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)