

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**

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

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,

Signature

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