CERTIFICATE

EC Certificate No. 1434-IVDD-491/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Shenzhen Microprofit Biotech Co., Ltd., Rm. 405, 406, Zone B /4F, Rm. 205, 206-1, 207, West Side of Zone B/ 2F, Haowei Building, No. 8 Langshan 2nd Road, Songpingshan, Songpingshan Community, Xili Street, Nanshan District, Shenzhen, P.R. China

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) REF: MF-68

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 22.11.2021 to 27.05.2024

The date of issue of the Certificate: 22.11.2021

The date of the first issue of the Certificate: 22.11.2021

CE 1434

Issued under the Contract No. MD-76/2021
Application No: 111/2021
Certificate bears the qualified signature.
Warsaw, 22/11/2021
Module A1

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.11.22 15:49:44 +01'00'
Vice-President

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SHENZHEN MICROPROFIT BIOTECH CO.,LTD
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2021.11.29

Shenzhen Microprofit Biotech Co. Ltd

Statement

To Whom it might concern

We, Shenzhen Microprofit Biotech Co., Ltd., as the manufacturer of fluorecare® SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) and SARS-CoV-2 Antigen Test Kit (Fluorescence Immunoassay) , hereby declare,

1, fluorecare® SARS-CoV-2 Antigen Test Kit only detects the nucleocapsid antigens of SARS-COV-2, and the product performance is not affected by mutations in SARS-COV-2 spike glycoprotein antigens.

2, Further In-vitro studies to investigate the impact of mutated SARS-CoV-2 N proteins and the analysis performance of the product is finished, B.1.1.7, B.1.351, B.1.429, B.1.427, B.1.2, P1, P2, B.1.617.2, B.1.617.3, C.37, P.3, B.1.617. 1. For B.1.525, B.1.526.1, B.1.526.2, **B.1.1.529** variants, the N protein mutation site is not in the recognition region of the coated and labeled antibody, can recognize the reaction well.

3, In the future, our company will continue to follow up the mutation of the new coronavirus, and timely evaluate and verify the detection ability of mutated recombinant protein and clinical performance to ensure the sensitivity and specificity of the detection kit.

Shenzhen Microprofit Biotech Co., Ltd

General Manager: TANG SHENG

Signature: