



# Certificate

No. Q5 052591 0010 Rev. 02

**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 Reagents 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 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 052591 0010 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 052591 0010 Rev. 02)

**Report No.:** SH2131901

**Valid from:** 2021-05-20  
**Valid until:** 2024-05-19

**Date,** 2021-05-05

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):

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

Design and Development, Production and Distribution of In Vitro  
Diagnostic Reagents 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 Reagents using PCR and  
Chemiluminescence Technologies

**Shanghai Kehua Bio-engineering Co., Ltd.**  
**F2, Building 2, No.26 West Zhangjing Road, Dongjing Town,**  
**Songjiang District, 201619 Shanghai, PEOPLE'S REPUBLIC**  
**OF CHINA**

Warehouse

**Shanghai Kehua Bio-engineering Co., Ltd.**  
**Room 106, Room 301, Room 302, Room 303, Room 304, Room**  
**402, Building 2, 99 Yinxi Road, Songjiang District, 201615**  
**Shanghai, PEOPLE'S REPUBLIC OF CHINA**

Warehouse