TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Hangzhou Laihe Biotech Co., Ltd.
Floor 1, Room 505-512 Floor 5
Building B
688 Bin'an Road, Binjiang District
Hangzhou
310052 Zhejiang
China

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

(see attachment for scope 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:	2018-05-11
Certificate Registration No.:	SX 60129243 0001
An audit was performed. Report No.:	15079748 004
This Certificate is valid until:	2021-05-10

Certification Body

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

Date 2018-05-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://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 60129243 0001
Report No.: 15079748 004

Organization:
Hangzhou Laihe Biotech Co., Ltd.
Floor 1, Room 505-512 Floor 5
Building B
688 Bin'an Road, Binjiang District
Hangzhou
310052 Zhejiang
China

Scope:
Manufacture and Distribution of In-vitro diagnostic rapid test kits used in the detection of autoimmune status, tumor markers, cardiac markers, drugs of abuse, fertility testing, immune status, sexually transmissible agents, transmissible agents, In Vitro Diagnostic Test Kits and Related Instruments for the field of fluorsscent immunoassay

Certification Body

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