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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;<br>GCN-SH251064A02;<br>GCN-SH251064A03;<br>SH25106400_CLI;<br>SH25106400_CLI_transfer1;<br>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](http://www.tuvsud.com/ps-cert?q=CLI 095123 0015)

In case of inquiries please contact [medical\\_devices@tuvsud.com](mailto: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 |
|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| <b>FSH Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510020PYK                                | Class B incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>hCG Pregnancy Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510020QYM                      | Class B incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>Digital hCG Pregnancy Test</b><br><br>Basic UDI-DI:<br>6970277510020RYP                    | Class B incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>hCG Pregnancy Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510020SYR                      | Class B incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>hCG Pregnancy Enhanced Sensitivity Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510020TYT | Class B incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>LH Ovulation Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510020UYV                       | Class B incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>LH Ovulation Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510020VYX                       | Class B incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>LH Ovulation Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510020WYZ                       | Class B incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>LH Ovulation Rapid Test</b>                                                                | Class B incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>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 |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| <b>Basic UDI-DI:</b><br>6970277510020XZ3                                            |                                                                                                     |                                                                                            | NB# 0123                                                                                       |
| <b>Chlamydia Rapid Test</b><br><br><b>Basic UDI-DI:</b><br>6970277510020YZ5         | Class C for professional use                                                                        | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>CMV IgM Rapid Test</b><br><br><b>Basic UDI-DI:</b><br>6970277510020ZZ7           | Class C for professional use                                                                        | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>H. pylori Antigen Rapid Test</b><br><br><b>Basic UDI-DI:</b><br>6970277510020OYH | Class C incl. ST/NPT/CDx                                                                            | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>Rubella IgM Rapid Test</b><br><br><b>Basic UDI-DI:</b><br>6970277510021AXQ       | Class C for professional use                                                                        | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>Toxo IgG/IgM Rapid Test</b><br><br><b>Basic UDI-DI:</b><br>6970277510021BXS      | Class C for professional use                                                                        | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>Toxo IgG/IgM Rapid Test</b><br><br><b>Basic UDI-DI:</b><br>6970277510021CXU      | Class C for professional use                                                                        | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>ToRCH IgM Combo Rapid Test</b><br><br><b>Basic UDI-DI:</b><br>6970277510021DXW   | Class C for professional use                                                                        | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>Vaginal pH Rapid Test</b><br><br><b>Basic UDI-DI:</b><br>6970277510021EXY        | Class C incl. ST/NPT/CDx                                                                            | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>Ferritin Rapid Test</b><br><br><b>Basic UDI-DI:</b><br>6970277510021FY2          | Class C incl. ST/NPT/CDx                                                                            | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| <b>Sperm Concentration Rapid Test</b>                                               | Class B incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;                                           |



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|--------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| Basic UDI-DI:<br>6970277510021GY4                                        |                                                                                                     |                                                                                            | VCQ 095123 0013 Rev. 00<br>NB# 0123                                                            |
| SP-10 Male Fertility Rapid Test<br><br>Basic UDI-DI:<br>6970277510021HY6 | Class B incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| TSH Rapid Test<br><br>Basic UDI-DI:<br>6970277510021IY8                  | Class C incl. ST/NPT/CDx                                                                            | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| Vitamin D Rapid Test<br><br>Basic UDI-DI:<br>6970277510021JYA            | Class C incl. ST/NPT/CDx                                                                            | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| FOB Rapid Test<br><br>Basic UDI-DI:<br>6970277510020NYF                  | Class C incl. ST/NPT/CDx                                                                            | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| PSA Rapid Test<br><br>Basic UDI-DI:<br>6970277510021KYC                  | Class C for professional use                                                                        | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| PSA Qualitative Rapid Test<br><br>Basic UDI-DI:<br>6970277510021LYE      | Class C for professional use                                                                        | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| Urinary Tract Infections Test<br><br>Basic UDI-DI:<br>6970277510019KYX   | Class C incl. ST/NPT/CDx                                                                            | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| Urinary Tract Infections Test<br><br>Basic UDI-DI:<br>6970277510019LYZ   | Class C incl. ST/NPT/CDx                                                                            | N/A                                                                                        | Certification as follows:<br>V1 095123 0008 Rev. 04;<br>VCQ 095123 0013 Rev. 00<br>NB# 0123    |
| HBsAg Rapid Test<br><br>Basic UDI-DI:<br>6970277510017FYF                | Class D incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>CeCert/102/W/E.1;<br>CeCert/101/W/E.1;<br>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 <b>2025-09-26</b>                                                                                        |
| <b>HCV Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510017CY9                                        | Class D incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>CeCert/107/W/E.1;<br>CeCert/106/W/E.1;<br>NB# 2934<br><br>NOTE: TÜV SÜD takes over responsibility for appropriate surveillance on <b>2025-09-26</b> |
| <b>HIV 1.2 Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510017BY7                                    | Class D incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>CeCert/097/W/E.1;<br>CeCert/096/W/E.1;<br>NB# 2934<br><br>NOTE: TÜV SÜD takes over responsibility for appropriate surveillance on <b>2025-09-26</b> |
| <b>ABO and RhD Blood Grouping Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510021MYG                 | Class D incl. ST/NPT                                                                                | N/A                                                                                        | Certification as follows:<br>CeCert/089/W/E.1;<br>CeCert/088/W/E.1;<br>NB# 2934<br><br>NOTE: TÜV SÜD takes over responsibility for appropriate surveillance on <b>2025-09-26</b> |
| <b>SARS-COV-2 and Influenza A+B Antigen Combo Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510021NYJ | Class C incl. ST/NPT/CDx                                                                            | N/A                                                                                        | Certification as follows:<br>1434-IVDD-217/2022;<br>NB# 1434<br><br>NOTE: TÜV SÜD takes over responsibility for appropriate surveillance on <b>2025-09-26</b>                    |
| <b>SARS-CoV-2 Antigen Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510013OYM                         | Class C incl. ST/NPT/CDx                                                                            | N/A                                                                                        | Certification as follows:<br>1434-IVDD-035/2022;<br>NB# 1434<br><br>NOTE: TÜV SÜD takes over responsibility for appropriate surveillance on <b>2025-09-26</b>                    |

**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<br>(under IVDR application)                                                                        | IVDR Device classification<br>(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 |
|--------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| <b>SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M. pneumoniae Antigen Combo Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510021QYQ | Class B for professional use                                                                           | N/A                                                                                        | N/A - Device did not require a Notified Body certificate under Directives                      |
| <b>SARS-CoV-2 Antigen Rapid Test</b><br><br>Basic UDI-DI:<br>6970277510021TYW                                                  | Class B for professional use                                                                           | N/A                                                                                        | N/A - Device did not require a Notified Body certificate under Directives                      |
| <b>COVID-19 IgG/IgM Rapid Test</b><br><br>Basic UDI-DI:<br>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:<br>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:<br>Correction of version history. Internal reference SH24167600_CLI_transfer removed                |