EC DECLARATION OF CONFORMITY

Manufacturer's Name: ArtBioTech

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Address: **UAB "YZZY biotech"**, Berzu str. 8, LT-36233, Panevezys, LITHUANIA

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Declares that:

The product: **In Vitro Polymerase Chain Reaction (PCR) Assay for COVID-19**

For Professional Use Only

***ArtTest*™ COVID-19 Test Kit**

Classification: **Other (Neither listed in the Annex II of the IVDD 98/79/EC nor Self-testing device)**

Conformity assessment Route: **Annex III of the IVDD 98/79/EC**

(EC Declaration of Conformity)

The above mentioned product is in conformity with the provisions of the Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices and therefore entitled to bear CE Mark.

Place of issue: **Minsk, Republic of Belarus**

Date of issue: **June 05, 2020**

Valid from: **June 05, 2020**

Attachment #1 – List of applied standards (1 page)

Signature: _____

Aliaksander Rymko,
Director ArBioTech LLC

Digitally signed by Chirtoacă Iurie
Date: 2022.03.11 18:17:04 EET
Reason: MoldSign Signature
Location: Moldova

Attachment #1 – List of applied standards

The product is in conformity with the relevant Harmonized Standards and/or other normative documents:

IVD Directive 98/79/EC	The European Parliament and the Council Directive dated 27 October 1998 on *in vitro* diagnostic medical devices
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 13612:2002	Performance evaluation of *in vitro* diagnostic medical devices
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of *in vitro* diagnostic reagents
CLSI MM03-A2:2006	Molecular Diagnostic Methods for Infectious Diseases
CLSI EP17-A:2004	Protocols for Determination of Limits of Detection and Limits of Quantitation Approved Guideline
CLSI EP12-A2:2008	User Protocol for Evaluation of Qualitative Test Performance