

# EC Declaration of Conformity

**Manufacturer:**

**Name:** Hangzhou Allsheng Instruments Co.,Ltd.  
**Address:** Building 9 No.7 of Zhuantang Science and Technology Economic Zone, Xihu District, Hangzhou City, 310024 Zhejiang, P.R. China  
**Tel:** 86-0751-88802738

**SRN:** CN-MF-000020502

**Whose Authorized Representative:**

**Name:** Riomavix S.L.  
**Address:** Calle de Almansa 55, 1D, Madrid 28039 Spain  
**Tel:** +34 658 396 230  
**SRN:** ES-AR-000001202

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

2017/746 (EU) on in vitro diagnostic medical devices

<b>Product Name</b>	Nucleic Acid Purification System
<b>Model</b>	MagnetaPure 32 Plus
<b>Basic UDI-DI:</b>	697514198AS180
<b>Classification</b>	Class A

**Conformity Assessment Route:** Class A, according to Rule 5 of IVDR Annex VIII

**Applicable Standards:**

EN ISO 14971:2019                      EN ISO 13485:2016                      EN ISO 15223-1:2016  
EN ISO 18113-1:2011                      EN ISO 18113-2:2011                      IEC 61010-1:2010  
IEC 61010-2-101:2015                      IEC 61326-1:2013                      EN 61326-2-6:2013  
IEC 62366-1:2015                      EN IEC 61010-2-010



杭州奥盛仪器有限公司  
HANGZHOU ALLSHENG INSTRUMENTS CO.,LTD

**Position Held in the Company**

**General Manager**

**Signature**

**Date**

Apr.13th, 2023

**Place**

Hangzhou, Zhejiang, China