



# Certificate

No. Q5 094846 0002 Rev. 02

**Holder of Certificate:** **Hangzhou Realy Tech Co., Ltd.**  
#2 Building, No. 763, Yuansha Village, Xinjie Street  
Xiaoshan District  
311200 Hangzhou City, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In vitro diagnostic reagent based on Colloidal gold method, and In vitro diagnostic POCT instrument based on Colloidal Gold method and CLIA method.**

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 094846 0002 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 094846 0002 Rev. 02)

**Report No.:** SH20105601

**Valid from:** 2021-03-02

**Valid until:** 2023-01-23

**Date,** 2021-03-02



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):** Hangzhou Realy Tech Co., Ltd.  
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District, 311200 Hangzhou City, Zhejiang Province, PEOPLE'S  
REPUBLIC OF CHINA

See Scope of Certificate