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 - ISCOVu002**

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 4 and 6**

Applicable standards:

EN ISO 13485:2016
EN ISO 23640:2015
EN13975:2003
EN ISO 18113-1:2011
EN 62366-1:2015
EN ISO 17511:2021
EN ISO 15223-1:2021
EN 13612:2002/AC:2002
EN ISO 14971:2019
EN ISO 18113-4:2011
EN 13532:2002
EN 13641:2002

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, May 10, 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.