



Product Service

# Certificate

No. Q5 095791 0008 Rev. 01

**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:**



**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**

**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.:** SH19107304

**Valid from:** 2019-10-21

**Valid until:** 2022-10-20

**Date,** 2019-09-19

Stefan Preiß  
Head of Certification/Notified Body