Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Core Technology Co., Ltd.
Room 100, C Building
No. 29 Life Park Road
Changping District
BEIJING 102206
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date November 05, 2019

Application for : QMS
Certificate No. : SX 60143808 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the
new certificate No. SX 60143808 0001
replacing the previous certificate.

Kind regards

Certification body

Jing Zhang

Test sample: no, documentation available

Digitally signed by Guțan Ghenadie
Date: 2021.10.11 17:32:37 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV Rheinland
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Web www.tuv.com/safety

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60143808 0001
Report No.: 16806537 004

Organization:
Core Technology Co., Ltd.
Room 100, C Building
No. 29 Life Park Road
Changping District
Beijing 102206
China

Scope:

Design and Development, Manufacture and Distribution of In-vitro Diagnostic Test Kits used in the Detection of Fertility Testing, Pregnancy Testing, Drug of Abuse and Cancer, Cardiac Markers, Protein Metabolism and used in Diagnostic of Disease Status, Sexually Transmissible Agents, Transmissible Agents including Home Use, Near Patient In-vitro Diagnostic Devices

Site included:

No.30, Area 9, Douda Avenue,Fangshan District, Beijing 102433, China

Same scope as mentioned above

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2019-11-05

TÜV Rheinland LGA Products GmbH

Jing Zhang

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Core Technology Co., Ltd.
Room 100, C Building
No. 29 Life Park Road
Changping District
Beijing 102206
China

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope and site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-11-05
Certificate Registration No.:	SX 60143808 0001
An audit was performed. Report No.:	16806537 004
This Certificate is valid until:	2022-10-30

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2019-11-05

Jing Zhang

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