



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 / V / VI
- 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: 96 Tests / Kit
- 6) COVID-19 IgM-IgG Rapid Test
Type: 1 pc / box
- 7) SARS-CoV-2 & Inuenza A/B Antigen Combo Rapid Test Kit (LFIA)
Type: I / II / III

Classification: IVDD Other

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

Signature:

Zongzhi Chai

Place and Date of issued:

Nanjing, China

Jan 14th, 2021