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 Name:	fluorecare SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit
Common Name:	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
Brand:	fluorecare®
Product code:	MF-71-1, MF-71-2, MF-71-5
Classification (IVDD):	Self-testing Device of IVDD 98/79/EC

Conformity Assessment Route: Annex III of 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

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.

DIRECTIVES

General applicable directives:

In Vitro Diagnostic Medical Device Directive: COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 concerning in vitro diagnostic medical devices (IVDD 98/79/EC).

Notified Body:	CeCert
Identification number:	CE 2934
(EC) Certificate(s):	CeCert/092/W/E.2
Expire date of the Certificate:	2025.05.26
DATE OF ISSUE:	**2022.05.18**
SIGNATURE:	

Shenzhen Microprofit Biotech Co., Ltd. 深圳市微柏生物技术有限公司 MICROPROFIT

Shenzhen Microprofit Biotech Co., Ltd.

Declaration of Conformity (DOC) Corrigendum

Product name:	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)
Brand	fluorecare®
Catalogue No.:	MF-71-1, MF-71-2, MF-71-5
Class:	Self-testing Device of IVDD 98/79/EC
Date of the DOC:	2022-05-18

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.....2023.11.8.....
Place/Date

.....
legally binding signature

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

Shenzhen Microprofit Biotech Co., Ltd. 深圳迈瑞生物技术有限公司 MICROPROFIT