EU Declaration of Conformity

In accordance with EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Manufacturer:	**Roche Molecular Systems, Inc.** **1080 US Highway 202 South** **Branchburg, NJ 08876** **USA**
Single Registration Number (SRN) Manufacturer:	**RMD7613336 (placeholder)**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**TBD (Application filled, confirmation pending)**

This declaration is issued under the sole responsibility of Roche Molecular Systems, Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
07290519001	MagNA Pure 24 Instrument	761333601933B8

Intended Purpose:	The MagNA Pure 24 System is an automated nucleic acid purification system consisting of the MagNA Pure 24 instrument, software, consumables and reagents. The MagNA Pure 24 System is intended for use by professional users for the purification of nucleic acids from biological samples for *in vitro* diagnostic purposes.
Risk Class and Classification Rule:	Class A, as per EU Regulation 2017/746, Annex VIII, Rule 5
Common Specifications:	Not applicable as no Common Specifications exist for the concerned device.

Conformity of the product with EU Regulation 2017/746 and the following EU legislation, which also require an EU Declaration of Conformity, and other applicable EU legislation, has been established.

- Complies with the requirements of Directive 2011/65/EU including amendment of Annex II 2015/863/EU of 31 March 2015 on the restriction of the use of certain hazardous substances according Annex II (lead, mercury, hexavalent chromium, cadmium, polybrominated biphenyls, polybrominated diphenyl ethers, bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP)) in electrical and electronic equipment.

  Starting with Serial No.: 1486

  Relevant harmonized standards and/or technical specifications in relation to which conformity is declared: EN 50581:2012 and EN IEC 63000:2018

On behalf of Roche Molecular Systems, Inc.

Place: Tucson, AZ	Place: Pleasanton, CA
Date: 20-Sep-2021	Date: 20-Sep-2021
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Jeff Boone	**Heinz Steneberg**
Vice President, Quality Management	Director, Regulatory Affairs