

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

Manufacturer's Name:

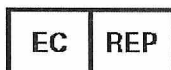


ArtBioTech LLC.

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EC-Representative:



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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 ArtBioTech LLC**

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 <i>in vitro</i> 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 <i>in vitro</i> diagnostic medical devices
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: <i>In vitro</i> 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 <i>in vitro</i> 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