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Reg. No. 575/P-051

Notified body 2854 | SKTC-180

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EC Certificate IVDD 21 042 0106

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices
Annex III section 6 (Devices for self-testing)

Certificate holder: **Guangzhou Decheng Biotechnology Co., Ltd**

Room 218 and Room 212, Building 2, No. 68, Nanxiang 1st Road, Science City, Huangpu District, Guangzhou, Guangdong, 510663, P.R. China

Related audit report: -

Other facility(ies): -

The certificate was issued with respect to the following scope:

2019-nCoV Ag Saliva Rapid Test Card (Immunochromatography)

This certificate is effective from 26 November 2021 until 26 May 2022 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 26 November 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 an examination of the design dossier relating to the device in accordance with Annex III section 6 of the directive and found that the design of the device conforms to the requirements laid down by Annex III. Please see also notes overleaf if any.

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Additional information on certification under 98/79/EC Annex III section 6

Related to certificate number:

IVDD 21 042 0106

Description of product(s) within the certification scope:

2019-nCoV Ag Saliva Rapid Test Card is an antigen rapid test on basis of lateral flow immunochromatographic assay intended for the rapid and qualitative detection of N-antigen of human coronavirus 2 (2019-nCoV) in saliva samples from individuals suspected of COVID-19.

Types/Categories/Models:	1 test per box, 5 tests per box, 20 tests per box (0699C8X001, 0699C8X005, 0699C8X020)
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 26 November 2021 until 26 May 2022 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 26 November 2021.

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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 an examination of the design dossier relating to the device in accordance with Annex III section 6 of the directive and found that the design of the device conforms to the requirements laid down by Annex III. Please see also notes overleaf if any.