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

Hangzhou Clongene Biotech Co., Ltd.
No.1 Yichuang Road, Yuhang Sub-district,Yuhang District,311121,Hangzhou, China

DECLARATION

26 October, 2021

To whom it may concern,

COVID-19 Antigen Rapid Test (test-ID AT079/20) and CLUGENE COVID-19 Antigen Rapid Test Cassette (test-ID AT526/21) are the same product.

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

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