



# Certificate

No. Q5 097027 0004 Rev. 02

**Holder of Certificate:** **Hangzhou Singclean Medical Products Co., Ltd.**  
No. 125(E), 10th Street, Qiantang New Area  
310018 Hangzhou, Zhejiang  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostic Devices (Colloidal Gold, Dry Chemical Enzymatic Reaction, Sialidase Detection, ELISA and Fluorescence Immunochemistry 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 097027 0004 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 097027 0004 Rev. 02)

**Report No.:** SH201115CN01

**Valid from:** 2021-03-05

**Valid until:** 2023-01-17

**Date,** 2021-03-05

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):** Hangzhou Singclean Medical Products Co., Ltd.  
No. 125(E), 10th Street, Qiantang New Area, 310018 Hangzhou,  
Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate