



File No: CE-TCF-006



EC Declaration of Conformity



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

Manufacturer:

Name: Beijing O&D Biotech Co., Ltd.

Address: West, Floor 4, Building 1, No. 1, Shunqiang Road, Renhe Town, Shunyi District, Beijing, China

EC Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: COVID-19 Antigen Rapid Test

Type: Cassette

Classification: IVDD Other

We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79EC) and the following harmonized standards.

EN ISO 14971:2012

EN 15223-1:2016

EN ISO 18113-1:2011

EN ISO 18113-3:2011

5.1.2e

Date: 2020-09-18

On behalf of SUNGO Europe office, I confirmed we are
EU REP of the company who issue this document.



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