



## 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 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, July.15.2020

Place, date

Shujian Zheng, Legal representative

Name and function