



# Certificate

No. Q5 097027 0004 Rev. 01

**Holder of Certificate:** Hangzhou Singclean Medical Products Co., Ltd.

No. 125(E), 10th Street  
Hangzhou Economic and Technological Development Zone  
310018 Hangzhou, Zhejiang  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Hangzhou Singclean Medical Products Co., Ltd.  
No. 125(E), 10th Street, Hangzhou Economic and Technological Development Zone, 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 Immunochromatography Method)

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)  
DIN EN ISO 13485:2016

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). See also notes overleaf.

**Report No.:** SH19111505

**Valid from:** 2020-01-18

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

**Date,** 2020-01-08

Christoph Dicks  
Head of Certification/Notified Body

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

