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

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

杭州隆基生物技术有限公司
HANGZHOU CLONGENE BIOTECH CO., LTD.

Hangzhou, July.15.2020
Place, date

Shujian Zheng, Legal representative
Name and function

TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-04-16

Wenxiang Zhang

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

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.

TÜV Rheinland
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