



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Manufacturer:

ACON Laboratories, Inc.

5850 Oberlin Drive, #340
San Diego CA 92121
USA

**Product Category(ies): Blood glucose measuring systems for self testing
and self-testing devices for clinical chemistry,
hematology and pregnancy and ovulation**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V1 104507 0003 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:V1_104507_0003_Rev.06)

Report no.:

SH22743EXT01

Valid from:

2022-05-04

Valid until:

2025-05-26

Date,

2022-05-04

Christoph Dicks
Head of Certification/Notified Body



EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Model(s):

On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
On Call Blood Ketone Test Strips (OGS-161),
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Cholesterol Monitoring System (CCM-111),
CHOL Total Cholesterol Test Devices (CCS-111),
TRIG Triglycerides Test Devices (CCS-112),
HDL High Density Lipoprotein Test Devices (CCS-113),
3-1 Lipid Panel Test Devices (CCS-114),
Cholesterol CTRL Control Devices,
Cholesterol Monitoring System (CCM-101),
CHOL Total Cholesterol Test Strips (CCS-101),
PT/INR Monitoring System (CCM-151),
PT/INR Test Strips (CCS-151),
Hemoglobin Testing System (CCM-141),
Hemoglobin Test Strips (CCS-141),
hCG Pregnancy Rapid Test Cassette (Urine),
Pregnancy Rapid Test Midstream,
On Call Extra Mobile Blood Glucose Monitoring System (OGM-281),
On Call Sure Blood Glucose Monitoring System (OGM-211),
On Call Sure Sync Blood Glucose Monitoring System (OGM-212),
On Call Sure Blood Glucose Test Strips (OGS-211),
GIMA Blood Glucose Monitoring System,
GIMA Bluetooth Blood Glucose Monitoring System,
GIMA Blood Glucose Test Strips,
On Call GU Dual Blood Glucose & Uric Acid Monitoring



EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

System (OGM-201),
On Call Blood Uric Acid Test Strips (OGS-201),
LH Ovulation Rapid Test Cassette (Urine),
Ovulation Rapid Test Midstream,
Ovulation & Pregnancy Test Combo Pack,
On Call Extra Voice Blood Glucose Monitoring System
(OGM-291),
Early Detection Pregnancy Test,
Digital Pregnancy Test,
Go-Keto Blood Glucose & Ketone Monitoring System (OGM-
161),
Go-Keto Blood Ketone Test Strips (OGS-161),
Go-Keto Blood Glucose Test Strips,
On Call Extra GM Blood Glucose Monitoring System(OGM-
191),
On Call Extra GM Blood Glucose Test Strips (OGS-191),
On Call Plus GM Blood Glucose Monitoring System,
On Call Plus GM Blood Glucose Test Strips,
Go-Keto Urinalysis Reagent Strips

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Acon Laboratories Inc.
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644 Tijuana
B.C. CP, MEXICO

Application Review Confirmation Letter



Add value.
Inspire trust.

TÜV SÜD Product Service GmbH Ridlerstr. 65 80339 Munich Germany

ACON Laboratories, Inc.
5850 Oberlin Drive, #340
San Diego, CA USA
92121

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
104507	ACON Lab. Application Review Confirmation Letter	medical_devices@tuvsud.com		2025-05-19	1 of 4

TÜV SÜD Product Service GmbH Receipt of formal application

Reference: ACON Lab. Application Review Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application in the framework of Regulation (EU) 2024/1860 amending Regulations (EU) 2017/746 (in the following referenced as IVDR) as regards the transitional provisions for in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under IVDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR with the above stated manufacturer with the following Single Registration Number (SRN)

Single Registration Number: US-MF-000023913

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application. To benefit from the additional transitional provisions in the framework of Regulation (EU) 2024/1860, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR latest until

- 26. September 2025 for devices covered by an IVDD (acc. to Directive 98/79/EC) EC-certificate and for class D devices that were "self-declared",
- 26. September 2026 for class C devices that were "self-declared" under the IVDD and
- 26. September 2027 for class B and class A sterile devices which were "self-declared" under the IVDD.

In case of inquiries please contact medical_devices@tuvsud.com.

