

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 IgG/IgM Rapid Test Cassette (WB/S/P)
REF: ICOV4212-A001, ICOV4212-A025**

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**

Hangzhou, August. 14. 2020

Place, date



Shujian Zheng, Legal representative

Name and function