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 095123 0008 Rev. 04

Manufacturer:

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street
Hangzhou Economic and Technological Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Products for determination of infection markers tumor markers and products 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 095123 0008 Rev. 04

Report no.: SH221064A02

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

Date, 2022-04-05

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

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 095123 0008 Rev. 04

Model(s):

Toxo IgG/IgM Rapid Test,
Rubella IgM Rapid Test,
CMV IgM Rapid Test,
ToRCH IgM Combo Rapid Test,
PSA Rapid Test,
PSA Qualitative Rapid Test,
Chlamydia Rapid Test,
Sperm Concentration Rapid Test,
SP-10 Male Fertility Rapid Test,
hCG Rapid Test,
Digital hCG Pregnancy Test
LH Rapid Test,
FSH Rapid Test,
Vaginal pH Rapid Test,
Ferritin Rapid Test,
TSH Rapid Test,
H.pylori Rapid Test,
Urinary Tract Infections Test,
FOB Rapid Test,
Vitamin D Rapid Test

Facility(ies):

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

.

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

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

Product Service

Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 095123 0013 Rev. 00

Manufacturer:

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street
Hangzhou Economic and Technological Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (IVDD):

V1 095123 0008 Rev. 04

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (IVDD). It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2022 or later.
The conditions laid down in Article 110 (3) of Regulation (EU) 2017/746 on in vitro diagnostic medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:VCQ 095123 0013 Rev. 00

Report No.: SH23106403

Valid until: 2025-05-26

Issue Date: 2023-09-20

Marta Carnielli
Head of Notified Body IVD

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Product Service

Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 095123 0013 Rev. 00

Product Category(ies): Products for determination of infection markers tumor markers and products for self testing

Toxo IgG/IgM Rapid Test,
Rubella IgM Rapid Test,
CMV IgM Rapid Test,
ToRCH IgM Combo Rapid Test,
PSA Rapid Test,
PSA Qualitative Rapid Test,
Chlamydia Rapid Test,
Sperm Concentration Rapid Test,
SP-10 Male Fertility Rapid Test,
hCG Rapid Test,
Digital hCG Pregnancy Test
LH Rapid Test,
FSH Rapid Test,
Vaginal pH Rapid Test,
Ferritin Rapid Test,
TSH Rapid Test,
H.pylori Rapid Test,
Urinary Tract Infections Test,
FOB Rapid Test,
Vitamin D Rapid Test

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Product Service

Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 095123 0013 Rev. 00

Description of Change:

Change of Facility(ies):

The facility(ies) of manufacturer has/have been changed

Old facility(ies):

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, People's Republic of China

New facility(ies):

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, People's Republic of China

Hangzhou AllTest Biotech Co., Ltd.
#383, Qiaoxin Road, Xiasha Street, Qiantang District, 310018 Hangzhou, Zhejiang, People's Republic of China

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Add value.
Inspire trust.

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

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai street, Hangzhou Economic and Technologic Development Area, 310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
095123	GCN-SH251064A01; GCN-SH251064A02; GCN-SH251064A03; SH25106400_CLI	medical_devices@tuvsud.com		2025-05-06	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter
CLI 095123 0015 Rev. 00

Reference: GCN-SH251064A01 | GCN-SH251064A02 | GCN-SH251064A03 | SH25106400_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-000010710

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 095123 0015

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

The current revision of this Confirmation Letter is valid until **2025-09-26.**

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2025-05-06

TÜV SÜD Product Service GmbH
Medical and Health Services

Chenchuan Weng
Chenchuan Weng (May 6, 2025 15:20 GMT+8)

Mr. Chenchuan WENG
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (May 6, 2025 09:03 GMT+2)

Mr. Michael MAUERMEIR
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
FSH Rapid Test **Basic UDI-DI: 6970277510020PYK**	Class B incl. ST/NPT	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
hCG Pregnancy Rapid Test **Basic UDI-DI: 6970277510020QYM**	Class B incl. ST/NPT	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
Digital hCG Pregnancy Test **Basic UDI-DI: 6970277510020RYP**	Class B incl. ST/NPT	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
hCG Pregnancy Rapid Test **Basic UDI-DI: 6970277510020SYR**	Class B incl. ST/NPT	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
hCG Pregnancy Enhanced Sensitivity Rapid Test **Basic UDI-DI: 6970277510020TYT**	Class B incl. ST/NPT	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
LH Ovulation Rapid Test **Basic UDI-DI: 6970277510020UYV**	Class B incl. ST/NPT	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
LH Ovulation Rapid Test **Basic UDI-DI: 6970277510020VYX**	Class B incl. ST/NPT	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
LH Ovulation Rapid Test **Basic UDI-DI: 6970277510020WYZ**	Class B incl. ST/NPT	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
LH Ovulation Rapid Test	Class B incl. ST/NPT	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00

