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, Cipalstraat 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

Zhaolingzhi

MedRhein