MICROPROFIT

DECLARATION OF CONFORMITY

MANUFACTURER	**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
EUROPEAN REPRESENTATIVE	CMC MEDICAL DEVICES & DRUGS, S.L. C/ Horacio Lengo n18 · C.P 29006 · Málaga-Spain
PRODUCT	See the attachment
CLASSIFICATION	Other Device of IVDD 98/79/EC
CONFORMITY ASSESSMENT	Annex III of IVDD 98/79/EC

We the manufacturer herewith declare on our solo responsibility that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

The products comply with the essential requirements in accordance with Annex I of the IVDD 98/79/EC.

STANDARDS APPLIED

EN 13612:2002/AC: 2002	EN ISO 13485:2016
EN ISO 14971:2012	EN ISO 23640:2015
EN ISO 18113-1:2011	EN ISO 18113-2:2011
EN ISO 15223-1:2016	EN 13641:2002
EN 62366-1:2015	

PLACE Shenzhen, China

DATE OF ISSUE 2022-4-23

SIGNATURE

General Manager

CE

Attachment

	Product name
MF-68-5	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-71-25	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)

Shenzhen Microprofit Biotech Co., Ltd.

Declaration of Conformity (DOC) Corrigendum

Product name:	See the attachment
Brand	fluorecare®
Model:	See the attachment
Class:	Other Device of IVDD 98/79/EC
Date of the DOC:	2022-04-23

This corrigendum intends to correct the following information in DoC(s) of the above listed product(s).

Change Old Manufacturing Address:	*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.*
To new Manufacturing Address:	*Room 1001 of Unit 2, Room 1001 and Room 1101 of Unit 1, Building 2, Hongchuang Technology Center, Xikeng Community, Fucheng Sub-district, Longhua District, 518000 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA*

According to Regulation (EU) 2017/746 (IVDR), for legacy devices according to Art. 110 (3), no changes to DOCs signed prior to May 26, 2022 can be performed. In case of the above described non-significant change(s) (as defined in MDCG 2022-6), the existing DOC(s) is (are) still valid and this Corrigendum will be attached to the originally signed DOC(s). The DOC(s) will be updated upon transition to IVDR.

...Shenzhen, China...2022.11.8
Place/Date

.....
legally binding signature

...Liu Ying.....General Manager....
Name and function

Attachment

	Product name
MF-68-5	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-71-25	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 109172 0001 Rev. 01

Holder of Certificate: **Shenzhen Microprofit Biotech Co., Ltd**
Room 1001 of Unit 2
Room 1001 and Room 1101 of Unit 1
Building 2, Hongchuang Technology Center
Xikeng Community, Fucheng Sub-district
Longhua District
518000 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents and In Vitro Diagnostic instruments for Immunochemistry**

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. 01

Report No.: GZ2343602, GZ2343602-CN

Valid from: 2024-03-24
Valid until: 2027-03-23

Date, 2024-02-01

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 109172 0001 Rev. 01

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Shenzhen Microprofit Biotech Co., Ltd
Room 1001 of Unit 2, Room 1001 and Room 1101 of Unit 1, Building 2, Hongchuang Technology Center, Xikeng Community, Fucheng Sub-district, Longhua District, 518000 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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

TÜV®

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

Product Service

Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 109172 0003 Rev. 00

Manufacturer:

Shenzhen Microprofit Biotech Co., Ltd
Room 1001 of Unit 2
Room 1001 and Room 1101 of Unit 1
Building 2, Hongchuang Technology Center
Xikeng Community, Fucheng Sub-district
Longhua District
518000 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (IVDD):

V1 109172 0002 Rev. 00

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (IVDD). It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2022 or later.
The conditions laid down in Article 110 (3) of Regulation (EU) 2017/746 on in vitro diagnostic medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:VCQ 109172 0003 Rev. 00

Report No.: GZ2343602-CN

Valid until: 2024-05-26

Marta Carnielli
Head of Certification IVD

Issue Date: 2024-02-01

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Product Service

Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 109172 0003 Rev. 00

Product Category(ies): Products for determination of tumor markers (PSA)

Description of Change:

Change company address.

Before change:

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

After change:

Room 1001 of Unit 2, Room 1001 and Room 1101 of Unit 1, Building 2, Hongchuang Technology Center, Xikeng Community, Fucheng Sub-district, Longhua District, 518000 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EU Regulation 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation restricted to the aspects of manufacture concerned with the conformity of the devices with sterility requirements - has been carried out following the requirements of EU Regulation 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620139275

Initial Certification Date:
5 January 2023

Date of Certification Decision:
5 January 2023

Certificate Issue Date:
5 January 2023

Certificate Expiry Date:
28 November 2027

Medico Technology Co., Ltd

Room 201, 301 and 401 Building A No.10, Bao long 5th Road, Tongle Community, Baolong Street, Longgang District, Shenzhen, Guangdong, China

Manufacturer SRN: CN-MF-000013067

Authorised Representative Name
Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

Scope:

Class I sterile devices

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

Certificate of Analysis (Flocked swab)

