

杭州隆基生物技术有限公司 Hangzhou Clongene Biotech Co., Ltd.

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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

Conformity assessment procedure:

according to article 9 of directive 98/79/EC

Directive 98/79/EC Annex III

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.

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

Hangzhou, 03/03/2020 Place, date Shujian Zheng, Legal representative

Name and function