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 092305 0002 Rev. 00

Manufacturer: **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Products for determination of infection markers**
Tumor markers and products 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 092305 0002 Rev. 00

Report no.: SH2098801

Valid from: 2021-03-17
Valid until: 2024-05-26

Date, 2021-03-03

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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No. V1 092305 0002 Rev. 00

Model(s):

In Vitro Diagnostic Rapid Test for Self-Testing, including
HCG Pregnancy Rapid Test,
LH Ovulation Rapid Test,
Digital Pregnancy Test

In Vitro Diagnostic Rapid Test, including
Toxoplasma Gondii (Toxo) IgG/IgM Rapid Test,
Toxoplasma Gondii (Toxo) IgG Rapid Test,
Toxoplasma Gondii (Toxo) IgM Rapid Test,
Prostate Specific Antigen (PSA) Rapid Test,
Chlamydia Trachomatis Antigen Rapid Test

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

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