
MICROPHOFFY
1 測試/盒
1 Test/box
IVD
自測
Self-test
CE 1434
fluorecare®
COVID-19
新型冠狀病毒抗原檢測試劑盒
(膠體金法)
SARS-CoV-2 Antigen Test Kit
(Colloidal Gold Chromatographic Immunoassay)
REF MF-68
您可以通過掃描二維碼
獲取操作視頻:
You can scan the QR code to get
the operation video:
可有效檢測Delta/Omicron毒株
檢測鼻拭子樣本中的新型冠狀病毒的N蛋白
SARS-CoV-2 Nucleocapsid protein
in Nasal swabs samples test

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11323-01-00

Product Service

Certificate

No. Q5 109172 0001 Rev. 00

Holder of Certificate: **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
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Immunochromatographic Assay Diagnostic Kit, Colloidal Gold Chromatographic Immunoassay Test Kit, and Dry-Type Immunofluorescence Quantitative Analyzer**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 109172 0001 Rev. 00

Report No.: GZ2043601

Valid from: 2021-03-24
Valid until: 2024-03-23

Date, 2021-03-24

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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