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® Hb Hemoglobin Meter	C111-3031
Mission® Hb Hemoglobin Testing System	C111-3021
Mission® Hb Hemoglobin Test Strips	C131-3011, C131-3021
Mission® Hb Hemoglobin Control Strips	C121-3031
Mission® Hb Hemoglobin Control Solution	C121-3091
Mission® Plus Hb Hemoglobin Testing System	C112-3021
Mission® Plus Hb Hemoglobin Testing System	C112-3031
Mission® Plus Hb Hemoglobin Test Devices	C132-3021
Mission® Plus Hb Hemoglobin Test Strips	C132-3011, C132-3031
Mission® Plus Hb Hemoglobin Control Devices	C122-3021
Mission® Plus Hb Hemoglobin Control Strips	C122-3011
Insight® Hb Hemoglobin Testing System	C111-3025
Insight® Hb Hemoglobin Test Strips	C131-3015
Insight® Hb Hemoglobin Control Strips	C121-3035

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 27 day of April, 2022
in San Diego, CA, USA

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

5850 Oberlin Drive, #340 · San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

To Whom It May Concern,

ACON Laboratories, Inc., with registered address at:

5850 Oberlin Drive, #340
San Diego, CA 92121
USA

and manufacturer of the following products:

Device Name	REF Number
Mission® Hb Hemoglobin Meter	C111-3031
Mission® Hb Hemoglobin Testing System	C111-3021
Mission® Hb Hemoglobin Test Strips	C131-3011, C131-3021
Mission® Hb Hemoglobin Control Strips	C121-3031
Mission® Hb Hemoglobin Control Solution	C121-3091

clarifies that the above listed devices are 'legacy products' whose conformity assessment procedure was carried out before May 26, 2022 in accordance with IVDD 98/79/EC. The self-declaration is according to Annex III (excluding Section 6) of the Directive. The 'legacy products', according to Regulation (EU) 2022/112, may continue to be placed on the market up to a maximum of the dates specified in the Regulation.

26 May 2025, for class D devices;
26 May 2026, for class C devices;
26 May 2027, for class B devices;
26 May 2027, for class A devices placed on the market in sterile condition.

The above listed products are classified as Class B devices under IVDR 2017/746.

Regards,

Qiyi Xie, MD, MPH
Sr. Officer, Regulatory & Clinical Affairs
ACON Laboratories, Inc.
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