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 aticle 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**

Standards Applied:

EN ISO 13485:2016	**EN ISO 15223-1:2016**
EN ISO 23640:2015	**EN 13612:2002/AC:2002**
EN 13975:2003	**EN ISO 14971:2012**
EN ISO 18113-1:2011	**EN ISO 18113-2:2011**
EN 62366-1:2015	

Registration number issued by the German Competent Authority: **DE/CA05/IvD-238321-1547-00**

Name and address of the Authorised 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

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