



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

Certificate

No. Q5 095295 0001 Rev. 00

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

ZERTIFIKAT ♦ CERTIFICADO ♦ CERTIFICATO ♦ CERTIFIKAT ♦ СЕРТИФИКАТ ♦ 認證證書 ♦ CERTIFICATE ♦ ZERTIFIKAT ♦ CERTIFICATE