



**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.

<b>STANDARDS APPLIED</b>	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



## 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... 2022.4.23  
Place/Date

.....  
legally binding signature

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



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	Chromatographic Immunoassay)
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