

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

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

Hangzhou, Mar.04.2020

Place, date

DE/CA05/IVD-238321-1330-00

**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*