CE

DECLARATION OF CONFORMITY

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

Manufacturer: BioTeke Corporation (Wuxi) Co., Ltd

Address: 4th Floor, D5&2nd Floor, D3& 1st and 2nd Floor,D16, No.1719, Huishan Avenue, Wuxi, JiangSu, CN 214174.

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: SARS-CoV-2 Antigen Test Kit (colloidal gold method)

Specification: TC1002 (1 Test/Kit; 20 Tests/Kit; 50 Tests/Kit)

Classification: Others (IVDD)

Conformity Assessment

Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

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

EN ISO 14971:2012	EN ISO 18113-1:2011	EN ISO 18113-2:2011
EN 13612:2002+AC:2002	EN ISO 23640:2015	EN 13641:2002

Signature:

Name/ Position: Zhitu Zhou / GM

Date: 9th November, 2020

Place: Wuxi, Jiangsu / China

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

Sungo global services

Authorized Signature (S)