



# 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 and 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: 2020-11-25  
Certificate Registration No.: SX 60152722 0001  
An audit was performed. Report No.: 15073650 008  
This Certificate is valid until: 2023-11-18

Certification Body



Date 2020-11-25



Herbert Zhong

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