

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, immuno-chromatographic 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 Database on Medical Devices.

Yours sincerely,

Swissmedic – Swiss Agency for Therapeutic Products
Division Medical Devices Operations



Sabina Carulli Amico
Assistant