IVD

CE

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

Product Identification Data.

Name: SARS-CoV-2 N-Protein Antigen Rapid Test

REF **LA-CoV-Ag**

Intended use:

The kit is used for the qualitative detection of new coronavirus SARS-CoV-2 nucleocapsid (N) antigen in human oropharyngeal swab samples in vitro.

It is used as a supplementary detection indicator for suspected cases of new coronavirus negative nucleic acid detection or used in conjunction with nucleic acid detection in the diagnosis of suspected cases. It cannot be used as a basis for the diagnosis and exclusion of pneumonitis infected by new coronavirus.

Edition for medical professionals.

Category of in vitro diagnostic medical device: **IVD OTHER**

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 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

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Position: General manager
Valid from: 2021/06/26