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 052126 0069 Rev. 03

Manufacturer: **TaiDoc Technology Corporation**
B1-7F, No. 127, Wugong 2nd Road, Wugu Dist.
24888 New Taipei City
TAIWAN

Product Category(ies): **In Vitro diagnostic devices for self testing including Blood Glucose Monitoring System for self-testing**

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 052126 0069 Rev. 03

Report no.: TW2201103

Valid from: 2022-04-29
Valid until: 2025-05-26

Date, 2022-04-29

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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(List A and B and devices for self-testing)

No. V1 052126 0069 Rev. 03

Model(s):

1. Blood Glucose Measuring Systems For Self-Testing
Blood Glucose Monitoring System
TD-41XX, TD-42XX (X=0-9, A-Z or blank), MEDISAFE EX, E1,I1
Blood Glucose Meter
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
Blood Glucose Test Strip
TD-43XX (X=0-9, A-Z or blank)
Blood Glucose Control Solution
TD-49XX (X=0-9, A-Z or blank)

2. Blood Glucose Plus Blood Pressure Monitoring System
TD-32XX (X=0-9, A-Z or blank), MD-300,
Blood Glucose Plus Blood Pressure Meter
TD-32XX (X=0-9, A-Z or blank), MD-300,

3. Pregnancy Test Systems
Digital Pregnancy Test
TD-52XY (X=0-4, Y=0-9, A-Z or blank)
Pregnancy Test and Test Strip
TD-53XY (X=0-4, Y=0-9, A-Z or blank),
TD-45XY (X=0-4, Y=0-9, A-Z or blank)

4. Ovulation Test Systems
Digital Ovulation Test
TD-52XY (X=5-9, Y=0-9, A-Z or blank)
Ovulation Test and Test Strip
TD-45XY (X=5-9, Y=0-9, A-Z or blank),
TD-53XY (X=5-9, Y=0-9, A-Z or blank)

5. Blood Glucose Plus ß-Ketone Monitoring System
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
Blood Glucose Plus ß-Ketone Meter :
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
Blood glucose Plus ß-Ketone control solution:
TD-49XX (X=0-9, A-Z or blank)

6. ß-Ketone Monitoring System
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
ß-Ketone Meter
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
ß-Ketone Test Strip
TD-463X (X=0-9, A-Z or blank)
ß-Ketone control solution
TD-49XX (X=0-9, A-Z or blank)

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(List A and B and devices for self-testing)

No. V1 052126 0069 Rev. 03

7. Blood glucose, total cholesterol and uric acid multi-Monitoring system
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
Blood glucose, total cholesterol and uric acid multi Meter
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
8. Total Cholesterol Test Strip
TD-464X (X=0-9, A-Z or blank)
9.Total Cholesterol control solution
TD-49XX (X=0-9, A-Z or blank)
10. Multi-functional Monitoring System
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
11. Hemoglobin Monitoring System
TD-42XX (X=0-9, A-Z or blank)
Hemoglobin Meter
TD-42XX (X=0-9, A-Z or blank)
Hemoglobin Test Strip
TD-46XX (X=0-9, A-Z or blank)
12. Lactate Monitoring System
TD-42XX (X=0-9, A-Z or blank)
Lactate Meter
TD-42XX (X=0-9, A-Z or blank)
Lactate Test Strip
TD-46XX (X=0-9, A-Z or blank)
Lactate Control Solution
TD-49XX (X=0-9, A-Z or blank)
13. Uric Acid Monitoring System
TD-41XX (X=0-9,A-Z or blank)
Uric Acid Test Strip:
TD-465X (X=0-9, A-Z or blank)
Uric acid control solution
TD-49XX (X=0-9, A-Z or blank)
14. Triglycerides Test Strip
TD-46XX (X=0-9, A-Z or blank)
15. Triglycerides Control Solution
TD-49XX (X=0-9, A-Z or blank)

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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 052126 0069 Rev. 03

Facility(ies):

TaiDoc Technology Corporation
B1-7F, No. 127, Wugong 2nd Road, Wugu Dist., 24888 New Taipei City, TAIWAN

TaiDoc Technology Corporation
1F & 2F & 3F, No. 12, Lane 5, Sec. 2, Nanshan Rd., Lujhu District, 33852 Taoyuan City, TAIWAN

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TaiDoc Technology Corporation
B1-7F, No. 127, Wugong 2nd Road, Wugu Dist.
24888 NEW TAIPEI CITY
TAIWAN

