4. EU-Konformitätserklärung

杭州隆基生物技术有限公司
Hangzhou Clongene Biotech Co., Ltd.
Tel: +86-571-88262120 Web: www.clongene.com
Fax: +86-571-88261752 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**

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

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

Hangzhou, July.15.2020
Place, date

Shujian Zheng, Legal representative
Name and function

EC Declaration of Conformity
Revision 1.0

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