

## EC DECLARATION OF CONFORMITY

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

**Bioinova, a.s.**

Vídeňská 1083

142 00 Prague 4 – Krc, Czech Republic

ID: 28452682

as a manufacturer of a medical device:

**Name: Bi-Reader**

**Intended purpose:** Bi-Reader® is designed for a quantitative readout of Bioinova's rapid immunochromatographic test results. The reader measures the signal strength on the immunochromatographic test and converts it to the analyte concentration in the sample. It is intended for a near-patient testing by a trained healthcare professional.

Risk class of medical device: **other IVD**

Bioinova, a.s. declares on its sole responsibility that the characteristics of the product meet the essential requirements of Directive 98/79/EC. That the medical device is suitable, safe, and effective during the provision of healthcare according to its intended purpose and instructions for use.

Conformity was assessed by the manufacturer based on the technical documentation, risk analysis, and performance evaluation report. The manufacturer affixes the CE marking to the product according to Article 16 of Directive 98/79/EC.

Prague, 25th May 2022

M.D. Peter Bauer, Ph.D., CEO

Place a of issue, date

Name, and position of the responsible person



Signature/stamp

 **Bioinova, a.s.** <sup>®</sup>  
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