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

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

TÜV SÜD Product Service

Certificate

No. Q5 112784 0001 Rev. 01

Holder of Certificate: **Genrui Biotech Inc.**
4-10F, Building 3, Geya Technology Park
Guangming District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Instruments, including Biochemistry Analyzers, Electrolyte Analyzers, Hematology Analyzers, Coagulation Analyzers, Specific Protein Analyzers, Quantitative Immunoassay Analyzers, Chemiluminescence Immunoassay Analyzers, Fully-Auto Nucleic Acid Extraction Instruments, Pre-processing System, and In Vitro Diagnostic Test Kits, including Reagents, Calibrators and Controls Used for Determination of Immune Status, Detection of Respiratory Infectious Disease, Determination or Monitoring of Physiological Markers, Confirmation of Specific Disorders/Impairments, Confirmation of Non-infectious Pathologies, Non-infectious Disease Staging, Detection of Pregnancy or Fertility.**

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 112784 0001 Rev. 01

Report No.: GZ2245901

Valid from: 2023-01-26
Valid until: 2024-10-28

Digitally signed by Bolea Petru
Date: 2024.01.31 10:30:28 EET
Reason: MoldSign Signature
Location: Moldova

Date, 2023-01-26

Christoph Dicks
Head of Certification/Notified Body

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

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No. Q5 112784 0001 Rev. 01

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):

Genrui Biotech Inc.
4-10F, Building 3, Geya Technology Park, Guangming District,
518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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