ZERTIFIKAT ◆ 认证证书 ◆ CERTIFICATE ◆ 認証書 ◆ CERTIFICATO ◆ 인증서 ◆ CERTIFICADO

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Certificate

No. Q5 095123 0007 Rev. 06

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

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents, Control Material and Instruments for Clinical Chemistry, Immunochemistry (Immunology), Haemostasis, Infectious Diseases, and Immunohaematology (Blood Grouping), including Professional Laboratory Use, Near Patient and Self Testing**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 095123 0007 Rev. 06

Report No.: SH26106413

Valid from: 2026-09-25
Valid until: 2029-09-24

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Date, 2026-09-18

Christoph Dicks
Head of Certification/Notified Body

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No. Q5 095123 0007 Rev. 06

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

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

Distribution of In Vitro Diagnostic Reagents, Control Material for Clinical Chemistry, Immunochemistry (Immunology), Haemostasis, Infectious Diseases, and Immunohaematology (Blood Grouping), including Professional Laboratory Use, Near Patient and Self Testing

Hangzhou AllTest Biotech Co., Ltd.
#383, Qiaoxin Road, Xiasha Street, Qiantang District, 310018 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of In Vitro Diagnostic Reagents, Control Material and Instruments for Clinical Chemistry, Immunochemistry (Immunology), Haemostasis, Infectious Diseases, and Immunohaematology (Blood Grouping), including Professional Laboratory Use, Near Patient and Self Testing

Hangzhou AllTest Biotech Co., Ltd.
No. 616, Dongwei Road, Hezhuang Street, Qiantang District, 311222 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of In Vitro Diagnostic Reagents, Control Material and Instruments for Clinical Chemistry, Immunochemistry (Immunology), Haemostasis, Infectious Diseases, and Immunohaematology (Blood Grouping), including Professional Laboratory Use, Near Patient and Self Testing

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