

Declaration of Conformity



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

BRAND fluorecare[®]

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 2022-5-25

SIGNATURE



General Manager



ATTACHMENT

No.	Catalog No.	Product name
1	MF-120	25-Hydroxyvitamin-D (25-OH-D) Diagnostic Kit (Immunochromatographic Assay)
2	MF-127	Anti-cyclic citrullinate peptide antibody (Anti-CCP) Diagnostic Kit (Immunochromatographic Assay)(semi-quantitative)
3	MF-278	Anti-TPO Control
4	MF-275	ASO Control
5	MF-118	C-Reactive Protein (CRP) Diagnostic Kit (Immunochromatographic Assay)
6	MF-274	cTnT Control
7	MF-125	Fecal Calprotectin Quantitative Detection Kit (Immunochromatographic Assay)
8	MF-126	Fecal Occult Blood (FOB) Quantitative Detection Kit (Immunochromatographic Assay)
9	MF-119	Ferritin (FERR) Diagnostic Kit (Immunochromatographic Assay)
10	MF-66	fluorecare COVID-19 & Influenza A/B Antigen Combo Test Kit(Colloidal Gold)
11	MF-122	Glycosylated Hemoglobin(HbA1c)Diagnostic Kit(Immunochromatographic Assay)
12	MF-80	Helicobacter pylori Antigen (Hp-Ag) Diagnostic Kit (Immunochromatographic Assay)
13	MF-276	I-PTH Control
14	MF-123	Malaria Pf / Pv Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)
15	MF-116	Malaria Pf/Pan Antigen Test Kit (Immunochromatographic Assay)
16	MF-124	Malaria Pf/Pv antigen Test Kit (Immunochromatographic Assay)
17	MF-71-1	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
18	MF-71-2	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
19	MF-71-5	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
20	MF-71	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
21	MF-69	SARS-CoV-2 & Influenza A/B Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
22	MF-59	SARS-CoV-2 Antibody Test Kit (Colloidal Gold Chromatographic Immunoassay)
23	MF-62	SARS-CoV-2 Antibody Test Kit (Fluorescence Immunoassay)
24	MF-68	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)
25	MF-91-1	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic

		Immunoassay) (Saliva)
26	MF-91-2	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) (Saliva)
27	MF-91-5	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) (Saliva)
28	MF-91	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)(Saliva)
29	MF-67	SARS-CoV-2 Antigen Test Kit (Fluorescence Immunoassay)
30	MF-61	SARS-CoV-2 IgG and IgM Antibody Combined Test Kit (Colloidal Gold Chromatographic Immunoassay)
31	MF-64	SARS-CoV-2 IgG and IgM Antibody Combined Test Kit (Fluorescence Immunoassay)
32	MF-90	SARS-CoV-2 Neutralizing Antibody Test Kit (Colloidal Gold Chromatographic Immunoassay)
33	MF-70	SARS-CoV-2 Neutralizing Antibody Test Kit (Fluorescence Immunoassay)
34	MF-60	SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)
35	MF-63	SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)
36	MF-121	Thyroid peroxidase antibody (Anti-TPO) Diagnostic Kit (Immunochromatographic Assay)
37	MF-117	Thyroid Stimulating Hormone (TSH) Diagnostic Kit (Immunochromatographic Assay)
38	MF-277	VB12 Control
39	MF-129	SARS-CoV-2 & Influenza A/B & RSV/ADV/hMPV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
40	MF-83	Herpes Simplex Virus-1IgG (HSV-1IgG) Diagnostic Kit (Immunochromatographic Assay)
41	MF-130	SARS-CoV-2/RhV/PIV & Influenza A/B & RSV/ADV/hMPV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
42	MF-283	Fecal Calprotectin Quantitative Control
43	MF-282	FOB Quantitative Control

Shenzhen Microprofit Biotech Co., Ltd.

Declaration of Conformity (DOC) Corrigendum

Product name: See the attachment
Model: See appendix for details
Class: Other Device of IVDD 98/79/EC
Date of the DOC: 2022-05-25

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.....2024.03.07
Place/Date

.....
legally binding signature

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



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