DECLARATION OF CONFORMITY

MANUFACTURER:	Shenzhen Dymind Biotechnology Co., Ltd. 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107, P. R. China
MEDICAL DEVICE:	Product: SARS-CoV-2 Antigen Test Kit (Colloidal Gold) Specification: 1T/Kit, 6T/Kit,20T/kit
CLASSIFICATION:	OTHERS, The device not in IVDD annex II and not for self testing/performance evaluation
Conformity Assessment Route:	IVDD Annex III(excluding Section 6)

We, the manufacturer, herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

SARS-CoV-2 Antigen Test Kit STANDARDS APPLIED:
EN13612:2002+AC:2002; EN ISO13485:2016; EN ISO 9001:2015; EN ISO14971:2019; EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN ISO15223-1:2016; EN 23640-2015; EN 13641-2002; EN 13975-2003.
STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

European Representative: SUNGO Europe B.V.
Olympisch Station 24, 1076DE Amsterdam, Netherlands

ISSUE DATE: 2021-03-12

PLACE, DATE OF DECLARATION: *SHENZHEN,*

SIGNATURE: 5.1.2e

NAME: 5.1.2e

POSITION: 5.1.2e

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

Sungo global service

5.1.2e

Authorized Signature (S)