Bioinova

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-VirTest

Intended purpose: A rapid immunochromatographic test that helps to distinguish the cause of an incipient generalized respiratory or other acute infection of viral or bacterial origin. The test is intended for near-patient testing by a healthcare professional to quantify the level of myxovirus resistance protein A (MxA) in a capillary blood sample.

In addition to the diagnosis of infectious diseases, another potential field of application is monitoring the efficacy of interferon therapies used for the treatment of various autoimmune diseases.

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. ②
Vídeňská 1083, 142 00 Praha 4
IČ: 28452682 DIČ: CZ28452682
Tel.: 241063352, info@bioinova.cz