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

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Level 2, Block 2, 146 East Chaofeng Rd. Yuhang Economy Development Zone
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PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
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TÜV SÜD Product Service GmbH
Confirmation Letter
CLI 115425 0011 Rev. 01

Reference: 713270977 | 713334350 | GCN-SH251927A01 | GCN-SH251927A02 |SH25192700_CLI02 | SH25192700_CLI03

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-000012160

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 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 July 2024, without having been withdrawn, this letter also confirms that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 115425 0011

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2025-09-01

TÜV SÜD Product Service GmbH
Medical and Health Services

Chenchuan Weng
Chenchuan Weng (Sep 1, 2025 17:49:19 GMT+8)

Mr. Chenchuan Weng
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Dr. Mostafa Mahmoud
Dr. Mostafa Mahmoud (Sep 1, 2025 11:52:04 GMT+2)

Dr. Mostafa Mahmoud
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:

TÜV SÜD Product Service GmbH is responsible for appropriate surveillance for all devices listed in table 1 starting from transfer date: 2025-09-26

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
VivaChek Ino Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM0100004BV	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Eco Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM0200004CA	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Fad Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM0300002CK	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Ino Smart Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM0400001CW	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Sync Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM0500001DB	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Fad Smart Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM0700003E9	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
H+ Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM0300003CM	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
IRIS Evolution Blood Glucose Monitoring System	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0

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
Basic UDI-DI: 697022176VGM0700001E5			NB 0197
VivaChek Ino Sound Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM0900001EX	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Fad Sound Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM1000001BT	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Eco Sound Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM1100001C8	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Ino Sound Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM2600001ES	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Ino Sound Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM2700001F7	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Fad Sound Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM2800001FL	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Fad Plus Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM2300001DK	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Eco Plus Blood Glucose Monitoring System **Basic UDI-DI:** 697022176VGM1800001F3	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197

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
DiaMan Mini Blood Glucose Monitoring System **Basic UDI-DI:** 697022176DMGM0100001QF	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Ino Blood Glucose Meter **Basic UDI-DI:** 697022176VGM0100003BT	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Eco Blood Glucose Meter **Basic UDI-DI:** 697022176VGM0200003C8	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek FAD Blood Glucose Meter **Basic UDI-DI:** 697022176VGM0300001CH	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Ino Smart Blood Glucose Meter **Basic UDI-DI:** 697022176VGM0400002CY	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Sync Blood Glucose Meter **Basic UDI-DI:** 697022176VGM0500002DD	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Fad Smart Blood Glucose Meter **Basic UDI-DI:** 697022176VGM0700004EB	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
H+ Blood Glucose Meter **Basic UDI-DI:** 697022176VGM0300004CP	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
IRIS Evolution Blood Glucose Meter	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197

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
Basic UDI-DI: 697022176VGM0700002E7			
VivaChek Ino Sound Blood Glucose Meter **Basic UDI-DI:** 697022176VGM0900002EZ	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Fad Sound Blood Glucose Meter **Basic UDI-DI:** 697022176VGM1000002BV	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Eco Sound Blood Glucose Meter **Basic UDI-DI:** 697022176VGM1100002CA	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Ino Sound Blood Glucose Meter **Basic UDI-DI:** 697022176VGM2600002EU	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Ino Sound Blood Glucose Meter **Basic UDI-DI:** 697022176VGM2700002F9	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Fad Sound Blood Glucose Meter **Basic UDI-DI:** 697022176VGM2800002FN	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Ino Plus Blood Glucose Meter **Basic UDI-DI:** 697022176VGM2200004DC	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Fad Plus Blood Glucose Meter **Basic UDI-DI:** 697022176VGM2300002DM	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197

