万泰生物®
WANTAI BioPharm

WT-CE-2020DoC(Ver.08)

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 Name:

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 RT-PCR Kit; Product code: WS-1248;

Wantai SARS-CoV-2 Ab Rapid Test Kit; 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-2910,WJ-2950

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, October 29, 2020

Zhaolingzhi

Digitally signed by Jighili Tatiana
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