Bioinova

EU DECLARATION OF CONFORMITY

in accordance with Article 17 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU („IVDR"),

Bioinova, a.s.
Vídeňská 1083
142 00 Prague 4 – Krč, Czech Republic
SRN: CZ-MF-000025483

as the manufacturer of the in vitro diagnostic medical device:

Name: **Bi-CoV®**

Basic UDI-DI: **859570990001P6**

Intended purpose: Non-invasive collection of biological material from the front of the nose or oral cavity (alternatively, a nasopharyngeal/oropharyngeal swab). The solution in the kit ensures the gradual decomposition of viral particles, the release of nucleic acids (RNA), and their protection from degradation during transport to the laboratory for PCR analysis.

Risk class: **A** according to Rule 5a (Annex VIII to the IVDR)

hereby declares under its sole responsibility that the product mentioned above **is in conformity with the IVDR**. Article 48(10) and Annexes II and III of the IVDR were used for the conformity assessment.

Prague, July 27, 2022	MUDr. Peter Bauer, Ph.D., Director	.....
Place of issue, date	Name and position of responsible person	Signature/stamp

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