

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. Ciplastraat 3, B-2440 Geel, Belgium

Products Name:

Wantai SARS-CoV-2 Ab ELISA Kit; Prduct code: WS-1096;
Wantai SARS-CoV-2 IgM ELISA Kit; Prduct code: WS-1196;
Wantai SARS-CoV-2 RT-PCR Kit; Prduct code: WS-1248;
Wantai SARS-CoV-2 Ab Rapid Test Kit; Prduct code: WJ-2701,WJ-2710,WJ-2750;

Classificaiton 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 6, 2020

