

# 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 Pas 257, 2440 Geel, Belgium

**Products Name:**

Wantai SARS-CoV-2 Ag Rapid Test (Colloidal Gold)

Product codes: WJ-2950 ,

Registration number: BE-CA01 /1-90054-00008-IVD

**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 12, 2021

