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®
Catalogue No.:	MF-71-1, MF-71-2, MF-71-5
Classification:	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.1
Expire date of the Certificate:	2025.05.26

DATE OF ISSUE: **2022.05.12**

SIGNATURE:

Shenzhen Microprofit Biotech Co., Ltd. 深圳市迈科龙生物技术有限公司 MICROPROFIT

CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

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

in vitro diagnostic medical device for self-testing

fluorecare SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit
catalogue numbers: MF-71-1, MF-71-2, MF-71-5

in term of the design conforms to the requirements of Annex III section 6 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the assessment conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 12.05.2022 – 26.05.2025

Edition issue date: 18.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

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Certificate no: CeCert/092/W/E.2