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
Pic Safe Gluco Monitor **Basic UDI-DI:** 697022176PSGM00001AC	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Eco Plus Blood Glucose Meter **Basic UDI-DI:** 697022176VGM1800002F5	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
DiaMan Mini Blood Glucose meter **Basic UDI-DI:** 697022176DMGM0100002QH	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Ino Blood Glucose Test Strips **Basic UDI-DI:** 697022176VCIBGTS133C5	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Eco Blood Glucose Test Strips **Basic UDI-DI:** 697022176VGS0100007FM	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Fad Blood Glucose Test Strips **Basic UDI-DI:** 697022176VCFBGTS133AC	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
H+ Test Strips **Basic UDI-DI:** 697022176VGS0200006FY	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
IRIS Evo Strips **Basic UDI-DI:** 697022176VGS0200003FS	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
Pic Safe test strips **Basic UDI-DI:** 697022176PSTS00001KP	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Eco Plus Blood Glucose Test Strips	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0

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
Basic UDI-DI: 697022176VGS0100006FK			NB 0197
VivaChek Fad Blood Glucose Test Strips **Basic UDI-DI:** 697022176DMGS0100001TZ	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Ino Control Solution (Low, Normal, High) **Basic UDI-DI:** 697022176VCICS133ZT	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Eco Control Solution (Low, Normal, High) **Basic UDI-DI:** 697022176VGC010000765	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Fad Control Solution (Low, Normal, High) **Basic UDI-DI:** 697022176VCFCS133YL	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
H+ Control Solution (Low, Normal, High) **Basic UDI-DI:** 697022176VGC02000066G	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
IRIS Evo Control Solution (Normal) **Basic UDI-DI:** 697022176VGC02000036A	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
Pic Safe Glucontrol **Basic UDI-DI:** 697022176PSG00001PR	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
VivaChek Eco Plus Control Solution (Low, Normal, High) **Basic UDI-DI:** 697022176VGC010000663	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197

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
DiaMan Mini Control Solution **Basic UDI-DI:** 697022176DMCS0100001R5	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
Keto-mojo GKI Multi-function Monitoring System **Basic UDI-DI:** 697022176VGM40000001S4	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
Keto-mojo GKI Multi-function Meter **Basic UDI-DI:** 697022176VGM40000002S6	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
Blood Ketone Test Strips **Basic UDI-DI:** 697022176VKS0100002J7	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
Blood Ketone Control Solution **Basic UDI-DI:** 697022176VKC01000028P	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
Uric Acid Test Strips **Basic UDI-DI:** 697022176VUS0100002RD	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
Uric Acid Control Solution **Basic UDI-DI:** 697022176VUC0100002FV	Class C incl. ST/NPT/CDx	NA	Certificate # HL2135127-1 Rev.0 NB 0197
SARS-CoV-2 Ag Rapid Test **Basic UDI-DI:** 697022176VCD160000162	Class C incl. ST/NPT/CDx	NA	Certificate # 1434-IVDD-200/2022 including Annex 1 & 2 NB1434

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
Whole C-Reactive Protein Test Kit (FIA) **Basic UDI-DI:** 697022176VID21400001NE	Class B for professional use	NA	N/A - Device did not require a Notified Body certificate under Directives
Cardiac Troponin I Test Kit (FIA) **Basic UDI-DI:** 697022176VID0900001B2	Class C for professional use	NA	N/A - Device did not require a Notified Body certificate under Directives
D-Dimer Test Kit (FIA) **Basic UDI-DI:** 697022176VID11000018B	Class C for professional use	NA	N/A - Device did not require a Notified Body certificate under Directives
N-terminal Pro-brain Natriuretic Peptide Test Kit (FIA) **Basic UDI-DI:** 697022176VID14000019J	Class C for professional use	NA	N/A - Device did not require a Notified Body certificate under Directives
Fecal Occult Blood Test Kit (FIA) **Basic UDI-DI:** 697022176VID2700001BA	Class C for professional use	NA	N/A - Device did not require a Notified Body certificate under Directives
Glycosylated Hemoglobin Test Kit (FIA) **Basic UDI-DI:** 697022176VID1600002AE	Class C for professional use	NA	N/A - Device did not require a Notified Body certificate under Directives
Strep A Test Kit (FIA) **Basic UDI-DI:** 697022176VID10700001NH	Class C for professional use	NA	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
2025-05-20	713270977; 713334350; GCN-SH251927A01; GCN-SH251927A02	Initial issue
2025-09-01	SH25192700_CLI02 | SH25192700_CLI03	Rev. 01: devices moved from table 2 to table 1 and addition of transfer date