File No: CE-TCF-007

EC Declaration of Conformity

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:

Name:Jiangsu Medomics medical technology Co.,Ltd
Address:F3,Building C,No.3-1 Xinjinhu road,Jiangbei new area, Nanjing,China

EC Representative

Name:R Sight B.V.
Address: Roald Dahllaan 47, 5629 MC, Eindhoven, the Netherlands

Product

Name:

1）SARS-CoV-2 antigen Test Kit (LFIA)
Type:I / II / III/ IV

2）SARS-CoV-2 antigen Test Kit (ELISA)
Type:I / II /BMI /BMII

3）SARS-CoV-2 Neutralizing antibody Test Kit (ELISA)
Type:I / II / III/BMI /BMII/BMIII

4）SARS-CoV-2 Neutralizing antibody Test Kit (LFIA)
Type: I / II / III/IV/V

5）SARS-CoV-2 Neutralizing antibody Test Kit (ELISA)
Type:96Tests/Kit

6）COVID-19 IgM-IgG Rapid Test
Type:1 pc/box

7）SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)
Type:I / II / III

Classification: IVDD Others
Conformity Assessment Route: IVDD 98/79/EC Annex III
We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 18113-3:2011	ISO 13485:2016	EN 13612:2016

Signature: Zong Zhi Chai

Place and Date of issued: Nanjing. China March 10th, 2021