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-59	SARS-CoV-2 Antibody Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-60	SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-61	SARS-CoV-2 IgG and IgM Antibody Combined Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-62	SARS-CoV-2 Antibody Test Kit (Fluorescence Immunoassay)
MF-63	SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)
MF-64	SARS-CoV-2 IgG and IgM Antibody Combined Test Kit (Fluorescence Immunoassay)
MF-66	fluorecare COVID-19 & Influenza A/B Antigen Combo Test Kit(Colloidal Gold)
MF-67	SARS-CoV-2 Antigen Test Kit (Fluorescence Immunoassay)
MF-68	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-69	SARS-CoV-2 & Influenza A/B Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-70	SARS-CoV-2 Neutralizing Antibody Test Kit (Fluorescence Immunoassay)
MF-71	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-90	SARS-CoV-2 Neutralizing Antibody Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-91	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)（Saliva）
MF-129	SARS-CoV-2 & Influenza A/B & RSV/ADV/hMPV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-82	Rubella Virus IgG Antibody (RV-IgG) Diagnostic Kit (Immunochromatographic Assay)
MF-83	Herpes Simplex Virus-1IgG (HSV-1IgG) Diagnostic Kit (Immunochromatographic Assay)
MF-282	FOB Quantitative Control
MF-283	Fecal Calprotectin Quantitative Control
MF-130	SARS-CoV-2/RhV/PIV & Influenza A/B & RSV/ADV/hMPV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-137	S.p/L.p/S.aureus/M.P Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-156	MPxV Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-139	SARS-CoV-2/RhV/PIV / Influenza A/B / RSV/ADV/hMPV/M.P Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
MF-138	S.p/L.p/S.aureus/Kpn/M.P Antigen Combo Test Kit (Colloidal Gold

	Chromatographic Immunoassay)
MF-140	Respiratory 9 Pathogen Antigen Detection Kit (Colloidal Gold Chromatographic Immunoassay)
MF-141	Respiratory 13 Pathogen Antigen Detection 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
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MF-141	Respiratory 13 Pathogen Antigen Detection Kit (Colloidal Gold Chromatographic Immunoassay)

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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.

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