

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**Hangzhou Clongene Biotech
Co., Ltd.**
No. 1 Yichuang Road, Yuhang Sub-district
Yuhang District
311121 Hangzhou
P.R. China

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

**Design/development, Manufacture and Distribution of
In-vitro Diagnostic Rapid Test of Fertility, Drug of Abuse,
Infectious Diseases, Tumour Markers and Cardiac Markers**

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: 2020-04-16
Certificate Registration No.: SX 60137252 0001
An audit was performed. Report No.: 15073650 006
This Certificate is valid until: 2020-11-12

Certification Body



Date 2020-04-16


Wenxiang Zhang



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2020-11-03

To Whom It May Concern

This is to confirm that a Re-certification Audit for ISO 13485, Surveillance Audit for IVDD was carried out on behalf of TÜV Rheinland LGA Products GmbH Notified Body ([CE0197](#)) as follows:

Applicant: **Hangzhou Clongene Biotech Co., Ltd.**

Address: **No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, Hangzhou 311121, China**

Scope: **Design/development, Manufacture and Distribution of In-vitro Diagnostic Rapid Test of Fertility, Drug of Abuse and Infectious Diseases, In-vitro Diagnostic Rapid Test of Tumour Markers, In-vitro Diagnostic Rapid Test of Cardiac Markers**

Standards: **EN ISO 13485:2016**

Date: 2020-04-09~10 remote, 2020-08-17~19 on-site

Report No.: 15073650

The result of on-site audit is positive. It is recommended that the TÜV Rheinland LGA Products GmbH Notified Body ([CE0197](#)) approval should be remained valid.

The corrective action proposed by the company are acceptable, therefore the auditors will recommend that TÜV Rheinland LGA Products GmbH Notified Body ([CE0197](#)) Certificate for a Quality Assurance System should be issued in soon.

Terry Zhang

Yours sincerely,
TÜV RHEINLAND (SHANGHAI) Co., Ltd.

TÜV Rheinland
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Confirmation letters do not permit the use of a test mark and are no equivalent substitute to a certificate.