

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)-ICOV4212

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 **Directive 98/79/EC Annex III**
procedure:

Name and address of
the Authorised Repre-
sentative **Shanghai International Holding Corporation GmbH**
(Europe)
Eiffestrasse 80
20537 Hamburg
Germany

Hangzhou, Mar.04.2020

Place, date

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

Name and function

Shujian Zheng