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

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:

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

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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

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