



# Certificate

No. Q5 095791 0008 Rev. 03

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

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

**Certification Mark:** See Scope of Certificate



**Scope of Certificate:** **Design and Development, Production and Distribution of  
Lateral-Flow Technique based In Vitro Diagnostic Medical  
Devices and Readers for Lateral-Flow Devices, Microfluidic  
Immunofluorescence In Vitro Diagnostic Test Kits and  
Fluorimetric Immunoassay Analyser**

**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). All applicable requirements of the testing and certification regulation of 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. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5 095791 0008 Rev. 03)

**Report No.:** SH22107301  
**Valid from:** 2022-10-21  
**Valid until:** 2025-10-20

**Date,** 2022-09-20



Christoph Dicks  
Head of Certification/Notified Body