Name	Flocked swab MFS96000BQ-E	Specification	100pcs/bag	lot number	20240706
Quantity	100000pcs	Number of samples	50pcs	Supplier	Production Department
Inspector	[illegible]	Reviewer	[illegible]	Approver	[illegible]
Inspection date	2024.07.11	Review date	2024.07.20	Approval date	2024.07.20
Sterilization batch number	2024070601				
Inspection basis	Specimen collection swab quality standard TS-ZL-139				
Test items	Standard		Test report		Results
Exterior	The shape of the swab should be straight, clean, smooth, uniform in color, free of burrs, mildew, scratches, scratches, cracks and other defects. The product should be clean, odorless, and tasteless, the swab head should be soft to the touch, and should not have yellow spots, smudges, or foreign objects.		Conformance		☑Qualified ☐Failed
Size	Maximum diameter or width of sampling head: 3.0±1mm		Conformance		☑Qualified ☐Failed
	Sampling head length: 20±5mm		Conformance		
	Total length: 149±5mm		Conformance		
	Handle diameter: 2.5±0.5mm		Conformance		
	Connecting rod length: 80±5mm		Conformance		
	Connecting rod diameter: 2.5±0.5mm		Conformance		
Mechanical properties	Connection strength≧2N		Conformance		☑Qualified ☐Failed
	Deformation bending strength ≧4N		Conformance		
	Breaking force≧20N		Conformance		
	Rotational friction≧3 times Amount of surface lint removed≦8 root		Conformance		
Aseptic performance	Should be sterile		Sterile		☑Qualified ☐Failed
Final conclusion	Qualified				

Declaration of Conformity

To Regulation (EU) 2017/745 Concerning Medical Devices

Medico Technology Co., Ltd
Room 201, 301 and 401 Building A No.10, Bao long 5th Road, Tongle Community, Baolong Street, Longgang District,Shenzhen, Guangdong, China
SRN: CN-MF-000013067

EC REP **Luxus Lebenswelt GmbH**
Kochstr. 1, 47877, Willich, Germany
SRN:DE-AR-000005110

Medical Device: Specimen Collection Swab

EMDN Code: A1101 Sample Collection Neutral Swabs

Model and Basic UDI-DI:

Model	Basic UDI-DI	Model	Basic UDI-DI
MFS96000BQ-E	697493165SCSWU	MFS95000KQ-E	697493165SCSWU
MFS93050KQ-E	697493165SCSWU	MFS96000KQ-E	697493165SCSWU
MFS98000KQ-E	697493165SCSWU	MFS97000KQ-E	697493165SCSWU
MFS95000BQ-E	697493165SCSWU	MFS740D-E	697493165SCSWU
MFS96000BQZ-E	697493165SCSWU	MFS712-E	697493165SCSWU
MFS93000BQ-E	697493165SCSWU	MFS708-E	697493165SCSWU
MFS94000BQ-E	697493165SCSWU	MFS740-E	697493165SCSWU
MFS91000KQ-E	697493165SCSWU	MPS713-E	697493165SCSWU
MFS92000KQ-E	697493165SCSWU	MPS714-E	697493165SCSWU
MFS93000KQ-E	697493165SCSWU	MPS707-E	697493165SCSWU
MFS94000KQ-E	697493165SCSWU	MPS761D-E	697493165SCSWU
MFS96000BQ-R	697493165SCSWU	MFS95000KQ-R	697493165SCSWU
MFS93050KQ-R	697493165SCSWU	MFS96000KQ-R	697493165SCSWU
MFS98000KQ-R	697493165SCSWU	MFS97000KQ-R	697493165SCSWU
MFS95000BQ-R	697493165SCSWU	MFS740D-R	697493165SCSWU
MFS96000BQZ-R	697493165SCSWU	MFS712-R	697493165SCSWU
MFS93000BQ-R	697493165SCSWU	MFS708-R	697493165SCSWU
MFS94000BQ-R	697493165SCSWU	MFS740-R	697493165SCSWU
MFS91000KQ-R	697493165SCSWU	MPS713-R	697493165SCSWU
MFS92000KQ-R	697493165SCSWU	MPS714-R	697493165SCSWU
MFS93000KQ-R	697493165SCSWU	MPS707-R	697493165SCSWU
MFS94000KQ-R	697493165SCSWU	MPS761D-R	697493165SCSWU

Intended use: Specimen Collection Swab is intended to be used as clinician-collected female and male throat swabs, buccal swabs, nasal swabs and nasopharyngeal swabs (collected in a clinical setting).

Classification by Annex VIII: class Is, rule 5

Conformity assessment Route: Annex II, III and Annex XI Part A

Application of CS statement: N/A

We, Medico Technology Co., Ltd., herewith declare at our sole responsibility that the above products comply with requirement of Regulation (EU) 2017/745. All supporting documentation is retained at the premises of the manufacturer.

The EU declaration of conformity is issued under the sole responsibility of the manufacturer. The device that is covered by the present declaration is in conformity with this Regulation and, with any other relevant

Union legislation that provides for the issuing of an EU declaration of conformity.
Notifed Body: Intertek Medical Notified Body AB Torshamnsgatan 43, Box 1103, 164 22 Kista, Sweden CE 2862
Certificate No: 28620139275 Certificate Issued date:2023-01-05
Signature: Mary Wang Name: Mary Wang Position: Representative of Quality Manager Place, Date of Declaration: Shenzhen, 2023-01-17

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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Medico Technology Co., Ltd.

Main Site: Room 201, 301 and 401 Building A No.10, Bao long 5th Road, Tongle Community, Baolong Street, Longgang District, Shenzhen, Guangdong, China

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

The manufacture of sterile specimen collection swabs, non-sterile disposable virus sampling kits, non-sterile swab applicators, non-sterile saliva collection kits.

Certificate Number:
0107888-03

Initial Certification Date:
29 November 2020

Date of Certification Decision:
14 November 2023

Issuing Date:
14 November 2023

Valid Until:
28 November 2026

ISO 13485:2016 CERTIFICATION TM
intertek

SCC Accredited CB-MS
OCSM Accrédité CCN TM
The SCC Accreditation Symbol is an official symbol of the Standards Council of Canada, used under licence.

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA Inc. dba Intertek,
900 Chelmsford Street,
Lowell, MA, USA