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SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

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EC Certificate IVDD 21 041 0104

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:

V-chek 2019-nCoV Ag Rapid Test Kit (Immunochromatography)

This certificate is effective from 22 October 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 22 October 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 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 21 041 0104

Description of product(s) within the certification scope:

V-chek 2019-nCoV Ag Rapid Test Kit is used for the in vitro qualitative detection of 2019-nCoV antigen. It is an immunochromatography sandwich assay, and intended to detect 2019- nCoV N-protein antigen in human nasal (NS) swab specimens. The kit can be used for individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection.

Types/Categories/Models:	1 test per box, 5 tests per box, 25 tests per box (0685C2X001, 0685C2X005, 0685C2X025)
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 22 October 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 22 October 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.