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® PT/INR Monitoring System (C112-4021)
Mission® PT/INR Test Strips (C132-4011)
Mission® PT/INR Control Solution (C122-4011)

classified for *Self-testing* 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. 02
Expiration Date: 2022-09-12

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

Signed this 2 day of October, 2020
in San Diego, CA USA

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

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