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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 097027 0002 Rev. 03

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

Product Category(ies): **In Vitro diagnostic for self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. 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:V1 097027 0002 Rev. 03

Report no.: SH211115EXT01

Valid from: 2022-01-26
Valid until: 2024-05-26

Date, 2022-01-26

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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Model(s):

**Luteinizing Hormone (LH)
Ovulation Test Kit (Colloidal Gold),
Follicle Stimulating Hormone
(FSH) Test Kit (Colloidal Gold),
Human Chorionic Gonadotropin (HCG)
Pregnancy Test Kit (Colloidal Gold),
Microalbuminuria(MAU) Rapid Test Kit(Colloidal Gold)**

Facility(ies):

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

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