



Certificate

No. Q5 093780 0003 Rev. 00

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

Facility(ies): 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, Sales and Distribution

of In-vitro Diagnostic of Immunofluorescence kits, Colloidal Gold Chromatography Kits, ELISA Filtration Assay Kits, Dry

Chemical Reagents, Biochemical Reagents.

Design and Development, Production, Sales, Distribution and Servicing of In-vitro Diagnostic Equipment: Biochemical Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer, Fluorescence Immunoassay Analyzer, Automatic

ELISA Filtration Assay Reader.

Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.: BJ18996041

 Valid from:
 2019-09-06

 Valid until:
 2022-03-31

2019-09-06 Stefan Prei

Head of Certification/Notified Body

Date,