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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.2

### 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 25 May 2022 until 26 May 2025 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

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.2**



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: -

This certificate is effective from 25 May 2022 until 26 May 2025 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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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.