SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

bqs. s.r.o.
Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

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Certificate EC20 0090 2020 0323 rev.2

EC Design-Examination Certificate

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

Certificate holder: **Lomina AG**

Oberer Gansbach 1,
9050 Appenzell
Switzerland

Related audit report: -

Facility(ies): Lomina AG
Oberer Gansbach 1, 9050 Appenzell, Switzerland

The certificate was issued with respect to the following scope:

In vitro diagnostic medical device Fast COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold) for self testing

This certificate is effective from 03 December 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 15 December 2020.

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:

EC20 0090 2020 0323 rev.2

Description of product(s) within the certification scope:

Fast COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold)
RYCHLOTEST COVID-19 IgM/IgG, Souprava pro detekci protilátek (Koloidní zlato)
In vitro diagnostic medical device for detection of IgM and IgG antibodies against SARS-CoV-2 virus in whole blood and for determination of approximate IgG antibody level in whole blood

Types/Categories/Models:	Test plastic strip – Cassette 5 tests package 2 tests package 1 test package
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.

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Initial version of the certificate was effective from 15 December 2020.

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