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

Product Service

CERTIFICATE

No. Q5 18 02 03200 001

Holder of Certificate: **Cellex, Inc.**
76 TW Alexander Dr
Research Triangle Park
Durham NC 27709-0002
USA

Facility(ies):
Cellex, Inc.
76 TW Alexander Dr, Research Triangle Park,
Durham NC 27709-0002, USA

CELLEX BIOTECH (Suzhou) Co., Ltd.
1F, North Black, 16 Building, 8 Jinfeng Road,
Suzhou New District, 215011 Suzhou,
Jiangsu, 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 In Vitro Diagnostic Test Kit based on Lateral Flow Chromatographic Immunoassay and In Vitro Diagnostic Test Kit and Analyzer based on Immunofluorescence Assay, Homogeneous Biochemiluminescence Assay(HBA)**

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.: SH17125501

Valid from: 2018-06-26
Valid until: 2021-06-25

Date, 2018-06-26

Stefan Preiß

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Deutsche Akkreditierungsstelle
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Page 1 of 1

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