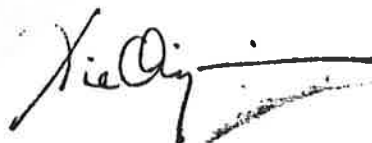
**classified as Others in the directive 98/79/EC,**

**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  
in San Diego, CA, USA



---

Qiyi Xie, MD, MPH  
Senior Staff, Regulatory Affairs & Clinical Affairs  
Acon Laboratories, Inc.

