



Certificate

No. Q5 071134 0011 Rev. 02

Holder of Certificate: **AUTOBIO DIAGNOSTICS CO., LTD.**
No.87 Jingbei Yi Road
National Eco & Tech Development Area
450016 Zhengzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Reagent Kits for ELISA, Chemiluminescence immunoassay, Colloidal gold rapid test, Microbiological culture medium and identification, Chemiluminescence microparticle immunoassay, and Real-Time PCR; Quality Control Materials.

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 071134 0011 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_071134_0011_Rev_02)

Report No.: SH2170701

Valid from: 2021-09-28

Valid until: 2024-09-27

Date, 2021-08-06



Christoph Dicks
Head of Certification/Notified Body



Product Service

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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):

AUTOBIO DIAGNOSTICS CO., LTD.
No.87 Jingbei Yi Road, National Eco & Tech Development Area,
450016 Zhengzhou, PEOPLE'S REPUBLIC OF CHINA

Certificate Holder and Receipt of Customer feedback

AUTOBIO DIAGNOSTICS CO., LTD.
No.199, 15th Ave, National Eco & Tech Zone, 450016 Zhengzhou,
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate