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SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

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Certificate EC20 0090 2020 0323

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 15 December 2020 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

Radovan Macaj
Head of Notified body

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 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.