



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
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 and Infectious Diseases, In-vitro
Diagnostic Rapid Test of Tumour 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: 2018-02-06
Certificate Registration No.: SX 60126181 0001
An audit was performed. Report No.: 15073650 005
This Certificate is valid until: 2020-11-12

Certification Body



Date 2018-02-06



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