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TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

ACON Biotech (Hangzhou) Co., Ltd.

No.210 Zhenzhong Road, West Lake District,
310030 Hangzhou,
People's Republic of China

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
42074	SH2410610_CLI	--- medical_devices@tuvsud.com	---	2025-04-29	1 of 6

**TÜV SÜD Product Service GmbH
Confirmation Letter
CLI 042074 0037 Rev. 00**

Reference: 713306228 | 713306237 | 713338490 | 713338723 | 713338742 | 713338755 | 713338773 | 713338775 | 713338776 | 713338777 | 713338778 | SH2410610_CLI

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: CN-MF-000006977

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.

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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





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=cert:CLI_042074_0037

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2025-04-29

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services

Yao He

Yao He (30. April 2025 09:45 GMT+8)

Yao He
Conformity Assessment Responsible (CARE)

Christian Ullmann

Christian Ullmann (30. April 2025 14:36 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
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing), 6921756499990035X8	Class D incl. ST/NPT	N/A	Certification as follows: V9 042074 0032 Rev.00; NB 0123
On Call Sure Blood Glucose Monitoring System, 6921756499990039XG	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Sure Blood Glucose Meter, 6921756499990040WZ	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Sure Blood Glucose Test Strips, 6921756499990041X3	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Sure Glucose Control Solution, 6921756499990042X5	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Sure Sync Blood Glucose Monitoring System, 6921756499990043X7	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Sure Sync Blood Glucose Meter, 6921756499990044X9	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Extra Blood Glucose Monitoring System, 6921756499990045XB	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Extra Blood Glucose Meter, 6921756499990046XD	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Extra Blood Glucose Test Strips, 6921756499990047XF	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Extra Glucose Control Solution, 6921756499990048XH	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Plus Blood Glucose Monitoring	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123



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, 6921756499990052X8			
On Call Plus Blood Glucose Meter, 6921756499990053XA	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Plus Blood Glucose Test Strips, 6921756499990054XC	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Plus Glucose Control Solution, 6921756499990055XE	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call EZ II Blood Glucose Monitoring System, 6921756499990056XG	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Blood Uric Acid Test Strips, 6921756499990050X4	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
On Call Uric Acid Control Solution, 6921756499990051X6	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
Mission Cholesterol Test Device 3-in-1 Lipid Panel, 6921756499990066XK	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
QUIK-CHECK Cholesterol Test Device 3-in-1 Lipid Panel, 6921756499990066XK	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
Mission Cholesterol Control Solution, 6921756499990067XM	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
QUIK-CHECK Cholesterol Control Solution, 6921756499990067XM	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
Mission Ultra Cholesterol Monitoring System, 6921756499990068XP	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
QUIK-CHECK Ultra Cholesterol Monitoring System, 6921756499990068XP	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123



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
Mission Ultra Total Cholesterol Test Strips, 6921756499990070XA	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
QUIK-CHECK Ultra Total Cholesterol Test Strips, 6921756499990070XA	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
Mission Ultra Cholesterol Control Solution, 6921756499990071XC	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
QUIK-CHECK Ultra Cholesterol Control Solution, 6921756499990071XC	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
Mission Ultra Hemoglobin Testing System, 6921756499990062XB	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
QUIK-CHECK Ultra Hemoglobin Testing System, 6921756499990062XB	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
Mission Ultra Hemoglobin Test Strips, 6921756499990063XD	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
QUIK-CHECK Ultra Hemoglobin Test Strips, 6921756499990063XD	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
Mission Ultra Hemoglobin Control Solution, 6921756499990064XF	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123
QUIK-CHECK Ultra Hemoglobin Control Solution, 6921756499990064XF	Class B incl. ST/NPT	N/A	Certification as follows: V1 042074 0026 Rev.04; NB 0123

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
On Call Blood Ketone Test Strips, 6921756499990074XJ	Class C incl. ST/NPT/CDx	N/A	N/A - Device did not require a Notified Body certificate under Directives
On Call Ketone Control Solution, 6921756499990075XL	Class C incl. ST/NPT/CDx	N/A	N/A - Device did not require a Notified Body certificate under Directives
Flowflex SARS-CoV-2 Antigen Rapid Test, 6921756499990081XF	Class B incl. ST/NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2025-04-29	SH2410610_CLI	Initial issue