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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
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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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Certified In Vitro diagnostic medical device

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.

bqs.
Certified In Vitro diagnostic medical device

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.