Bioinova

EC DECLARATION OF CONFORMITY

According to the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices,

Bioinova, s.r.o.
Vídeňská 1083
142 00 Prague 4 – Krč, Czech Republic
Company ID: CZ28452682

as a manufacturer of a medical device:

Title: **Bi-CoV ™ set**

Intended use: Noninvasive collection of biological material from the oral cavity or nasopharynx by soaking the fluid into an inserted swab, placing it in an ampoule with a collection (or transport) solution and then transporting the sample to the laboratory for PCR determination of SARS-COV-2 virus.

Risk class: **other IVD**

declares under its responsibility that the abovementioned product conforms to the requirements of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

The said medical device is suitable, safe and effective for its intended use. Conformity has been assessed by the manufacturer based on technical documentation, risk analysis and the final report from the performance evaluation. CE marking is affixed according to Article 16 of the Directive.

Prague, December 3, 2020 — Place and date of issue

Peter Bauer, M.D., Ph.D., CEO — Responsible person

..... — Signature / stamp

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