CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: BEIJING KEWEI CLINICAL DIAGNOSTIC REAGENT INC.
Address: No.7,Yan Qi He,Xi Yi Rd.,Huai Rou District,Beijing,China.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague, Netherlands.

In Vitro Diagnostic Directive:

- COVID-19 IgG/IgM Antibody Rapid Test Kit.

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed:

Place Beijing,China.

European Representative:

Seal/Stamp:
Lotus NL B.V.

Lotus NL B.V. 72313

Name of authorized signatory: Wang Baojun
Position held in the company: General Manager

Seal/Stamp:
BEIJING KEWEI CLINICAL DIAGNOSTIC REAGENT INC.

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