



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

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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**

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	

Applicable standards:

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