



# Declaration of Conformity

No. ZYIN2020006

According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

## Manufacturer

Zybio Inc.

Floor 1 to Floor 4, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park,  
Dadukou District, Chongqing, China 400082

## EC Representative

Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany

## Product Name

Nucleic Acid Isolation System

## Model

EXM3000, EXM3200, EXM6000, EXM6200

## Product Classification

Others device, not in annex II and not for self-testing, not for performance evaluation

## Conformity Assessment Route

IVDD 98/79/EC Annex III (excludes section 6)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices, and they are with both Directive 2011/65/EU of the European Parliament and of the Council of 8 Jun 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Directive

2012/19/EU of the European Parliament and of the Council on waste electrical and electronic equipment. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Directive 2012/19/EU of the European Parliament and of the Council on waste electrical and electronic equipment.

**Standards Applied**

EN ISO13485:2016	EN ISO9001:2015	EN ISO 14971:2019	EN ISO 18113-1:2011
EN ISO 18113-3:2011	EN ISO 15223-1:2016	EN 62304:2006	IEC 61010-1:2010
IEC 61010-2-081:2015	IEC 61010-2-101:2015	EN 61326-1:2013	EN 61326-2-6:2013
EN ISO 23640:2015	ISO 20916:2019		

Place

Chongqing, China



Date of Issue

2020-06-29

Signature:

Name of Authorized Signatory:

Tommy Hu

Position:

Management  
Representative

