

## EC DECLARATION OF CONFORMITY

We, Beijing Wantai Biological Pharmacy Enterprise Co., Ltd which are located at No. 31 Kexueyuan Road, Changping District, Beijing, 102206, P.R. of China

declare under our sole responsibility that the product(s)

Type(s)	Devices	Catalog No.	GMDN Code	Notified Body's Certificate no.
Self testing	WANTAI SARS-CoV-2 Ag Rapid Test (Colloidal Gold)	WJ-2901, WJ-2905, WJ-2910, WJ-2925,	64787	IVDD 21 014 0103 rev.1

which is classified under IVDD as SELF TEST product (no List A/B according the Annex II IVDD) meet(s) the provisions of the European Directive 98/79/EC for *in vitro* Diagnostic Medical Devices. The following (harmonized) standards have been applied: EN ISO 18113-1:2011, ISO 18113-4:2009, EN ISO18113-2:2011, EN18113-3:2011, EN ISO 18113-4:2011, EN ISO 15223-1:2016, EN 13612: 2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019, EN ISO 13485:2016. The conformity assesment route with the requirements of the Directive 98/79/EC has been assessed following the procedure(s) outlined in the following annexes of the Directive 98/79/EC : **ANNEX IV (excluding section 4 and section 6)**

The Design Examination and Full Quality Assurance System Certificates have been issued by: **bqs. s.r.o., Notified Body, NB number 2854,**  
**Address: Študentská 1641/12, 91101 Trenčín, SLOVAKIA.**

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe.

**QARAD BV,**  
**Address: Ciplastraat 3, 2440 Geel, Belgium**

  
  
Ms. Zhao Lingzhi (QA Director)  
Beijing, June 4, 2021

Revision History	Content	Date
v1	Establishment	June 4, 2021