Registered Office: Munich
Trade Register Munich HRB 85742
UniCredit Bank GmbH · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 (1) DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Zertifizierstelle für Medizinprodukte /
Certification Body for Medical Products
Ridlerstr. 65
80339 Munich
Germany

tuvsud.com/ps
Hotline: +49 89 50084-747



Application Review Confirmation Letter



On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2025-05-19

TÜV SÜD Product Service GmbH
Medical and Health Services

Shilpa Jais-Stewart

Digitally signed by: Shilpa Jais-Stewart
DN: CN = Shilpa Jais-Stewart email =
shilpa.jais-stewart@tuvsud.com C = AD
Date: 2025.05.19 13:05:56 -05'00'

Shilpa Jais-Stewart
Conformity Assessment Responsible (CARE)

Application Review Confirmation Letter



Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR

Device name or Basic UDI-DI (under IVDR application)
On Call Plus Blood Glucose Monitoring System
On Call Plus Blood Glucose Meter
On Call Plus Blood Glucose Test Strips
On Call Plus Glucose Control Solution
On Call EZ II Blood Glucose Monitoring System
On Call EZ II Blood Glucose Meter
On Call Advanced Blood Glucose Monitoring System
On Call Advanced Blood Glucose Meter
On Call Advanced Blood Glucose Test Strips
On Call Advanced Glucose Control Solution
On Call Chosen Blood Glucose Test Strips
[REDACTED]
On Call Vivid Blood Glucose Monitoring System (OGM-101)
On Call Vivid Blood Glucose Meter
On Call Vivid Blood Glucose Test Strips (OGS-101)
On Call Vivid Glucose Control Solution
On Call Sharp Blood Glucose Monitoring System (OGM-121)
On Call Sharp Blood Glucose Meter
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call® Sharp Glucose Control Solution
On Call Plus II Blood Glucose Monitoring System (OGM-171)
On Call Plus II Blood Glucose Meter
On Call Plus II Blood Glucose Test Strips (OGS-171)
On Call Plus II Blood Glucose Control Solution
On Call Extra Blood Glucose Monitoring System (OGM-191)
[REDACTED]
On Call Extra Blood Glucose Meter
On Call Extra Blood Glucose Test Strips (OGS-191)
[REDACTED]
On Call Extra Glucose Control Solution
[REDACTED]
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161)
[REDACTED]
On Call Blood Ketone Test Strips (OGS-161)
[REDACTED]
On Call Ketone Control Solution
[REDACTED]
On Call Chosen Glucose Control Solution
[REDACTED]
Mission UTI Urinary Tract Infection Test Strips
HealthyMe UTI Urinary Tract Infection Test Strips
[REDACTED]
Mission Cholesterol Monitoring System (CCM-111)

Application Review Confirmation Letter



Device name or Basic UDI-DI (under IVDR application)
Mission Cholesterol Meter [REDACTED]
Mission Cholesterol 3-in-1 Lipid Panel Test Device (CCS-114) [REDACTED]
Mission Cholesterol CTRL Control Devices [REDACTED]
Mission Cholesterol Control Solution
Mission Ultra Cholesterol Monitoring System (CCM-101)
Mission Ultra CHOL Total Cholesterol Test Strips (CCS-101)
Mission Ultra Cholesterol Control Solution
Distinct hCG Pregnancy Rapid Test Cassette (Urine)
Distinct Pregnancy Rapid Test Midstream
HealthyMe Pregnancy Rapid Test Midstream
On Call Extra Mobile Blood Glucose Monitoring System (OGM-281)
On Call Extra Mobile Blood Glucose Meter
On Call Sure Blood Glucose Monitoring System (OGM-211)
GIMA Blood Glucose Monitoring System
On Call Sure Blood Glucose Meter
GIMA Blood Glucose Meter
On Call Sure Sync Blood Glucose Monitoring System (OGM-212)
GIMA Bluetooth Blood Glucose Monitoring System
On Call Sure Sync Blood Glucose Meter
On Call Sure Blood Glucose Test Strips (OGS-211)
GIMA Blood Glucose Test Strips
On Call Sure Glucose Control Solution
GIMA Glucose Control Solution
On Call GU Dual Blood Glucose & Uric Acid Meter (OGM-201)
On Call Blood Uric Acid Test Strips (OGS-201)
On Call Uric Acid Control Solution
Distinct LH Ovulation Rapid Test Cassette (Urine)
Distinct Ovulation Rapid Test Midstream
HealthyMe Ovulation Rapid Test Midstream
Distinct Ovulation & Pregnancy Test Combo Pack
On Call Extra Voice Blood Glucose Monitoring System (OGM-291)
On Call Extra Voice Blood Glucose Meter
Distinct Early Detection Pregnancy Test
HealthyMe Early Detection Pregnancy Test
Distinct Digital Pregnancy Test
HealthyMe Digital Pregnancy Test [REDACTED]
Mission® Urinalysis Reagent Strips [REDACTED]

2025-05-19

Application Review Confirmation Letter



TÜV SÜD Product Service GmbH
Medical and Health Services

Shilpa Jais-Stewart

Digitally signed by: Shilpa Jais-Stewart
DN: CN = Shilpa Jais-Stewart email =
shilpa.jais-stewart@tuv-sud.com C = AD
Date: 2025.05.19 13:06:14 -05'00'

Shilpa Jais-
Conformity Assessment Responsible (CARE)