Verification of CE Registration

Certificate No.:C-WC-20200318-001

This is to certify that during the examination of the Technical Documentation provided by the manufacturer:

Name: Changchun Wancheng Bio Electron Co., Ltd.

Address: 3rd Floor, Building 3, Hongda Optoelectronics Industrial Park, No. 789 Shunda Road, High-tech Development Zone, Changchun City, Jilin Province

On its product as follows:

Product Name: COVID-2019 ANTIGEN RAPID TEST KIT (Colloid Gold Immunochromatography)

COVID-19 IgG/IgM ANTIBODY RAPID TEST KIT(Colloidal Gold Immunochromatography)

Classification: Other IVD Product

No Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected, and the aforementioned device complies with Directive including all essential requirements.

The manufacturer has provided all the appropriate declaration according to the Directive 98/79/EC - article 10 requirements including the EC Declaration of Conformity confirming that this In vitro diagnostics medical device, as stipulated above, is fulfilling the applicable requirements of the Directive 98/79/EC.

The notification of aforementioned device has been completed by the European Representative in Germany. The German Competent Authority is notified of the manufacturer's in vitro medical devices and has allocated registration.

Issue Date: Mar. 18, 2020

Date of expiry: May 25, 2022

SIGNATURE

CE

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