



Certificate

No. Q5 077434 0014 Rev. 04

Holder of Certificate: **HANGZHOU BIOTEST BIOTECH CO., LTD.**
17#, Futai Road, Zhongtai Street
Yuhang District
311121 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Kits for Clinical Chemistry, Immunochemistry (Immunology) and Infectious Diseases**

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 077434 0014 Rev. 04

Report No.: SH2370801, SH2370801_CN

Valid from: 2023-09-06

Valid until: 2026-09-05

Date, 2023-08-24

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 077434 0014 Rev. 04

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 BIOTEST BIOTECH CO., LTD.

17#, Futai Road, Zhongtai Street, Yuhang District, 311121
Hangzhou, PEOPLE'S REPUBLIC OF CHINA

Production of In Vitro Diagnostic Kits for Clinical Chemistry,
Immunochemistry (Immunology) and Infectious Diseases

CITUS DIAGNOSTICS INC.

300-422 Richards street, Vancouver, British Columbia V6B 2Z4,
CANADA

Distribution of In Vitro Diagnostic Kits for Clinical Chemistry,
Immunochemistry (Immunology) and Infectious Diseases

HANGZHOU BIOTEST BIOTECH CO., LTD.

No. 27, Tuyi Road, Cangqian Street, Yuhang District, 311121
Hangzhou, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of In Vitro
Diagnostic Kits for Clinical Chemistry, Immunochemistry
(Immunology) and Infectious Diseases