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
52126	713336770 | 713372606 713373667 | 713374895 713374877	medical_devices@tuvsud.com		2025-08-11	1 of 21

TÜV SÜD Product Service GmbH
Confirmation Letter
CLI 052126 0073 Rev. 01

Reference: **713336770 | 713372606 | 713373667 | 713374895 | 713374877**
TW2401104 | TW25001103 | TW25001104 | TW25001105 | TW25001106

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: TW-MF-000017956

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=cert:CLI 052126 0073

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2025-08-11

TÜV SÜD Product Service GmbH
Medical and Health Services

Will Hsu
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Matthias Mumme
Matthias Mumme (13. August 2025 08:20:09 GMT+2)

Matthias Mumme
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**
Device 1 URIGHT Blood Glucose Monitoring System TD-4125 CLEVER CHECK Blood Glucose Monitoring System TD-4125 **Basic UDI** 471046987084125OOJD	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 2 Blood Glucose Monitoring System TD-4129 **Basic UDI** 471046987084129OOJZ	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 3 GlucoX Blood Glucose Monitoring System TD-4183 **Basic UDI** 471046987084183OOKF	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 4 FORA COMFORT plus G30a Blood Glucose Monitoring System TD-4241 GLUCOQUICK G30A BLOOD GLUCOSE MONITORING SYSTEM TD-4241 **Basic UDI** 471046987084241OOJJ	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 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
Device 5 FORA COMFORT basic G20 Blood Glucose Monitoring System TD-4251 **Basic UDI** 47104698708425100JR	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 6 URIGHT Blood Glucose Monitoring System TD-4266 **Basic UDI** 47104698708426600KR	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 7 URIGHT Blood Glucose Monitoring System TD-4268 **Basic UDI** 47104698708426800L3	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 8 FORA COMFORT check G40 Blood Glucose Monitoring System TD-4270 DIAVUE ToGo Blood Glucose Monitoring System TD-4270 **Basic UDI** 47104698708427000K2	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 9 URIGHT Blood Glucose Monitoring System TD-4277 **Basic UDI** 47104698708427700L5	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 10	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
Blood Glucose Monitoring System TD-4278 **Basic UDI** 47104698708427800LA			Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 11 Blood Glucose Monitoring System TD-4285 **Basic UDI** 47104698708428500L2	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 12 FORA Diamond GD50 Blood Glucose Monitoring System TD-4286 GLUCOQUICK DIAMOND GD50 BLOOD GLUCOSE MONITORING SYSTEM TD-4286 **Basic UDI** 47104698708428600L7	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 13 XPER Technology Blood Glucose Monitoring System TD-4289 **Basic UDI** 47104698708428900LN	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 14 XPER Technology A1 Blood Glucose Plus β-Ketone Monitoring System TD-4183 **Basic UDI** 47104698716418301JY	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 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
Device 15 VTRUST Advance Blood Glucose Plus β-Ketone Monitoring System TD-4279 **Basic UDI** 47104698716427900KY	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 16 VTRUST Advance Plus Multi-Functional Monitoring System TD-4206 Optinuvit Diabetes care Advance Plus Multi-Functional Monitoring System TD-4206 **Basic UDI** 47104698715420600HF	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 17 VTRUST Advance Plus Multi-Functional Meter TD-4206 Optinuvit Diabetes care Advance Plus Multi-Functional Meter TD-4206 **Basic UDI** 47104698742420600HM	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 18 XPER Technology PREMIUM Multi-Functional Monitoring System TD-4216 **Basic UDI** 47104698735421600JU	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 19	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
XPER Technology PREMIUM Multi-Functional Meter TD-4216 **Basic UDI** 47104698743421600JD			Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 20 XPER Technology I1 Multi-Functional Monitoring System TD-4289 **Basic UDI** 47104698754428900MH	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 21 XPER Technology I1 Multi-Functional Meter TD-4289 **Basic UDI** 47104698755428900N2	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 22 XPER Technology L1 Lactate Monitoring System TD-4261 **Basic UDI** 47104698757426100ME	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 23 URIGHT Blood Glucose Meter TD-4125 CLEVER CHECK Blood Glucose Meter TD-4125 **Basic UDI** 47104698747412500L8	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 24	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**
Blood Glucose Meter TD-4129 **Basic UDI** 47104698747412900LU			Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 25 GlucoX Blood Glucose Meter TD-4183 **Basic UDI** 47104698747418301MA	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 26 XPER Technology A1 Blood Glucose Plus β-Ketone Meter TD-4183 **Basic UDI** 47104698746418301LR	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 27 FORA COMFORT plus G30a Blood Glucose Meter TD-4241 **Basic UDI** 47104698747424100LD	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 28 URIGHT Blood Glucose Meter TD-4266 **Basic UDI** 47104698747426600ML	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 29 URIGHT Blood Glucose Meter TD-4268 **Basic UDI** 47104698747426800MW	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 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
Device 30 URIGHT Blood Glucose Meter TD-4277 **Basic UDI** 47104698747427700MY	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 31 FORA COMFORT check G40 Blood Glucose Meter TD-4270 DIAVUE ToGo Blood Glucose Meter TD-4270 **Basic UDI** 47104698747427000LV	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 32 Blood Glucose Meter TD-4278 **Basic UDI** 47104698747427800N5	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 33 VTRUST Advance Blood Glucose Plus β-Ketone Monitoring Meter TD-4279 **Basic UDI** 47104698746427900MR	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 34 Blood Glucose Meter TD-4285 **Basic UDI** 47104698747428500MV	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 35 FORA Diamond GD50 Blood Glucose Meter	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03

