

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

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

SRN: CN-MF-000020502

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

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|-----------------------|----------------------------------|
| Product Name | Nucleic Acid Purification System |
| Model | MagnetaPure 32 Plus |
| Basic UDI-DI: | 697514198AS180 |
| Classification | 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

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| Position Held in the Company | General Manager |
| Signature | |
| Date | Apr.13th, 2023 |
| Place | Hangzhou, Zhejiang, China |

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