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

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

Digitally signed by Iurchevici Valeriu
Date: 2023.12.27 16:10:13 EET
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service

# Certificate

## No. Q5 092305 0001 Rev. 00

**Holder of Certificate:** **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, 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 Reagents for Cardiac Diseases, Infectious Diseases, Oncology and for Biochemistry as well as Rapid Tests for Fertility, Rapid Tests for Drugs of Abuse, Chlamydia Trachomatis Antigen, Toxoplasma gondii(Toxo) IgG/IgM, Toxoplasma gondii(Toxo) IgG, Toxoplasma gondii(Toxo) IgM, Digital Pregnancy Tests for Self-testing, and Distribution of Urine Analyzer as well**

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 092305 0001 Rev. 00

**Report No.:** SH2098801

**Valid from:** 2021-03-17
**Valid until:** 2024-03-16

**Date,** 2021-03-03

Christoph Dicks
Head of Certification/Notified Body

"TECHIPAMED-PLUS" SOCIETATEA CU RĂSPUNDERE LIMITATĂ mun. CHIȘINĂU IDNO 1003600077677


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

# Certificate

## No. Q5 092305 0001 Rev. 00

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

See Scope of Certificate


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