ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Report no.: SH22743EXT01

Valid from: 2022-05-04
Valid until: 2025-05-26

Date, 2022-05-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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

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

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

Add value.
Inspire trust.

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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	713352623 | 200210014024	--- medical_devices@tuvsud.com	---	2025-08-19	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter
CLI 104507 0010 Rev. 01

Reference: 713352623 | 200210014024

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance 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 certain 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 and has signed a written agreement in accordance with Section 4.3, second 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 and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

- Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive or these devices did not require a Notified Body certificate under Directives.

If devices covered by certificates issued under Directive Directive 98/79/EC (IVDD) that expired after 26. May 2022 and before 09. July 2024, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54(1) of IVDR or Article 92(1) of the IVDR respectively.

The transition timelines in accordance Article 110 (3) of IVDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110 (3c) of IVDR, are shown below:

- 31. December 2027, for devices certified under IVDD
- 31. December 2027, for class D devices;
- 31. December 2028, for class C devices;
- 31. December 2029, for class B devices and for class A devices placed on the market in sterile condition

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=CLI 104507 0010

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2025-08-19

TÜV SÜD Product Service GmbH
Medical and Health Services

Shilpa Jais-Stewart
Shilpa Jais-Stewart (19. August 2025 10:41:34 EDT)

Shilpa Jais-Stewart
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Christian Ullmann
Christian Ullmann (19. August 2025 17:27:40 GMT+2)

Dr. Christian Ullmann
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
On Call Plus Blood Glucose Monitoring System	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Plus Blood Glucose Meter	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Plus Blood Glucose Test Strips	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Plus Glucose Control Solution	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call EZ II Blood Glucose Monitoring System	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call EZ II Blood Glucose Meter	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Advanced Blood Glucose Monitoring System	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Advanced Blood Glucose Meter	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Advanced Blood Glucose Test Strips	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Advanced Glucose Control Solution	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Chosen Blood Glucose Test Strips [redacted]	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Vivid Blood Glucose Monitoring System (OGM-101)	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Vivid Blood Glucose Meter	Class C incl. ST/NPT/CDx	N/A	Certification as follows:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB identification
			V1 104507 0003 Rev. 06; NB0123
On Call Vivid Blood Glucose Test Strips (OGS-101)	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Vivid Glucose Control Solution	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Sharp Blood Glucose Monitoring System (OGM-121)	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Sharp Blood Glucose Meter	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Sharp Blood Glucose Test Strips (OGS-121)	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call® Sharp Glucose Control Solution	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Plus II Blood Glucose Monitoring System (OGM-171)	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Plus II Blood Glucose Meter	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Plus II Blood Glucose Test Strips (OGS-171)	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Plus II Blood Glucose Control Solution	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Extra Blood Glucose Monitoring System (OGM-191), [redacted]	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Extra Blood Glucose Meter	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Extra Blood Glucose Test Strips (OGS-	Class C incl. ST/NPT/CDx	N/A	Certification as follows:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
191) [redacted]			V1 104507 0003 Rev. 06; NB0123
On Call Extra Glucose Control Solution, [redacted]	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161), [redacted]	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Blood Ketone Test Strips (OGS-161), [redacted]	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Ketone Control Solution, [redacted]	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Chosen Glucose Control Solution, [redacted]	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Mission UTI Urinary Tract Infection Test Strips, HealthyMe UTI Urinary Tract Infection Test Strips, [redacted]	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Mission Cholesterol Monitoring System (CCM-111)	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Mission Cholesterol Meter, [redacted]	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Mission Cholesterol 3-in-1 [redacted]	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
[redacted]			
Mission Cholesterol CTRL Control Devices, [redacted]	Will not be sold under IVDR	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Mission Cholesterol Control Solution	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Mission Ultra Cholesterol Monitoring System (CCM-101)	Class B incl. ST/NPT	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Mission Ultra CHOL Total Cholesterol Test Strips (CCS-101)	Class B incl. ST/NPT	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Mission Ultra Cholesterol Control Solution	Class B incl. ST/NPT Class B incl. ST/NPT	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Distinct hCG Pregnancy Rapid Test Cassette (Urine)	Class B incl. ST/NPT	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Distinct Pregnancy Rapid Test Midstream, HealthyMe Pregnancy Rapid Test Midstream	Class B incl. ST/NPT	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Extra Mobile Blood Glucose Monitoring System (OGM-281)	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Extra Mobile Blood Glucose Meter	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Sure Blood Glucose Monitoring System (OGM-211), GIMA Blood Glucose Monitoring System	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Sure Blood Glucose Meter, GIMA Blood Glucose Meter	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Sure Sync Blood Glucose Monitoring	Class C incl. ST/NPT/CDx	N/A	Certification as follows:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
System (OGM-212), GIMA Bluetooth Blood Glucose Monitoring System			V1 104507 0003 Rev. 06; NB0123
On Call Sure Sync Blood Glucose Meter	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Sure Blood Glucose Test Strips (OGS-211), GIMA Blood Glucose Test Strips	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Sure Glucose Control Solution, GIMA Glucose Control Solution	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call GU Dual Blood Glucose & Uric Acid Meter (OGM-201)	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Blood Uric Acid Test Strips (OGS-201)	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Uric Acid Control Solution	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Distinct LH Ovulation Rapid Test Cassette (Urine)	Class B incl. ST/NPT	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Distinct Ovulation Rapid Test Midstream HealthyMe Ovulation Rapid Test Midstream	Class B incl. ST/NPT	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Distinct Ovulation & Pregnancy Test Combo Pack	Class B incl. ST/NPT	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Extra Voice Blood Glucose Monitoring System (OGM-291),	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
On Call Extra Voice Blood Glucose Meter	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Distinct Early Detection Pregnancy Test,	Class B incl. ST/NPT	N/A	Certification as follows:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
HealthyMe Early Detection Pregnancy Test			V1 104507 0003 Rev. 06; NB0123
Distinct Digital Pregnancy Test, HealthyMe Digital Pregnancy Test, [redacted]	Class B incl. ST/NPT	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123
Mission® Urinalysis Reagent Strips, [redacted]	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 104507 0003 Rev. 06; NB0123

Legend: ST – self-testing; NPT – near-patient testing; CDx – companion diagnostics

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Not Applicable			

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2025-08-11	713352623 | 200210014024	Initial issue
2025-08-19		Editorial adjustments