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:

Device Name	REF Number
Mission® PT/INR Monitoring System	C112-4021
Mission® PT/INR Test Strips	C132-4021, C132-4011
Mission® PT/INR Control Solution	C122-4011

classified for S*elf-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. 06
Expiration Date: 2025-05-26

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

Signed this 24 day of May, 2022
in San Diego, CA USA

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

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