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

TÜV SÜD
Product Service

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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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

Date, 2019-09-06

Stefan Preiß
Head of Certification/Notified Body

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

TÜV®