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
TD-4286 **Basic UDI** 47104698747428600N2			NB #0123
Device 36 XPER Technology Blood Glucose Meter TD-4289 **Basic UDI** 47104698747428900NH	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 37 XPER Technology L1 Lactate Meter TD-4261 **Basic UDI** 47104698758426100MX	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 38 URIGHT Blood Glucose Test Strips TD-4302 CLEVER CHECK Blood Glucose Test Strips TD-4302 **Basic UDI** 47104698710430200EH	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 39 FORA COMFORT basic Blood Glucose Test Strip TD-4304 **Basic UDI** 47104698710430400ET	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 40 FORA COMFORT Blood Glucose Test Strip TD-4308	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 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
GLUCOQUICK G30A GLUCOSE TEST STRIPS TD-4308 **Basic UDI** 47104698710430800FF			
Device 41 VTRUST Advance Blood Glucose Test Strips TD-4330 **Basic UDI** 47104698710433000EU	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 42 Blood Glucose Test Strips TD-4333 **Basic UDI** 47104698710433300FB	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 43 VTRUST Advance Plus Blood Glucose Test Strips TD-4335 Optinuvit Diabetes care Advance Plus Blood Glucose Test Strips TD-4335 **Basic UDI** 47104698710433500FM	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 44 FORA COMFORT check G40 Blood Glucose Test Strip TD-4352 DIAVUE ToGo Blood Glucose Test Strip TD-4352 **Basic UDI** 47104698710435200FL	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 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
Device 45 URIGHT Blood Glucose Test Strips TD-4353 **Basic UDI** 47104698710435300FR	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 46 Blood Glucose Test Strips TD-4353 **Basic UDI** 47104698710435301FT	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 47 URIGHT Blood Glucose Test Strips TD-4360 **Basic UDI** 47104698710436000FH	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 48 URIGHT Blood Glucose Test Strips TD-4360 **Basic UDI** 47104698710436001FK	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 49 GlucoX Blood Glucose Test Strips TD-4363 **Basic UDI** 47104698710436300FY	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 50 Blood Glucose Test Strips TD-4363 **Basic UDI** 47104698710436301G2	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 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
Device 51 FORA Diamond Blood Glucose Test Strip TD-4365 GLUCOQUICK DIAMOND GD50 BLOOD GLUCOSE TEST STRIPS TD-4365 **Basic UDI** 47104698710436500GA	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 52 XPER Technology A1 Blood Glucose Test Strips TD-4370 **Basic UDI** 47104698710437002FU	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 53 XPER Technology Blood Glucose Test Strips TD-4370 **Basic UDI** 47104698710437003FW	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 54 XPER Technology PREMIUM Blood Glucose Test Strips TD-4371 **Basic UDI** 47104698710437100FV	Class C incl. ST/NPT/CDx	Identification of the corresponding device under IVDD: XPER Technology PREMIUM Blood Glucose Test Strips TD-4370	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 55 XPER Technology I1 Blood Glucose Test Strips TD-4370 **Basic UDI** 47104698710437000FQ	Class C incl. ST/NPT/CDx	Identification of the corresponding device under IVDD: XPER Technology I1 Blood Glucose Test Strips TD-4371	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 56	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**
VTRUST Advance β-ketone Test Strips TD-4631 **Basic UDI** 4710469872146310 0H6			Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 57 VTRUST Advance Plus β-ketone Test Strips TD-4631 Optinuvit Diabetes care Advance Plus β-ketone Test Strips TD-4631 **Basic UDI** 4710469872146310 1H8	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 58 XPER Technology A1 β-ketone Test Strips TD-4633 **Basic UDI** 4710469872146330 3HN	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 59 XPER Technology PREMIUM β-Ketone Test Strips TD-4633 **Basic UDI** 4710469872146330 0HG	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 60 XPER Technology I1 β-ketone Test Strips TD-4633 **Basic UDI** 4710469872146330 1HJ	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 61	Class B incl. ST/NPT	Identification of the corresponding device under IVDD:	Certification as follows: Certificate #1

