EC Declaration of Conformity

IVD

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 Superbio a.s.
Na Radosti 184/59, Prague 5, 158 00, Czech Republic
ID: CZ07420099, www.lomina.ch, SÚKL reg.: 061583

Medical Device (Product) Identification Data.

Name: **Lomina SARS-CoV-2 Antigen LTX Selftest** REF L-LTX-ST

Versions/variants:	Catalogue Nr.:
1 piece in a package - pouch	L-LTX-ST/1P
1 piece in a package - box	L-LTX-ST/1B
2 pieces in a package - box	L-LTX-ST/2B
5 pieces in a package - box	L-LTX-ST/5B
25 pieces in a package - box	L-LTX-ST/25B
50 pieces in a package - box	L-LTX-ST/50B

Intended use:
Lomina SARS-CoV-2 Antigen LTX Selftest is a test kit designed for home use by lay persons for qualitative detection of the new coronavirus nucleocapsid (N) antigen in self-collected human nasal swab samples in vitro. It is used as a supplementary detection indicator for suspected cases of new coronavirus designed for virus detection from approximately 5th day after infection including asymptomatic cases. It should not be used as the only basis for the diagnosis and exclusion of pneumonitis caused by the new coronavirus. Lomina SARS-CoV-2 Antigen LTX Selftest is intended for self-testing of all age groups for adults or under adults supervision. Patients with limited abilities shall ask an assistance of a professional or for this purpose trained person.

Version for lay persons (for selftesting)

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 18113-4:2011 EN ISO 18113-1:2011, EN ISO 18113:2011, EN 13612:2002, EN ISO 23640:2015.

Name of the notified body: **CeCert Sp. z o.o.**
Notified body number: **2934**
Address of the notified body: ul. Żurawia 32/34 lok.49, Warszawa, Poland, EU
Notified body's website: https://cecert.pl/
Certificate Number: CeCert/083/W/E.3
Certificate validity: 2025-05-26

Manufacturer: LOMINA SUPERBIO a.s.
Name: Ales MRKACEK
Position: CEO
Valid from: 2022-09-15
Signature:

CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

LOMINA Superbio a.s.
Na Radosti 184/59, Prague 5,
155 21, Czech Republic

in vitro diagnostic medical device for self-testing

Lomina SARS-CoV-2
Antigen LTX Selftest
catalogue numbers:
L-LTX-ST/1P, L-LTX-ST/1B, L-LTX-ST/2B,
L-LTX-ST/5B, L-LTX-ST/25B, L-LTX-ST/50B

in term of the design conforms to the requirements of Annex III section 6 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the assessment conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 10.05.2022 – 26.05.2025

Edition issue date: 15.09.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

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Certificate no: CeCert/083/W/E.3