

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-Micro**

Basic UDI-DI: **859570990007PJ**

Intended purpose: Non-invasive collection of biological material from various surfaces and anatomical locations, including the oral cavity, oropharynx, front part of the nose, nasopharynx, etc. Absorption of fluid into an inserted swab, insertion into an ampoule with a collection (or transport) solution, and subsequent transport of the sample to the laboratory for PCR determination of viruses and bacteria. The device is also suitable for swabbing various surfaces and for self-collection.

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, November 24, 2022

Place of issue, date

MUDr. Peter Bauer, Ph.D., Director

Name and position of responsible person



Signature/stamp
 **Bioinova, a.s.**
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