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
GIMA Blood Glucose Monitoring System	24110, 24111
GIMA Blood Glucose Meter	24108
GIMA Bluetooth® Blood Glucose Monitoring System	24114
GIMA Blood Glucose Test Strips	24118, 24119, 24120
GIMA Glucose Control Solution	24121

classified for *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. 05
Expiration Date: 2022-09-12

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

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

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs

ACON Laboratories, Inc.

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