



DECLARATION OF CONFORMITY

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

Manufacturer: Wuxi Techstar Technology Co.,Ltd
Address: Meiyu Road No.117 Workshop No.2,Meicun Road Street,
Xinwu District, Wuxi City, Jiangsu Province, PRC
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: SARS-CoV-2 Antigen Test
Specification: 1 Reaction/bag, 1 Reaction/box, 10 Reactions/box, 20
Reactions/box, 25 Reactions/box, 30 Reactions/box, 40
Reactions/box, 50 Reactions/box
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 14971:2019

EN 14254: 2004

EN ISO 15223-1: 2016

EN ISO 18113-1:2011

Signature: Dayun Tang

Name/ Position: Dayun Tang/ GM

Date: 2021.02.01

Place: Wuxi/ China

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



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Authorized Signature (S)