TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street
Anji, Huzhou
313300 Zhejiang
China

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

(see attachment for scope)

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:	2018-03-17
Certificate Registration No.:	SX 60126352 0001
An audit was performed. Report No.:	15077992 008
This Certificate is valid until:	2021-03-16

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-01-30

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60126352 0001
Report No.: 15077992 008

Organization:
Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street
Anji, Huzhou
313300 Zhejiang
China

Scope:

Design and Development, Manufacture and Distribution of In Vitro Diagnostic Reagents for Cardiac Diseases, Infectious Diseases Oncology and for Biochemistry as well as Rapid Tests for Fertility, Rapid Tests for Drugs of Abuse, Chlamydia Trachomatis Antigen, Toxoplasma gondii(Toxo) IgG/IgM, Toxoplasma gondii(Toxo) IgG, Toxoplasma gondii(Toxo) IgM, Digital Pregnancy Tests for Self-testing, and Distribution of Urine Analyzer as well

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

X. Ren

Date: 2018-01-30