# EC DECLARATION OF CONFORMITY
# (FRM-31)
# (rev. b)

**Manufacturer's Name:** **ArtBioTech LLC.**

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*Declares that:*

**The product:** **ArtRNA extract kit**
**For Professional Use Only**

**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.**

Attachment #1 – List of applied standards

Digitally signed by Chirtoacă Iurie
Date: 2021.07.13 10:07:17 EEST
Reason: MoldSign Signature
Location: Moldova

*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 |