



Product Service

Certificate

No. Q5 042074 0031 Rev. 04

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 and instruments for the detection of Infection Diseases, Tumor/Cardiac Marker, Allergen, Fertility/ Pregnancy, Hormone, Blood Glucose Monitoring System and Clinical Chemistry Analytes, Extraction/Isolation/Detection of Nucleic Acid; Specimen Preservation Media 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 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:Q5 042074 0031 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_042074_0031_Rev_04)

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Valid from: 2022-07-28
Valid until: 2025-07-14

Date, 2022-07-28

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): EN ISO 13485:2016
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2016)
 DIN EN ISO 13485:2016

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 and instruments for the detection of Infection Diseases, Tumor/Cardiac Marker, Allergen, Fertility/Pregnancy, Hormone, Blood Glucose Monitoring System and Clinical Chemistry Analytes, Extraction/Isolation/Detection of Nucleic Acid; Specimen Preservation Media
 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 and Reagents for the detection of Infection Diseases, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose monitoring system

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 the detection of Blood Glucose and Clinical Chemistry Analytes