



Product Service

Certificate

No. Q5 120095 0001 Rev. 00

Holder of Certificate: Hangzhou Tongzhou Biotechnology Co., Ltd.

Room 102, Building 4, No. 191, Xintian Road, Yunhe Street
Linping District
311103 Hangzhou, Zhejiang Province
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) and Infectious Diseases, 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 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 120095 0001 Rev. 00

Report No.: SH23211001

Valid from: 2023-07-20

Valid until: 2026-07-19

Date, 2023-07-21

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): **Hangzhou Tongzhou Biotechnology Co., Ltd.**
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See Scope of Certificate

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