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

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

TÜV SÜD Product Service

Certificate

No. Q5 093780 0003 Rev. 01

Holder of Certificate: **Qingdao Hightop Biotech Co., LTD.**
No. 369 Hedong Road, Hi-tech Industrial Development Zone
266112 Qingdao, Shandong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution of In-vitro Diagnostic Reagent: Immunofluorescence Test Kits, Colloidal Gold Chromatography Test Kits, ELISA Filtration Assay Kits, Dry Chemical Reagents, Clinical Chemistry Test Reagents, Reagents for Hematology Analysis (composed of Lyse-HE and Lyse-SF which are used for hemolysis, and diluent which is used for blood dilution), Reagents for Sample Treatment (Disposable Virus Sampling Tube, Nucleic Acid Extraction/Purification Reagent, Nucleic Acid Purification Reagent).**
Design and Development, Production, Distribution and Servicing of In-vitro Diagnostic Equipment: Biochemical Analyzer, Urine Analyzer, Fluorescence Immunoassay Analyzer, Automatic Analyzer for Colloidal Gold Rapid Test, Analyzer for Colloidal Gold Rapid Test, Hematology Analyzer.

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 093780 0003 Rev. 01

Report No.:	BJ21099602
Valid from:	2022-04-01
Valid until:	2025-03-31

Date, 2022-03-29

Christoph Dicks
Head of Certification/Notified Body

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

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Product Service

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No. Q5 093780 0003 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):

Qingdao Hightop Biotech Co., LTD.
No. 369 Hedong Road, Hi-tech Industrial Development Zone,
266112 Qingdao, Shandong, PEOPLE'S REPUBLIC OF CHINA

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