TÜVRheinland®
Precisely Right.

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.

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

TÜV Rheinland
(Shanghai) Co., Ltd.

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