



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#, Yin Hai 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](http://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



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#, Yin Hai Street, Hangzhou Economic and Technological
Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC OF
CHINA



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#, Yin Hai 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

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

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#, Yin Hai Street, Hangzhou Economic and Technological
Development Area, 310018 Hangzhou, People's Republic of China

New facility(ies):

Hangzhou AllTest Biotech Co., Ltd.
550#, Yin Hai 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



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; SH25106400_CLI_transfer1; SH25106400_CLI_transfer2	medical_devices@tuvsud.com		2025-09-26	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter
CLI 095123 0015 Rev. 02

Reference: GCN-SH251064A01 | GCN-SH251064A02 | GCN-SH251064A03 | SH25106400_CLI | SH25106400_CLI_transfer1 | SH25106400_CLI_transfer2

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.

Registered Office: Munich
Trade Register Munich HRB 85742
UniCredit Bank GmbH · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at [tuvsud.com/imprint](https://www.tuvsud.com/imprint)

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Wolfgang Hübl (CEO)
Karl Meier
Patrick van Welij

TÜV SÜD Product Service GmbH
Zertifizierstelle für Medizinprodukte /
Certification Body for Medical Products
Ridlerstr. 65
80339 Munich
Germany

[tuvsud.com/ps](https://www.tuvsud.com/ps)
Hotline: +49 89 50084-747





- 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.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2025-09-26

TÜV SÜD Product Service GmbH
Medical and Health Services

Chenchuan Weng

Chenchuan Weng (26. September 2025 22:06:55 GMT+8)

26/09/2025

Mr. Chenchuan WENG
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

A. Bohms

26/09/2025

Andreas Bohms
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
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



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
			NOTE: TÜV SÜD takes over responsibility for appropriate surveillance on 2025-09-26
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 NOTE: TÜV SÜD takes over responsibility for appropriate surveillance on 2025-09-26
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 NOTE: TÜV SÜD takes over responsibility for appropriate surveillance on 2025-09-26
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 NOTE: TÜV SÜD takes over responsibility for appropriate surveillance on 2025-09-26
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 NOTE: TÜV SÜD takes over responsibility for appropriate surveillance on 2025-09-26
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 NOTE: TÜV SÜD takes over responsibility for appropriate surveillance on 2025-09-26

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
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
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
2025-09-24	SH24167600_CLI_transfer; SH25106400_CLI_transfer1; SH25106400_CLI_transfer2	Revision 01: Moved devices from Table 2 to Table 1 and added date of transfer, general formatting adjustments
2025-09-26	SH25106400_CLI_transfer1; SH25106400_CLI_transfer2	Revision 02: Correction of version history. Internal reference SH24167600_CLI_transfer removed