

# EU Declaration of Conformity

Type: Biomagpure 12 Plus, Automated nucleic acid extraction system and reagents

Catalogue numbers:

Cat.Nr.

BS-060202

Model:

Biomagpure 12 plus

Manufacturer

SIA BIOSAN

Latvia, LV-1067, Riga, Ratsupites str. 7, build.2.

Applicable Directives

IVD Directive 98/79/EC, Classification – « all other IVD Medical Devices » according to Annex I.

Applicable Union harmonized Standards

LVD 2014/35/EU

EMC 2014/30/EU

RoHS3 2015/863/EU

WEEE 2-12/12/EU

We declare that this product conforms to the requirements of the above Directives and Standards

Signature

Svetlana Bankovska  
Managing director

09/09/2020

Date



# EU Declaration of Conformity

**Type** Automated Nucleic Acid extraction system Biomagpure compatible nucleic acid extraction reagents

<b>Catalogue number</b>	<b>Model</b>
BS-060201-AK	Blood DNA Extraction Kit 200
BS-060201-BK	Blood DNA Extraction Kit 1200
BS-060201-CK	Viral Nucleic Acid Extraction Kit
BS-060201-DK	Tissue DNA Extraction Kit
BS-060201-FK	Bacterial DNA Extraction Kit
BS-060201-GK	HPV DNA Extraction Kit for swab
BS-060201-IK	TB DNA Extraction Kit
BS-060201-LK	Viral/Pathogen Nucleic Acids Extraction Kit A
BS-060201-MK	Viral/Pathogen Nucleic Acids Extraction Kit B
BS-060201-NK	Viral Nucleic RNA Extraction Kit
BS-060201-PK	Total RNA Extraction Kit
BS-060201-QK	Viral Nucleic Acid Large Volume Extraction Kit
BS-060201-RK	CFC DNA Extraction Kit Large Volume

**Manufacturer** SIA BIOSAN  
Latvia, LV-1067, Riga, Ratsupites 7 k-2

The objects of the declaration described above is in conformity with the following relevant Union harmonization legislations:

<b>IVD Directive 98/79/EC</b>	Classification – “all other IVD Medical Devices” according to Annex I.
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I declare that the Declaration of Conformity is issued under sole responsibility of the manufacturer and belongs to the above-mentioned objects of the declaration.

Svetlana Bankovska  
Managing director

  
Signature  
25/09/2020  
Date

