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SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

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Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

EC Certificate IVDD 21 014 0103 rev.1

Full Quality Assurance System Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices
Annex IV excluding section 4 and section 6

Certificate holder: **Beijing Wantai Biological Pharmacy Enterprise Co., Ltd**
No. 31 Kexueyuan Rd.,
Changping District, Beijing
China

Related audit report: AIVDD 2021NB014 I01

Other Facility(ies): -

The certificate was issued with respect to the following scope:

WANTAI SARS-COV-2 Ag Rapid Test (Colloidal Gold)

This certificate is effective from 13 September 2021 until 26 May 2024 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 16 July 2021.

Certification has been authorized by

Digitally signed by Radovan Máčaj

Radovan Macaj
Head of Notified body

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bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed examination of quality assurance system in accordance with Annex IV excluding section 4 and section 6 of the directive and found that the quality assurance system meets the requirements laid down by Annex IV. For the placing on the market of List A devices an EC design-examination certificate according to Annex IV section 4 is required. Please see also notes overleaf if any.

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Additional information on certification

Related to certificate number:

IVDD 21 014 0103 rev.1

Description of product(s) within the certification scope:

Lateral flow immunochromatographic assay intended for qualitative detection of SARS- CoV-2 nucleocapsid (N) antigen in anterior nasal swab and saliva specimens intended for self testing.

Types/Categories/Models:	WJ-2901, WJ-2905, WJ-2910, WJ-2925 1 test/kit; 5 tests/kit; 10 tests/kit; 25 tests/kit
Classification:	Devices for self-testing
Validity conditions:	The manufacturer has a duty to submit to the Notified body testing results as per established procedure of each manufactured batch prior its releasing.

This certificate is effective from 13 September 2021 until 26 May 2024 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 16 July 2021.

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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	Nodified 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: Cipalstraat 3, 2440 Geel, Belgium

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

Revision History	Content	Date
v1	Establishment	June 4, 2021