

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



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>



杭州隆基生物技术有限公司
Hangzhou Clongene Biotech Co., Ltd.

Tel: +86-571-88262120
Fax: +86-571-88261752

Web: www.clongene.com
Email: marketing@clongene.com

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Hangzhou Clongene Biotech Co., Ltd.**
No.1 Yichuang Road, Yuhang Sub-district
Yuhang District
311121 Hangzhou
China

We declare under our sole responsibility that

the medical device: **COVID-19 Antigen Rapid Test**

of class: **Other**
according to article 9 of directive 98/79/EC

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: **Directive 98/79/EC Annex III**

Applicable standards:

EN ISO 13485:2016	EN ISO 15223-1:2016
EN ISO 23640:2015	EN13612:2002/AC:2002
EN 13975:2003	EN ISO 14971:2012
EN ISO 18113-1:2011	EN ISO 18113-2:2011
EN 62366-1:2015	

Name and address of the authorized representative: **Shanghai International Holding Corporation GmbH (Europe)**
Eiffestrasse 80
20537 Hamburg
Germany



Hangzhou, July.15.2020

Place, date

Shujian Zheng, Legal representative

Name and function