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: 6970277510020XZ3			NB# 0123
Chlamydia Rapid Test **Basic UDI-DI: 6970277510020YZ5**	Class C for professional use	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
CMV IgM Rapid Test **Basic UDI-DI: 6970277510020ZZ7**	Class C for professional use	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
H. pylori Antigen Rapid Test **Basic UDI-DI: 6970277510020OYH**	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
Rubella IgM Rapid Test **Basic UDI-DI: 6970277510021AXQ**	Class C for professional use	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
Toxo IgG/IgM Rapid Test **Basic UDI-DI: 6970277510021BXS**	Class C for professional use	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
Toxo IgG/IgM Rapid Test **Basic UDI-DI: 6970277510021CXU**	Class C for professional use	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
ToRCH IgM Combo Rapid Test **Basic UDI-DI: 6970277510021DXW**	Class C for professional use	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
Vaginal pH Rapid Test **Basic UDI-DI: 6970277510021EXY**	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
Ferritin Rapid Test **Basic UDI-DI: 6970277510021FY2**	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
Sperm Concentration Rapid Test	Class B incl. ST/NPT	N/A	Certification as follows: V1 095123 0008 Rev. 04;

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: 6970277510021GY4			VCQ 095123 0013 Rev. 00 NB# 0123
SP-10 Male Fertility Rapid Test **Basic UDI-DI: 6970277510021HY6**	Class B incl. ST/NPT	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
TSH Rapid Test **Basic UDI-DI: 6970277510021IY8**	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
Vitamin D Rapid Test **Basic UDI-DI: 6970277510021JYA**	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
FOB Rapid Test **Basic UDI-DI: 6970277510020NYF**	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
PSA Rapid Test **Basic UDI-DI: 6970277510021KYC**	Class C for professional use	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
PSA Qualitative Rapid Test **Basic UDI-DI: 6970277510021LYE**	Class C for professional use	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
Urinary Tract Infections Test **Basic UDI-DI: 6970277510019KYX**	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 NB# 0123
Urinary Tract Infections Test **Basic UDI-DI: 6970277510019LYZ**	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 095123 0008 Rev. 04; VCQ 095123 0013 Rev. 00 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
HBsAg Rapid Test **Basic UDI-DI: 6970277510017FYF**	Class D incl. ST/NPT	N/A	Certification as follows: CeCert/102/W/E.1; CeCert/101/W/E.1; NB# 2934
HCV Rapid Test **Basic UDI-DI: 6970277510017CY9**	Class D incl. ST/NPT	N/A	Certification as follows: CeCert/107/W/E.1; CeCert/106/W/E.1; NB# 2934
HIV 1.2 Rapid Test **Basic UDI-DI: 6970277510017BY7**	Class D incl. ST/NPT	N/A	Certification as follows: CeCert/097/W/E.1; CeCert/096/W/E.1; NB# 2934
ABO and RhD Blood Grouping Rapid Test **Basic UDI-DI: 6970277510021MYG**	Class D incl. ST/NPT	N/A	Certification as follows: CeCert/089/W/E.1; CeCert/088/W/E.1; NB# 2934
SARS-COV-2 and Influenza A+B Antigen Combo Rapid Test **Basic UDI-DI: 6970277510021NYJ**	Class C incl. ST/NPT/CDx	N/A	Certification as follows: 1434-IVDD-217/2022; NB# 1434
SARS-CoV-2 Antigen Rapid Test **Basic UDI-DI: 6970277510013OYM**	Class C incl. ST/NPT/CDx	N/A	Certification as follows: 1434-IVDD-035/2022; NB# 1434
SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M. pneumoniae Antigen Combo Rapid Test **Basic UDI-DI: 6970277510021QYQ**	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives
SARS-CoV-2 Antigen Rapid Test **Basic UDI-DI: 6970277510021TYW**	Class B for professional use	N/A	N/A - Device did not require a Notified Body certificate under Directives

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
COVID-19 IgG/IgM Rapid Test **Basic UDI-DI: 6970277510021SYU**	Class B for professional use	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
2025-05-06	GCN-SH251064A01; GCN-SH251064A02; GCN-SH251064A03; SH25106400_CLI	Initial issue