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: ICOV5002-B001, ICOV5002-B005, ICOV5002-B025

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, excluding Section 6

Applicable standards:

EN ISO 13485:2016
EN ISO 18113-1:2011
EN ISO 23640:2015
EN 13641:2002
EN 13975:2003
EN ISO 17511:2021
EN ISO 15223-1:2021
EN ISO 18113-2:2011
EN ISO 14971:2019
EN13612:2002/AC:2002
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, May 18, 2022
Place, date

Shuijian Zheng, Legal representative
Name and function