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The Trust We Make

SNAS Reg. No. 575/P-051

Notified body 2854 | SKTC-180

bqs. s.r.o.

**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:

Digitally signed by Radovan Mačaj

Radovan Macaj
Head of Notified body

bqs.

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

Related to certificate number:
**EC20 0090 2020 0323**

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 antibodies IgM and IgG in whole blood.

| | |
|---|---|
| Types/Categories/Models: | Test plastic strip – Cassette<br>5 tests 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. |

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.

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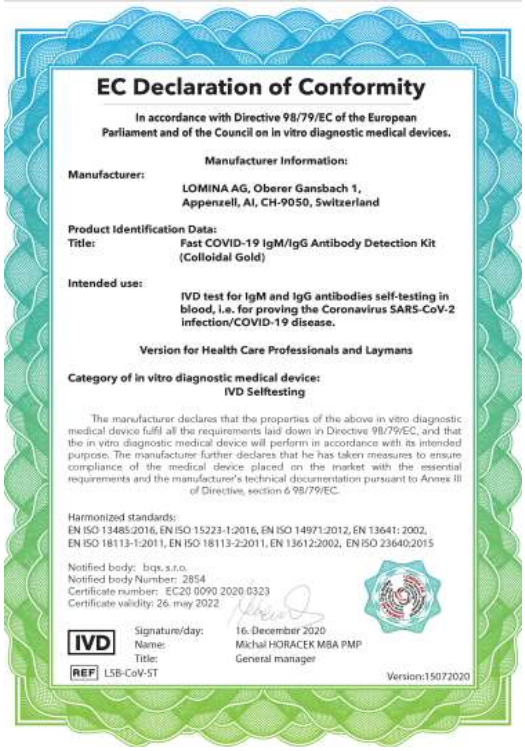

**EC Declaration of Conformity**

**In accordance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices.**

**Manufacturer Information:**

**Manufacturer:**
**LOMINA AG, Oberer Gansbach 1, Appenzell, AI, CH-9050, Switzerland**

**Product Identification Data:**
**Title:** **Fast COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold)**

**Intended use:**
**IVD test for IgM and IgG antibodies self-testing in blood, i.e. for proving the Coronavirus SARS-CoV-2 infection/COVID-19 disease.**

**Version for Health Care Professionals and Laymans**

**Category of in vitro diagnostic medical device:**
**IVD Selftesting**

The manufacturer declares that the properties of the above in vitro diagnostic medical device fulfil all the requirements laid down in Directive 98/79/EC, and that the in vitro diagnostic medical device will perform in accordance with its intended purpose. The manufacturer further declares that he has taken measures to ensure compliance of the medical device placed on the market with the essential requirements and the manufacturer's technical documentation pursuant to Annex III of Directive, section 6 98/79/EC.

Harmonized standards:
EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2012, EN 13641: 2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002, EN ISO 23640:2015

Notified body: bqs s.r.o.
Notified body Number: 2854
Certificate number: EC20 0090 2020 0323
Certificate validity: 26. may 2022

IVD

Signature/day: 16. December 2020
Name: Michal HORACEK MBA PMP
Title: General manager

REF L5B-CoV-5T

Version:15072020

**LOMINA SUPERBIO a.s.**
**Bucharova 2657/12**
**Praha 5, 158 00**
**Ičo/Dič: CZ 07420099**
**EU - CZECH Republic**

**LOMINA A.G.**
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**CH-9050, Appenzell(AI)**
**CHE - 114.687.389**
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