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
VTRUST Advance Plus Total Cholesterol Test Strips TD-4667 Optinuvit Diabetes care Advance Plus Total Cholesterol Test Strips TD-4667 **Basic UDI** 4710469872246701KC		Total Cholesterol Test Strip TD-4642	V1 052126 0069 Rev.03 NB #0123
Device 62 XPER Technology PREMIUM Total Cholesterol Test Strips TD-4665 **Basic UDI** 47104698722466500JY	Class B incl. ST/NPT	Identification of the corresponding device under IVDD: Total Cholesterol Test Strip TD-4643	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 63 XPER Technology I1 Total Cholesterol Test Strips TD-4665 **Basic UDI** 4710469872246501K2	Class B incl. ST/NPT	Identification of the corresponding device under IVDD: Total Cholesterol Test Strip TD-4643	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 64 XPER Technology PREMIUM Triglycerides Test Strips TD-4645 **Basic UDI** 47104698736464500M9	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 65 XPER Technology PREMIUM Uric Acid Test Strips TD-4653 **Basic UDI** 47104698718465300M2	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 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
Device 66 XPER Technology I1 Uric Acid Test Strips TD-4653 **Basic UDI** 47104698718465301M4	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 67 XPER Technology L1 Lactate Test Strips TD-4663 **Basic UDI** 47104698737466302N2	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 68 XPER Technology PREMIUM Lactate Test Strips TD-4663 **Basic UDI** 47104698737466300MW	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 69 XPER Technology I1 Lactate Test Strips TD-4663 **Basic UDI** 47104698737466301MY	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 70 L1 Blood Glucose Control Solution TD-4907 L2 Blood Glucose Control Solution TD-4908 L3 Blood Glucose Control Solution TD-4909	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 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
NORMAL Blood Glucose Control Solution TD-4911 HIGH Blood Glucose Control Solution TD-4912 **Basic UDI** 47104698709490000LF			
Device 71 FORA Blood Glucose Control Solution TD-4907 GLUCOQUICK CONTROL SOLUTION FOR GLUCOSE TEST TD-4907 FORA Blood Glucose Control Solution TD-4908 GLUCOQUICK CONTROL SOLUTION FOR GLUCOSE TEST TD-4908 FORA Blood Glucose Control Solution TD-4909 GLUCOQUICK CONTROL SOLUTION FOR GLUCOSE TEST TD-4909 FORA Blood Glucose Control Solution TD-4911 GLUCOQUICK CONTROL SOLUTION FOR GLUCOSE TEST TD-4911	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 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
FORA Blood Glucose Control Solution TD-4912 GLUCOQUICK CONTROL SOLUTION FOR GLUCOSE TEST TD-4912 **Basic UDI** 47104698709490001LH			
Device 72 L1 β-ketone Control Solution TD-4914 L2 β-ketone Control Solution TD-4915 **Basic UDI** 47104698723490000JF	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 73 L1 Lactate Control Solution TD-4923 L2 Lactate Control Solution TD-4924 **Basic UDI** 47104698740490000J2	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 74 L1 Total Cholesterol Control Solution TD-4919 **Basic UDI** 47104698724490000JY	Class B incl. ST/NPT	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 NB #0123
Device 75	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1

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
L1 Uric Acid Control Solution TD-4920 **Basic UDI** 47104698725490000KH			V1 052126 0069 Rev.03 NB #0123
Device 76 L1 Triglycerides Control Solution TD-4925 **Basic UDI** 47104698739490000N8	Class C incl. ST/NPT/CDx	N/A	Certification as follows: Certificate #1 V1 052126 0069 Rev.03 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
N/A	N/A	N/A	N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2025-06-02	713336770 | 713372606 | 713373667 | 713374895 | 713374877	Initial issue
2025-08-11	713336770 | 713372606 | 713373667 | 713374895 | 713374877	Modify the BUDI to add country code of Taiwan (471) Add brand name to device 1, 8, 16, 17, 23, 31, 38, 43, 44, 57, & 61