

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:

1 piece in a package - box
1 piece in a package - pouch
2 pieces in a package - box
5 pieces in a package - box
25 pieces in a package - box
50 pieces in a package - box

Catalogue Nr.:

L-LTX-ST/1P
L-LTX-ST/1B
L-LTX-ST/2B
L-LTX-ST/5B
L-LTX-ST/25B
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. Warecka 11A
00-034 Warszawa
Poland, EU
Notified body's website: <https://cecert.pl/>
Certificate Number: **CeCert/083/W/E.3**

Manufacturer: LOMINA SUPERBIO a.s.

Name: Ales MRKACEK

Position: CEO

Valid from: 2022-09-16

Signature:

