



Product Service

# Certificate

No. Q5 093780 0003 Rev. 02

**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

See Scope of Certificate

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Sales of in vitro diagnostic reagents and instruments for Clinical Chemistry, Immunochemistry (immunology), Haematology, Haemostasis, Cytokines, Infectious Diseases, and of Sample Transport, Sample Analysis in vitro diagnostic Consumables**

**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

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, Certification, Validation and Verification Regulations 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. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_093780_0003_Rev.02)

**Report No.:** BJ24099602  
**Valid from:** 2025-04-01  
**Valid until:** 2028-03-31

**Date,** 2025-03-12

Christoph Dicks  
Head of Certification/Notified Body