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.
Bucharova 2657/12, Praha 5, 158 00, Česká Republika
ID: CZ07420099, www.lomina.ch, SÚKL reg.: 061583

Product Identification Data:

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

REF LA-CoV-Ag **RZPRO/EUDAMED: 00909708**

GMDN # 64912

Intended use:

Rapid test intended for qualitative detection of the SARS-CoV-2 nucleocapsid (N) antigen in human oropharyngeal swab samples in vitro.

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 18113-1:201, EN ISO 18113-2:2011, EN 13612:2002, EN ISO 23640:2015

Signature:
Name: Michal HORACEK MBA PMP
Position: General manager
Issued as of: 29. SEPTEMBER 2020
Valid trough: 14.OCTOBER 2025

CE IVD

Czech State Institute for Drug Control registration number # 061583