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 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

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

Date 2020-11-25

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Herbert Zhong

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, excluding Section 6**

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, February 22, 2021.
Place, date

Shujian Zheng, Legal representative
Name and function

Hangzhou Clongene Biotech Co., Ltd.
No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, 311121Hangzhou, China
Tel: +86-571-88262120 Fax: +86-571-88262112
http://en.clongene.com/

November 29, 2021

To whom it may concern,

We, as the manufacturer of COVID-19/Influenza A+B Antigen Combo Rapid Test, COVID-19 Antigen Rapid Test Cassette (Saliva), COVID-19 Antigen Rapid Test Cassette (Nasal swab) and COVID-19 Antigen Rapid Test assure that the following major SARS-CoV-2 variants which seem to spread more easily and quickly than other variants, can be detected by these antigen tests:

- ✓ **B.1.1.7 (Alpha)**
- ✓ **B.1.351 (Beta)**
- ✓ **P.1 (Gamma)**
- ✓ **B.1.617.2 (Delta)**
- ✓ **C.37 (Lambda)**
- ✓ **B.1.1.529 (Omicron)**

Yours sincerely,

Hangzhou Clongene Biotech Co., Ltd.

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