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Declaration of Conformity

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According to the *In Vitro* Diagnostic Medical Devices Directive 98/79/EC

Manufacturer: MedicalSystem Biotechnology Co., Ltd.

Address: No.299, Qiming South Road, Yinzhou District, 315104 Ningbo, China

Authorised Representative: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Product: Coronavirus Disease 2019 Antibody (IgM/IgG) Combined Test Kit

Model: COVID-19

Classification: Other IVD

The manufacturer, herewith, declares that the product as specified above meets the applicable provisions of the following the Directive and Standards and fulfils the obligations imposed by Annex III section 2 to 5 of Directive 98/79/EC. All supporting documentation is retained under the premise of authorised representative.

Directive:

In Vitro Diagnostic Medical Devices Directive: DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUCIL of 27 October 1998 on *in vitro* diagnostic medical device.

Standard:

All applicable harmonised standards (published in the Official Journal of the European Communities on 17th November 2017).

The above declaration of conformity is issued under the sole responsibility of the manufacturer.

Ningbo 2020.3.2
(Place and Date of Issue)

Zou Jihua General Manager
(Signature and Position)

Signed for and on behalf of the Manufacturer