



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,
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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 2021-9-23

SIGNATURE

General Manager



ATTACHMENT

Catalog No.	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-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)