



Certificate

No. Q5 107987 0001 Rev. 02

Holder of Certificate: **Ameritech Diagnostic
Reagent (Jiaxing) Co., Ltd.**

K4-2 Science Technology Garden, Economic Development Zone
314500 Tongxiang, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution
of In Vitro Diagnostic Reagents and Kits for
Immunochemistry, Clinical Chemistry and Infectious
Disease**

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 107987 0001 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_107987_0001_Rev_02)

Report No.: SH24163401, SH24163401_CN

Valid from: 2024-07-08

Valid until: 2027-07-07

Date, 2024-05-03

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): **Ameritech Diagnostic Reagent (Jiaxing) Co., Ltd.**
K4-2 Science Technology Garden, Economic Development Zone,
314500 Tongxiang, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate