IVD

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 A.G.
Oberer Gansbach 1, Appenzell, CH-9050, Switzerland
ID: CHE-114-687-389, www.lomina.ch

Medical Device (Product) Identification Data.

Name: **Fast COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold)**

REF **LSB-CoV-ST**

Intended use:

IVD test designed for self-testing for the detection of IgG and IgM antibodies against S1-protein in the blood after the COVID-19 disease. The test is also designed to detect the approximate level of IgG antibodies after vaccination. The product does not serve as the primary tool for early detection of COVID19!

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 section 6 of Directive 98/79/EC.

Harmonized standards:

EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2019, 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.
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Certificate validity: 26.May 2022

Michal Horáček

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Version: 2021/11/23