



Product Service

# Certificate

No. Q5 095791 0008 Rev. 05

**Holder of Certificate:** **NewScen Coast  
Bio-Pharmaceutical Co., Ltd.**  
No. 65, 6th Street  
Tianjin TEDA  
300457 Tianjin  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution  
of In Vitro Diagnostic Reagents and Instruments for  
Clinical Chemistry, Immunochemistry, Haemostasias  
and Infectious Immunology**

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 095791 0008 Rev. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5 095791 0008 Rev. 05)

**Report No.:** SH25107302

**Valid from:** 2025-10-21

**Valid until:** 2028-10-20

**Date,** 2025-10-02

Christoph Dicks  
Head of Certification/Notified Body



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**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

**Facility(ies):** **NewScen Coast Bio-Pharmaceutical Co., Ltd.**  
No. 65, 6th Street, Tianjin TEDA, 300457 Tianjin, PEOPLE'S  
REPUBLIC OF CHINA

See Scope of Certificate