



Certificate

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

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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

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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