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,West Wangjiang Road No.800,High-Tech Zones, Hefei, Anhui,PR China

European Representative: ScheBo® · Biotech AG

Address: Netanyastr.3/35394 Gießen/Germany

Product: SARS-CoV-2 ANTIGEN RAPID TEST KIT (Fluorescence Immunochromatography)

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.

Standards applied:

EN 1041:2008	EN ISO 13485:2016	EN 13612:2002
EN 13641:2002	EN ISO 13975:2009	EN ISO 14971:2019EN
EN ISO 15193:2009	EN ISO 15194:2009	EN ISO 15223-1:2016
EN ISO 17511:2003	EN ISO 18113-1:2013	EN ISO 18113-2:2013
EN ISO 20916:2019	EN ISO 23640:2015	

Other directives applied: Directive 94/92/EEC

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

CE

HeFei,Dec.8th,2020

(Place and Date of Issue)

BIOHIT HEALTHCARE (HEFEI) CO., LTD. 必欧瀚生物技术(合肥)有限公司 340131017586

Liu Feng

General Manager

(Signature and Seal)