



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 042074 0031 Rev. 06

Holder of Certificate: **Acon Biotech (Hangzhou) Co., Ltd.**
No. 210 Zhenzhong Road
West Lake District
310030 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and development, manufacture and distribution of In Vitro Diagnostic Test Kits, Reagents, controls and instruments for detection of Infectious Diseases, Clinical chemistry, Immunochemistry (Immunology), Hematology, Nucleic Acid Test**
Design and development, manufacture and distribution of IVD Generic use consumables, and In Vitro Diagnostic Reagents and instruments for Sample processing
Manufacture and distribution of Lancing Device and Lancets

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 042074 0031 Rev. 06

Report No.: SH25010613

Valid from: 2025-07-15

Valid until: 2028-07-14

Date, 2025-07-08

Christoph Dicks
Head of Certification/Notified Body



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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): **Acon Biotech (Hangzhou) Co., Ltd.**
No. 210 Zhenzhong Road, West Lake District, 310030 Hangzhou,
PEOPLE'S REPUBLIC OF CHINA

Design and development, manufacture and distribution of In Vitro
Diagnostic Test Kits, Reagents, controls and instruments for
detection of Infectious Diseases, Clinical chemistry,
Immunochemistry (Immunology), Hematology, Nucleic Acid Test
Design and development, manufacture and distribution of IVD
Generic use consumables, and In Vitro Diagnostic Reagents and
instruments for Sample processing
Manufacture and distribution of Lancing Device and Lancets

Acon Biotech (Hangzhou) Co., Ltd.
Qingshanhu Subdistrict, Linan District, 311305 Hangzhou,
PEOPLE'S REPUBLIC OF CHINA

Manufacture of In Vitro Diagnostic Test Kits, reagents and controls
for detection of Infectious Diseases, Clinical chemistry,
Immunochemistry (Immunology)



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Acon Biotech (Hangzhou) Co., Ltd.

No. 22-1 Zhimawu, Shanghu Village, Yuhang Street, Yuhang District, 311121 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

Manufacture of In Vitro Diagnostic instruments for Clinical chemistry

Acon Biotech (Hangzhou) Co., Ltd.

No. 2 Qiancheng Road of Fengdu Village, Pingyao Town, Yuhang District, 311115 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

Storage of the materials and finished products related to In Vitro Diagnostic Test Kits, Reagents, controls and instruments for detection of Infectious Diseases, Clinical chemistry, Immunochemistry (Immunology), Hematology, Nucleic Acid Test; IVD Generic use consumables; In Vitro Diagnostic Reagents and instruments for Sample processing; Lancing Device and Lancets