



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 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, February 22, 2021.

Place, date

Shujian Zheng, Legal representative

Name and function