



DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Shenzhen Huaree Technology Co.,Ltd
Address: 101, 201, No.17, Shouli Road, Central Community, Pingdi Street, Longgang District, 518117 Shenzhen, China
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: COVID-19 Ag Saliva Easy Test Device
(Immunochromatography)
Specification: HRK-8620(20test/kit), HRK-8605(5test/kit),HRK-8601(1test/kit)
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011
EN 13612:2002+AC:2002 EN ISO 23640:2015 EN ISO13485:2016 EN 13641:2002

Signature: 

Position: GM

Date: 2021-9-15

Place: Shenzhen / China

