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:	**US-MF-000018066**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
06541089001	MagNA Pure 96 Instrument	761333601934BA

Intended Purpose:	The MagNA Pure 96 Instrument is designed to perform automated purification of nucleic acids for *in vitro* diagnostic purposes. The MagNA Pure 96 Instrument is intended to be used in combination with specified MagNA Pure 96 Kits. The MagNA Pure 96 System is intended to be used with the defined robotic workstation, computer (control unit) with operating software, software protocol, sample preparation kit and consumables and by professional users.
Risk Class and Classification Rule:	Class A, as per EU Regulation 2017/746, Annex VIII, Rule 5 (b)
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.

- 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 (RoHS).

  Starting with Serial No.: 4750

On behalf of Roche Molecular Systems, Inc.

Place: Tucson, AZ	Place: Santa Clara, CA
Date: 21-Dec-2021	Date: 20-Dec-2021
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Jeff Boone Vice President, Quality Management	**Carolyn Glickman** Director, Regulatory Affairs