



Product Service

CERTIFICATE

No. Q1N 15 10 93780 001

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, 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.

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.: BJ1599601

Valid from: 2016-11-16

Valid until: 2019-11-15

Date, 2016-11-16

Stefan Preiß



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Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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

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

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