

EC Declaration of Conformity

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

Manufacturer: BIOHIT HealthCare (Hefei) Co., Ltd.
Address: Building D9 floor 1-4, Innovation Park, No.800 West Wangjiang Road, High-Tech Zones, Hefei, Anhui, PR China
European Representative: Wellkang Ltd
Address: 16 Castle St, Dover, CT16 1PW, UK

Product: SARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method)
Classification: Others

We, the manufacturer, herewith declare with sole responsibility that our product mentioned above meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.

General Applicable Directive DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

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

General Manager: Liu Feng



HeFei, March 18th, 2020

(Place and Date of Issue)



Liu Feng

(Signature and Seal)