

Shenzhen Microprofit Biotech Co., Ltd.

Declaration of Conformity (DOC) Corrigendum

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
Class: Self-testing Device of IVDD 98/79/EC
Date of the DOC: 2022-05-12

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

