CE

DECLARATION OF CONFORMITY

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

Manufacturer:	GUANGZHOU BALLYA BIO-MED CO LTD
Address:	Room 308, Building 1, No. 1, Yangkan 1st Road, Beicun, Baiyun District, Guangzhou, Guangdong, China
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name:	COVID-19 Antigen Rapid Test
Model:	CAG-19 / CAG-20 / CAG-21 / CAG-22 / CAG-23
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 13641:2002

Signature: Liang Zhanhong

Name/ Position: / GM Liang Zhanhong

Date: 2021.3.26

Place: Guangzhou / China