Verification of CE Registration

Certificate No.:CE20200309-02

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

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Address: 18th Fool, A02 Building, KIC, Luyang District, Hefei Province, China.

Anhui,China

Product name: COVID-19（SARS-CoV-2）IgM Antibody Test Kit (Colloidal Gold)

COVID-19（SARS-CoV-2）IgG/IgM Antibody Test Kit(Colloidal Gold)

COVID-19（SARS-CoV-2）IgG Antibody Test Kit(Colloidal Gold)

Dengue IgG/IgM/NS1 Combo Test Device (Colloidal Gold) (Whole Blood /Serum / Plasma)

Dengue NS1 Ag Test Cassette (Colloidal Gold) (Whole Blood /Serum / Plasma)

Dengue NS1 Ag Test Strip (Colloidal Gold) (Whole Blood /Serum / Plasma)

Dengue IgM/IgG Test Strip (Colloidal Gold) (Whole Blood /Serum / Plasma)

Dengue IgM/IgG Test Cassette (Colloidal Gold) (Whole Blood /Serum / Plasma)

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.

Justin

Issue Date:Mar.09,2020

Date of expiry:May.26 2 22

CE

SIGNATURE