

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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