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.

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June 2, 2025

Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- the compliance of the devices and us, as their manufacturer, with the conditions for the continued placing on the market and putting into service

Manufacturer name	ACON Laboratories, Inc.
Manufacturer address and contact details	5850 Oberlin Drive, #340 San Diego, CA, 92121 858-875-8000
Single Registration Number (SRN) (if available)	US-MF-000023913

Authorised Representative name (if applicable)	MDSS GmbH
Authorised Representative address and contact details	Schiffgraben 41, 30175 Hannover, Germany
Single Registration Number (SRN) (if available)	DE-AR-000005430

Notified body name (if applicable)	TUV SUD	☒ See attached schedule ☐ Not applicable
Notified body number (if applicable)	0123	☒ See attached schedule

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	☐ Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	☐ See attached schedule ☒ Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	☐ See attached schedule ☒ Not applicable
End date of extended validity/transition period	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the **device(s)** listed in the attached schedule the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met *and/or*
- for the **Directive Certificate(s)** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**

In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 May 2025 for class D devices

☒ 26 May 2026 for class C devices

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☒ 27 May 2027 for class B and class A (sterile) devices

☒ Signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 September 2025 for class D devices

☒ 26 September 2026 for class C devices

☒ 27 September 2027 for class B and class A (sterile) devices

☐ We do not intend to lodge an application for conformity for the device as indicated on the attached schedule.

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the device(s) listed in the attached schedule was/were issued after 25 May 2017, was/were valid on 26 May 2022 and has/have not been withdrawn afterwards.

Choose applicable statements:

☐ Original expiry date *before 9 July 2024*:

☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of its/their substitute(s), or

☐ Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 54(1) IVDR (may be provided upon request), or

☐ Competent Authority has required us as the manufacturer, in accordance with Article 92(1) IVDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 54(1) or a requirement per Article 92(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

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☐ We do not intend to lodge an application for conformity assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

☐ Original expiry date *after 9 July 2024*:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

☐ We do not intend to lodge an application for conformity assessment by 26 May 2025 for the devices as indicated on the attached schedule, therefore the transition period will end on 26 May 2025.

☐ assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ QMS in accordance with Article 10(8) IVDR will be put in place by no later than 26 May 2025.

☒ QMS in accordance with Article 10(8) IVDR is in place.

☐ Notified body has issued the attached certificate for the IVDR-compliant QMS.

➢ **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**

- The device(s) continue(s) to comply with the IVDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: ACON Laboratories, Inc.

Location & Date: San Diego, California 2025-06-02

Signature, Print Name, Title:

Qiyi Xie
V.P. of Regulatory & Clinical Affairs
qxie@aconlabs.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)	**Directive Certificate number to which this declaration is issued** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the IVDR application was lodged/contract signed** (if applicable)
Mission® ALT Alanine Aminotransferase Test Strips	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® AST Aspartate Aminotransferase Test Strips	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
On Call® A1c HbA1c Control Solution	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Liquid Urine Control	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Insight® Liquid Urine Control	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Liquid Diptube Urine Control	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Insight® Liquid Diptube Urine Control	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Dry Strip Urine Control	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Insight® Dry Strip Urine Control	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
[redacted]						
Mission® ALT Control	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123

[1] for devices with IVDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above

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On Call® A1c HbA1c Test Kit	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
On Call® MultiPro HbA1c Test Kit	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
On Call® MultiPro HbA1c Individual Controls	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
On Call® MultiPro HbA1c Controls	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Urinalysis Reagent Strips	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Insight® Urinalysis Reagent Strips	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Expert Urinalysis Reagent Strips	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Insight® Expert Urinalysis Reagent Strips	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
On Call® MultiPro ACR Controls	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
On Call® MultiPro ACR Test Kit	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
On Call® KFT Kidney Function Test Strips	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
On Call® KFT Kidney Function Test Control Solution	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Foresight® Allergen Test Kit	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
On Call® MultiPro CRP Controls	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON Fecal Occult Blood Rapid Test Cassette (Feces)	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON Fecal Occult Blood Rapid Test Strips (Feces)	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON LH Ovulation Rapid Test Strip (Urine)	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON® LH Ovulation Rapid Test Cassette (Urine)	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
On Call® MultiPro CRP Test Kit	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON® Troponin I Rapid Test Cassette (Serum/Plasma/Whole	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123

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Blood)						
ACON hCG Pregnancy Rapid Test Strip (Urine)	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON hCG Pregnancy Rapid Test Strip (Urine/Serum)	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON hCG Pregnancy Rapid Test Cassette (Urine/Serum)	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® 3D Hematology Control	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Hb Hemoglobin Control Strip	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Insight® Hb Hemoglobin Control Strip	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Plus Hb Hemoglobin Control Strip	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Plus Hb Hemoglobin Control Device	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Hb Hemoglobin Control Solution	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Hb Hemoglobin Test Strips	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Insight® Hb Hemoglobin Test Strips	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Plus Hb Hemoglobin Test Strips	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Plus Hb Hemoglobin Test Devices	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
H. pylori Antibody Rapid Test Cassette (Serum/Plasma)	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON H. pylori Antigen Rapid Test Cassette (Feces)	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON Syphilis Rapid Test Strip (Serum/Plasma)	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON Syphilis Rapid	2028-12-	N/A	N/A	N/A	N/A	TUV SUD; 0123

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Test Strip (Serum/Plasma/Whole Blood)	31					
ACON Syphilis Rapid Test Cassette (Serum/Plasma)	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON Syphilis Rapid Test Cassette (Serum/Plasma/Whole Blood)	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Malaria P.f/P.v Antigen Rapid Test Cassette (Whole Blood)	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Malaria P.f/Pan Antigen Rapid Test Cassette (Whole Blood)	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON® Dengue NS1 Antigen Rapid Test Cassette (Serum/Plasma/Whole Blood)	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON® Dengue IgG/IgM Rapid Test Cassette (Serum/Plasma/Whole Blood)	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
ACON® Dengue NS1 Ag & IgG/IgM Combo Rapid Test Cassette (Serum/Plasma/Whole Blood)	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® C 100 Dry Chemistry Analyzer	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Optical Check Strips	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® C 100 Data Transfer Kit	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
On Call® A1c HbA1c Analyzer	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
On Call® KFT Kidney Function Test Analyzer	2028-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® HA-360 3-Diff Automatic Hematology Analyzer	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Hb Hemoglobin Testing System	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123

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Insight® Hb Hemoglobin Testing System	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Plus Hb Hemoglobin Testing System	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123
Mission® Hb Data Transfer Kit	2029-12-31	N/A	N/A	N/A	N/A	TUV SUD; 0123