

Declaration of Conformity

CE

Manufacturer:

BEIJING WANTAI BIOLOGICAL PHARMACY ENTERPRISE CO.,LTD, located at No. 31
Kexueyuan Road, Changping District, Beijing, 102206, P.R. of China
TEL +86 10 59528888 FAX +86 10 89705849

European Representative: Qarad b.v.b.a. ,Cipalstraat 3, B-2440 Geel, Belgium

Products:

Wantai SARS-CoV-2 Ab ELISA Kit; Product code: WS-1096;
Wantai SARS-CoV-2 IgM ELISA Kit; Product code: WS-1196;
Wantai SARS-CoV-2 IgG ELISA Kit (Quantitative); Product code: WS-1396;
Wantai SARS-CoV-2 Ab Rapid Test Kit; Product code: WJ-2701,WJ-2710,WJ-2750;
Wantai SARS-CoV-2 IgG Rapid Test Kit (Semi-Quantitative); Product code: WJ-3010, WJ-3050;

Wantai SARS-CoV-2 Ag ELISA ; Product code: WS-1496;
Wantai SARS-CoV-2 Ag Rapid Test (FIA); Product code: WJ-2810,WJ-2850;
Wantai SARS-CoV-2 Ag Rapid Test (Colloidal Gold); Product code: WJ-2910,WJ-2950 ;

Wantai SARS-CoV-2 RT-PCR Kit; Product code: WS-1248;

Classification Under IVDD: Not listed in Annex II

Conformity assessment route: Annex III

We hereby declare that the product mentioned above meets the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices. All supporting documentations are retained at the premises of the manufacturer.

General applicable directive: Directive 98/79/EC of European Parliament and of the Council of 27 October 1998 on in vitro Diagnostic Medical Devices.

Standards applied:

EN ISO 18113-1:2011, EN ISO18113-2:2011, EN ISO 15223-1:2016, EN 13612: 2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN ISO 13485:2016.

Ms. Zhao Lingzhi(Vice General Manager)

Beijing, January 26, 2021

