



Product Service

Certificate

GIÁM ĐỐC
LIANG JIANGING

No. Q5 052591 0010 Rev. 04

Holder of Certificate: **Shanghai Kehua Bio-engineering Co., Ltd.**
1189 North Qinzhou Road
200233 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent for Clinical Chemistry, Immunochemistry (Immunology), Haematology, Cytokines and Infectious Diseases using ELISA, PCR, Clinical Chemistry, Chemiluminescence and Rapid Test Technologies**

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_052591_0010_Rev_04

Report No.: SH2431901
Valid from: 2024-05-20
Valid until: 2027-05-19

Date, 2024-04-11

Christoph Dicks
Head of Certification/Notified Body

Certificate

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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): **Shanghai Kehua Bio-engineering Co., Ltd.**
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Diagnostic Reagent for Clinical Chemistry, Immunochemistry
(Immunology), Haematology, Cytokines and Infectious Diseases
using ELISA, PCR, Clinical Chemistry, Chemiluminescence and
Rapid Test Technologies

Shanghai Kehua Bio-engineering Co., Ltd.
701, Guiping Road, 200233 Shanghai, PEOPLE'S REPUBLIC OF
CHINA

Production of In Vitro Diagnostic Reagent for Immunochemistry
(Immunology), Haematology, Cytokines and Infectious Diseases
using PCR, Chemiluminescence and Rapid Test Technologies

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Warehouse