



杭州隆基生物技术有限公司
Hangzhou Clongene Biotech Co., Ltd.
Tel: +86-571-88262120 Web: www.dongene.com
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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 15223-1:2016
EN ISO 23840:2015 EN ISO 14971:2012
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)
Eiffelstrasse 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

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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