## **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.