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**
REF: ISCOVu002-B001, ISCOVu002-B005, ISCOVu002-B025

of class: **Self-testing**
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, Section 6**

Registration No.: **1434-IVDD-017/2022**

Notified Body: **POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A**
ul. Pulawska 469
02-844 Warszawa
Poland
CE 1434

Hangzhou, 16 February, 2022
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.