

# Certificate

No. Q5 095295 0001 Rev. 00

**Holder of Certificate:** **Hangzhou Sejoy  
Electronics & Instruments Co., Ltd.**  
Area C, Building 2, No. 365, Wuzhou Road  
Yuhang Economic Development Zone  
311100 Hangzhou City, Zhejiang  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and  
Distribution of In Vitro Diagnostic Medical Device  
based on Immunochromatography, Dry Chemistry  
and Electrochemistry Method, Include Instrument,  
Test Strip and Control Solution**

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 095295 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_095295_0001_Rev_00)

**Report No.:** SH20167601

**Valid from:** 2020-10-30  
**Valid until:** 2023-10-29

**Date,** 2020-10-30



Christoph Dicks  
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

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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 Sejoy Electronics & Instruments Co., Ltd.  
Area C, Building 2, No. 365, Wuzhou Road, Yuhang Economic  
Development Zone, 311100 Hangzhou City, Zhejiang, PEOPLE'S  
REPUBLIC OF CHINA

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