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 LSB-CoV-ST

Version:15072020

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SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

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

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.

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SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

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Trencin | Slovakia
www.bqsgroup.eu

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 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.

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.

Lomina AG
Andreas Scherrer
Oberer Gansbach 1
9050 Appenzell

Bern, 18 January 2021

Notification according to Art 6. of the Medical Devices Ordinance (MedDO)[1] respectively Art. 10 of the European Directive 98/79/EC
Product(s): 64756 SARS-CoV-2 immunoglobulin G (IgG)/IgM antibody IVD, kit, immunochromatographic test (ICT), rapid; -
Fast COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold)

Acknowledgement of receipt

Dear Sir,

Swissmedic (Competent Authority No. CH/CA01) hereby acknowledges the receipt of your notification dated 11.01.2021 for the above-mentioned product(s).

The obligation of notification for the above mentioned product(s) according to Art 6. of the Swiss Medical Devices Ordinance (MedDO) respectively Art. 10 of the European Directive 98/79/EC is thus fulfilled.

This acknowledgement of receipt does not, however, constitute either an attestation of conformity, or an approval, or a quality assessment of the product(s). With this acknowledgement, Swissmedic merely takes knowledge of the fact that the notifying person placing medical devices on the market in Switzerland or in a treaty country does so at her own responsibility.

[1] Medical Devices Ordinance of 17 October 2001; SR 812.213

Please note that we have entered the following data in our records for the notified product. For future contact or correspondence, please always quote the notification number provided below:

Notification No.:	**CH-202101-0042**
Date of Notification:	**11.01.2021**
Classification of IVD:	**IVD Self Testing**
GMDN / EDMS Code:	**64756**
Generic Device Group Term:	**SARS-CoV-2 immunoglobulin G (IgG)/IgM antibody IVD, kit, immunochromatographic test (ICT), rapid**
Manufacturer's Product Name:	**Fast COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold)**
Manufacturer:	**Lomina AG**
Notified Body:	**bqs. s.r.o.**

In the context of additional monitoring, Swissmedic reserves the right to ask for supplementary documentation or information.

Swissmedic has uploaded the notification information to Eudamed, the European Databank on Medical Devices.

Yours sincerely,

Swissmedic – Swiss Agency for Therapeutic Products
Division Medical Devices Operations

Sabina Carulli Amico
Assistant