

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 Cassette (Saliva)

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

Standards Applied:

EN ISO 13485:2016

EN ISO 15223-1:2016

EN ISO 23640:2015

EN 13612:2002/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
Authorised Representative:

Shanghai International Holding Corporation GmbH (Europe)
Eiffestrasse 80
20537 Hamburg
Germany

Hangzhou, February 03, 2021
Place, date

Shujian Zheng,

Name and function

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