DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD
Product Service

认 证 证 书

证书号. Q5 097027 0004 Rev. 01

证书持有者： **杭州协合医疗用品有限公司**

中华人民共和国浙江杭州经济技术开发区10号大街（东）125号
310018

生产场地： 杭州协合医疗用品有限公司
中华人民共和国浙江杭州经济技术开发区10号大街（东）125号
310018

认证标志：

认证范围： **设计和开发、生产和分销：**
体外诊断试剂（胶体金法，干化学酶法，唾液酸酶法，酶联免疫法，荧光免疫层析法）

认证标准： EN ISO 13485:2016
医疗器械 - 质量管理体系 - 用于法规的要求
(ISO 13485:2016)
DIN EN ISO 13485:2016

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。

报告号： SH19111505
生效期： 2020-01-18
有效期： 2023-01-17
发证日期， 2020-01-08

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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本证书是由具有法律效力的英文证书翻译而来

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