

# 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 BV, Ciplastraat 3, 2440 Geel, Belgium

### Products:

Wantai SARS-CoV-2 Ab ELISA; Product code: WS-1096;

Wantai SARS-CoV-2 IgM ELISA; Product code: WS-1196;

Wantai SARS-CoV-2 IgG ELISA (Quantitative); Product code: WS-1396;

Wantai SARS-CoV-2 Ag ELISA; Product code: WS-1496;

Wantai SARS-CoV-2 NAbS ELISA; Product code: WS-1596;

Wantai SARS-CoV-2 IGRA; Product code: WS-1696;

Wantai SARS-CoV-2 Ab Rapid Test; Product code: WJ-2701, WJ-2710, WJ-2750;

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-2901, WJ-2910, WJ-2950;

Wantai SARS-CoV-2 IgG Rapid Test (Semi-Quantitative); Product code: WJ-3010, WJ-3050;

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, March 22, 2021



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